

CLOSING SYSTEMS

Once filled, the package must be closed by sealing, seaming, lidding, plugging or capping. Various machines handle these functions. Sealing of flexible packaging typically relies on heat, ultrasonic energy and/or adhesive and is discussed in Chapter 15, Flexible Packaging Laminates. Can seaming, a traditional yet continuously updated process, is described in Chapter 8, Metal Cans and Containers. Closure application systems are covered in Chapter 13, Closures.

Lidding can consist of flexible lidstock, typically heat-sealed to trays or cups, or a friction-fit lid like an overcap on a tub of sour cream. Lids generally are pressed into place.

Plugs are pressed into place too, according to Henry's *Packaging Machinery Handbook* and most commonly seen in the form of corks in wine bottles or stoppers in pharmaceutical vials. The latter often are combined with a crimped-on aluminum cap.

LABELING AND CODING

Henry's *Packaging Machinery Handbook* notes brand owners have many choices when it comes to labels: pressure-sensitive (the most common), hot-glue, cold-glue, heat-transfer, sleeve (shrink or stretch) and in-mold. Labeling machines receive labels via rollstock or in stacks of cut labels. Systems can be inline or rotary, intermittent- or continuous-motion.

Other decoration options include preprinted containers via stencil, screen, rubber-mat, pad, offset or flexographic processes. (See Chapter 4, Package Printing and Decorating)

Many primary containers and secondary packaging also are printed online to apply information such as a Sell By date. In some cases, a coding system is integrated with the labeler to provide print-and-apply functionality.

Online coding is divided between contact and noncontact processes. Contact coding options include roller coder, rubber stamp, hot stamp, debossing, thermal and thermal transfer. Noncontact coders rely on inkjet or laser technologies. Digital coders, which include thermal, thermal-transfer, inkjet and laser systems, can apply variable information and are specified when products like pharmaceuticals must be serialized.

GROUPING AND PACKING

Cartoning, multipacking and case packing protect the primary package through the distribution process.

Folding cartons can serve as primary packages (think pasta or tapioca) but usually function as a secondary package to provide additional protection or shelf impact. The intermittent- or continuous-motion cartoner erects the carton blank, loads the carton and closes the flaps.

Vertical cartoners are set up to top-load the product manually or automatically. Horizontal cartoners are designed for side loading. Wraparound cartoners do not erect a blank but form the carton from a flat diecut piece of paperboard using the

product as a mandrel. If needed, an integrated system can apply glue or tape to carton flaps to provide a secure seal and/or tamper evidence.

The most flexible machines handle multiple carton sizes and styles but change-over time, especially between straight (airplane) tuck, reverse tuck, or fifth-panel cartons can be lengthy, according to Henry's *Packaging Machinery Handbook*.

To simplify handling and retail display and support special marketing offers a multipacker machine will collate the desired number of products and unitize them with shrink film, a film or paperboard sleeve, a paperboard carrier or shrink-wrapped corrugated tray to create a two-pack, four-pack, six-pack, etc. Multipacking equipment may serve more than one packaging line, especially when the goal is to produce variety packs with an assortment of flavors. Orienting devices can position each container so its primary label faces outward.

Case packers are located at the end of the line to gather product for distribution. Separate machines may be used to erect, load and tape-, glue-seal or staple the case, usually a corrugated regular slotted case. However, according to Henry, many of today's machines integrate all three operations in one system that also includes a built-in label printer/applicator capable of applying a two-panel (around-the-corner) label. The most flexible units can switch between tape or glue sealing and also can handle trays, which are shrink-wrapped after loading. Systems can be designed to load product from the top, bottom or side. Case packer classifications include side-loading, vertical-placing, drop packing, down packing, rotary and wraparound.

PREPARING FOR SHIPMENT

Palletizers collate and stack filled containers, cartons or cases on pallets. This can be done mechanically by collating product into layers and then stacking the layers on the pallet or robotically where the robot picks product off the line and places it on the pallet either one-by-one or in groups. Pallets may be delivered automatically or via forklift or pallet jack. Filled pallets may exit directly to downstream operations or be picked up and move by forklift or pallet jack.

To ensure stacks remain in place during transit, filled pallets are banded or stretch wrapped. For bags or corrugated boxes, an adhesive treatment can be applied that bonds the layers together but releases without any surface damage when it's time to unload the pallet.

ANCILLARY OPERATIONS AND CONVEYORS

Ancillary operations include quality control systems such as machine vision inspection, checkweighers, metal detectors and x-ray inspection. The importance of integrating quality control on the packaging line cannot be understated. Without it, faulty product can reach the consumer and potentially cause injury, illness or death; damage brand identity; and spur a costly recall.

On virtually all packaging lines conveyors link machines together and serve as infeed and outfeed functions. There are many types of conveyor, but according to

Henry's *Packaging Machinery Handbook*, the two most commonly specified on packaging lines feature a motor-driven chain or belt enclosed in a frame and running in a continuous loop. Hygienic construction and washdown-compatible designs are available for food and pharmaceutical applications.

Conveyor specs are not standardized so when specifying dimensions, Henry recommends making sure everyone is discussing the same width, length and height. A wide range of speeds is available and motion may be continuous or intermittent. Modular designs can simplify installation and reconfiguration.

Special attention needs to be paid to transfers to ensure packaging components and product move smoothly across the transition. Guide rails are another important consideration especially if changeovers necessitate frequent adjustment. Quick-adjust and automated guide rail systems are available.

Other conveyors serve specific functions, says Henry. For example, vibratory conveyors feed bulk products like potato chips or packaging components like caps in a trough that moves back, down and forward to gently propel the product or component forward.

THE ROLE OF ROBOTICS

In recent years brand owners have faced multiple challenges such as difficulties in recruiting and retaining workers, health and safety concerns related to tasks requiring repetitive motion and/or heavy lifting, and the need for greater line flexibility due to a growing demand for shorter runs and an explosion in the number of stock-keeping units. Increasingly, robots are chosen to address one or more of these challenges, particularly at the end of the line. Robots can be used for a wide range of packaging

Table 20.2
Robot and cobots are playing many roles in packaging as shown in this table.

Primary packaging using robots, occasionally cobots	bag handling, bottle handling, can stacking, container loading, kit assembly	multipacks, package inserts, pick-and-place, quality inspection, tray loading/unloading	variety packs, customized gift packs, vision inspection, polishing/finishing
Secondary packaging using robots, occasionally cobots	carton loading, case packing, case sealing	retail ready tray unloading	variety packing/bundling
Transport packaging using robots	palletizing	building efficient pack patterns	transport

Source: *Packaging Robots Playbook, 2020 Edition, published by PMMI Media Group.*

tasks and advances in end-of-arm tooling and tactile sensors make it possible to handle virtually any package or product. (See Table 20.2)

Today's robotic systems cost less and are easier to program than earlier systems and often are equipped with machine vision especially when the product to be handled is presented randomly. Vision-equipped systems also can detect faulty product and check label accuracy. Higher speeds are achieved simply by adding units. Robots also can check product weight to ensure the package is properly filled and complete. Some hygienic designs can withstand washdown conditions encountered on lines that handle products such as fresh meat.

Packaging robots fall into several categories: articulated (usually six-axis), SCARA (selective compliance articulated robot arm), delta-style, cartesian (gantry), mobile and collaborative robots, which are the fastest-growing segment of packaging robots, according to the *Packaging Robots Playbook*, 2020 Edition, published by *Packaging World*.

Delta-style robots are sometimes called parallel or spider robots. Capable of high speeds, the units are well-suited for pick-and-place tasks such as loading trays.

Sensor-equipped collaborative robots, or cobots, can work safely next to human operators eliminating the need for guarding and related expenses. The compact, flexible units excel at handling random packages for tasks such as palletizing boxes of different sizes and weights. Movable and affordable, cobots operate relatively slowly and handle smaller payloads.

Mobile robots also are sensor-equipped and designed to move product and materials around the plant floor, within the warehouse or between the two. Today's systems are more maneuverable and smarter, enabling more autonomous operation.

Whatever type of robot is chosen, it's essential to match features to current and anticipated tasks. Critical considerations include payload weight, speed, number of axes, work envelope, footprint, accuracy and repeatability, associated safety requirements, programming and training needs.

MACHINE CONTROL

The motions of machine components are achieved, timed and controlled by various methods. They may be mechanically actuated by levers, cams, chains, push rods or gears. Motions can be controlled and implemented by microswitches, timers, electromagnetic relays, hydraulics, pneumatics and electronic means. Each method has its advantages and applications.

Maintenance is an important aspect of machine motion and control systems. In a plant where the machines are controlled by electrical relay logic or mechanical systems, the change to a hydraulic/electronic system will require considerable re-education of the maintenance and operating staff.

A machine runs best when all components are at their optimum settings. These settings should be determined and quantified, *not* left to operator discretion. Running a machine should not depend on the anonymous turn of a temperature control knob or on moving a feed roll "just a touch."

For example, critical heat-sealing stations should have direct temperature readouts taken at a specific location or several locations. Critical mechanical adjustments should be made to a scale or vernier. Quantified machine adjustments provide a bet-

ter understanding of what the machine is doing and make line operation a science rather than an art.

Microelectronics and microprocessors have provided packaging engineers with endless possibilities for continuous monitoring of station variables, such as fill weight, throughput, production speed and machine settings. With programmable controllers, feedback circuits and servo-stepping drives, in-process changes can be controlled by the microprocessor.

A programmable logic controller (PLC) is a solid-state unit that replaces hard-wired relays, cam controls and other electromechanical devices with software-driven electronics. PLCs can store recipes in memory to expedite setup and changeover. In addition, operators can reprogram, troubleshoot and operate the machine via a laptop or remotely via the Internet or a phone line. Advantages of PLCs include smaller size, reduced hardwiring, simpler operation, greater reliability and the potential for closed-loop feedback and on-the-fly adjustments to maintain tolerances, according to Henry's *Packaging Machinery Handbook*.

Henry notes, programmable automation controllers (PACs) work similarly to perform these tasks alone or in conjunction with PLCs. These ruggedized personal computers may run other programs and store information such as manuals, wiring diagrams, parts lists and instructional videos for the machine.

Another important component of the control system is the human/machine interface (HMI). It has evolved from a few switches and dials to a touchscreen color display that activates machine functions, troubleshoots problems, displays a performance dashboard and stores data for analysis and reports, according to Henry's *Packaging Machinery Handbook*. If the HMI is linked to the manufacturing execution system, this information is available to anyone with access and can be transmitted as needed to the enterprise resource planning system.

In short, digitalization is gaining ground with digital flows receiving equal or even more attention than physical flows. This is changing how machines are designed, operated and maintained and is shifting training and field service experiences from physical to virtual.

Remote access and digital tools have been available for some time but really gained ground during the pandemic when in-person troubleshooting, repair and training were severely limited, if not completely eliminated. As a result, remote access has gained functionality and is more efficient than ever. However, with greater usage comes greater risk of unauthorized access to systems and potential havoc on the line and in the plant, so close attention must be paid to system security.

The pandemic also has spurred interest in the use of AR and VR technology for machine design, field service, remote maintenance and operator training.

According to *Healthcare Packaging*, “VR is an artificial, computer-generated simulation of a real-life environment. Virtual headsets provide a firsthand experience of a simulated reality, to the exclusion of the actual surroundings. ... The environment itself can be created through a coding language known as virtual reality modeling language, or VRML, which can also be found in the AutoCAD files that OEMs already use to create 3D models of their equipment. Since operators cannot see the real world around them when they are using a VR headset, the opportunities VR brings to manufacturing and service are limited.” However, it can be extremely useful for training where it allows the operator to “operate” the machine without affecting production. Through VR, operators also can experience safety dos and don’ts.

“AR, on the other hand, layers computer-generated enhancements, like digital images and graphics, over an existing reality. This allows users and operators to interact with the world around them while in an AR state. AR uses headsets, too, but unlike VR headsets, they allow operators to see through the headset into the real world.” This ability to see the real world makes it possible for OEMs to remotely fix equipment, eliminating the need for in-person field service calls and related travel time and expenses.

“Control” is also a concept that applies to the package itself. A bottle traveling freely on a conveyor is not in control; it moves with minimal limitations. Yet, the bottle must be precisely located to apply a closure to it—that means bringing it under control. A package traveling along a production line may go in and out of control several times as it passes through different machines and functional stations.

Earlier, it was mentioned that a machine’s design speed (running empty) is greater than the speed it will run at when loaded with product and packages. This difference comes about partly because every component in a machine is always under control, whereas the package and product are not.

Gaining and maintaining package control is an important part of packaging machinery design. On a rotary machine, control is gained by the infeed timing screw. On a typical rotary filling machine, the package is then handed off (in control) to the starwheel, which changes the direction of movement and then hands off the package to a filling stage. On most contemporary machines, the filled package would then be placed (now out-of-control) onto a conveyor that goes to the capper. At the capper, the whole process of gaining control must be repeated, a process that occurs again at the labeler.

Current packaging line design thinking proposes that once control of the package has been gained, it should be maintained until all operations are completed (a “monobloc machine”). In the above example, the filled bottle would be indexed directly, in control, to the capper and again to the labeler. In other words, instead of several machines being linked together to form a line, where control is gained and lost at each machine, the entire filling/capping/labeling process is accomplished on one extended machine with only one infeed timing screw. This means a significantly smaller footprint and higher reliability, at least in principle. On the negative side, the monobloc machine is less versatile and comes to a halt with any malfunction because it does not include buffers.

INTRODUCTION TO STATISTICAL PROCESS CONTROL (SPC)

Terminology

assignable cause	Identifiable changes in the relationships of materials, methods, machines or people.
attribute	A characteristic quality that can be directly quantified in numerical units. The mean, range and standard deviation of the numbers can be calculated.

average	Not a commonly used term in statistics. See mean.
bell curve	A curve or distribution having a central peak and tapering off smoothly and symmetrically to either side.
common cause	Those sources of variability in a process that are truly random and inherent in the process itself. The standard distribution bell curve of a machine running at stable steady state can be said to represent common cause variations.
control limits	The limits within which a product or process is expected to remain. When a process goes beyond these limits it is said to be out of control. On control charts, the limits are designated as upper control limit (UCL) and lower control limit (LCL).
mean	The value or statistic that is the result of the sum of the observations in a sample divided by the number of specimens in the sample. The mathematical average. The mean is abbreviated as \bar{x} , pronounced x-bar.
median	The value in a set of measurements that divides the set into two groups having equal numbers. If the sample size is odd, the median is the middle value.
mode	The value of the variable in a set of statistical data at which the greatest concentration of observations occur.
population	In statistics, the total of all possible objects of the same kind from which a statistical sample is drawn.
random	Variations that have no discernible pattern.
range	The difference between the least and the greatest values in a group of attribute measurements.
sample	A quantity of a product, drawn from a specific lot or process and being reasonably representative of the product for purposes of testing or evaluation.
sigma	A number representing the standard deviation of a data set from the average. Sigma is abbreviated σ .
stability (of a process)	A process is said to be stable if it shows no recognizable pattern of change.
standard deviation	A measure of the dispersion of a set of values relative to the mean.
standard distribution	A distribution of values that can be represented by a standard bell curve.
specimen	An individual unit in the sample.
variables	Quantities that are subject to change or variability.

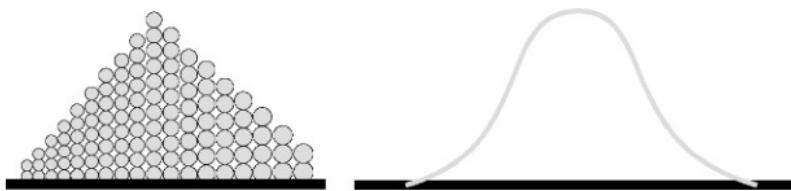


Figure 20.23

A pictorial representation of pea sizes and a standard distribution bell curve that would mathematically describe the distribution around the average size. The mean, mode and medium values of the curve are all at the same point and the slopes on both sides are symmetrical about the mean. The tails of the sloped side continue to infinity.

Standard Deviation

Numbers representing average values are a common and useful part of our lives, but in terms of science and engineering, “average” is often not specific enough for critical calculations and at times can be completely misleading. (Lying down with your head in the refrigerator and your feet in the oven, your average temperature would be a comfortable 22°C.)

Furthermore, average, as a single point, provides little information on the range or dispersion of values around that point. Median and mode are other terms used to describe data dispersions but have limited statistical use.

In the 1860s, English scientist Francis Galton observed that if you graded peas according to their size, there was an equal distribution to either side of the average size. After observing various other natural phenomena he proposed the idea of standard distribution and developed a mathematical formula to quantify his observations. Transferring the data from a pictorial image to a mathematical representation resulted in a uniform bell-shaped curve such as that illustrated in Figure 20.23. Moreover, it was soon realized that Galton’s bell curve represented many other natural random distributions. For example, the speed of 100 cars on an expressway, the shoe size of 60 male university students or the fill weight of a peanut package could be represented by similar bell curves. The bell curves became known as standard distributions (because they seemed to apply to so many common phenomena) and the dispersion about the main peak became the standard deviation or sigma.

(In a reverse application of his theories, Galton tabulated the submissions of a contest where local farmers were trying to guess the weight of a large bull. The tabulated results formed a standard bell curve and the average value of all the guesses was the closest to the bull’s actual weight).

In more recent times the standard distribution concept was found to be useful for quantifying, controlling and improving production processes. Using packaging as an example, closure torques, fill weights, dimensional variations and other production attributes can be described with standard distribution bell curves and the calculation of standard deviations. The practical application of this technology to production processes has come to be known as statistical process control (SPC).

Calculating the Standard Deviation

The shape of the bell curve can be described numerically by the standard deviation or sigma, a value that quantifies the dispersion of data about the mean.

For example, if we wished to find the standard deviation of the spread of values 2, 4, 6 and 9.

Step 1. Find the arithmetic mean. $\frac{(2+4+6+9)}{4} = 5.25$

Step 2. Find the deviation of each number from the mean

$$2 - 5.25 = -3.25$$

$$4 - 5.25 = -1.25$$

$$6 - 5.25 = 0.75$$

$$9 - 5.25 = 3.75$$

Step 3. Square each of the deviations. (This amplifies the larger values)

$$-3.25^2 = 10.56$$

$$-1.25^2 = 1.56$$

$$0.75^2 = 0.56$$

$$3.75^2 = 14.06$$

Step 4. Sum the calculated squares = 26.74

Step 5. Divide the squared sum by the number of values added together

$$\frac{26.74}{4} = 6.69$$

Step 6. Take the square root of the result.

The standard deviation (σ) of this group of numbers is = 2.58.

In standard mathematical terms the formula is expressed as:

$$\text{standard deviation } (\sigma) = \sqrt{\frac{\sum_{i=1}^n (x_i - \bar{x})^2}{n-1}}$$

Where n = number of values etc.

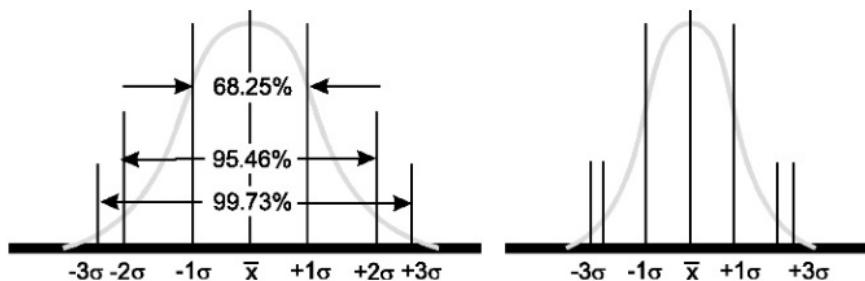
Calculating standard deviation using this formula is a long and laborious process. Fortunately, all statistical and many scientific hand calculators incorporate the formula so all that needs to be done is enter the numbers and press σ_- .

Standard Deviation Characteristics

The characteristics of a normal distribution as shown in Figure 20.24 are:

Figure 20.24

Two standard distribution curves, showing wide and narrow standard deviations. About 0.1% beyond 3σ would account for another 0.1% on each side of the curve.



- 68.25% of all measurements will fall between -1σ and $+1\sigma$.
- 95.46% of all measurements will fall between -2σ and $+2\sigma$.
- 99.73% of all measurements will fall between -3σ and $+3\sigma$.
- Other values such as the percent of values higher than -1σ can be calculated

Suppose 20 packages are removed from a filling line and the following weights in grams recorded:

95	97	105	103	98
96	104	102	99	100
100	99	98	101	102
99	100	101	101	100

The average and standard deviation are calculated.

$$\text{Average fill weight} = 100 \text{ g (target weight)}$$

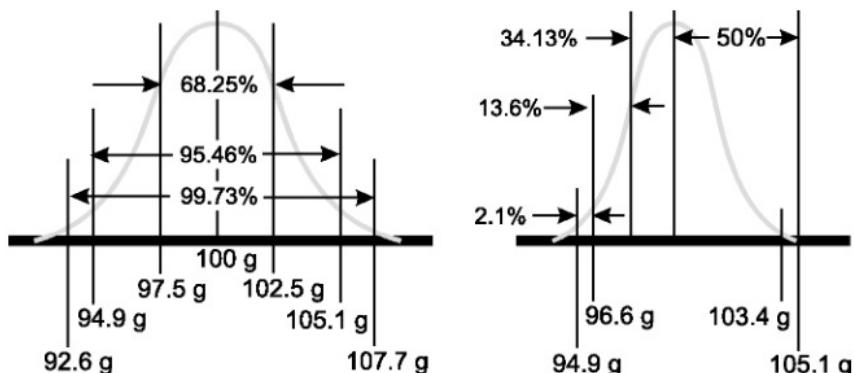
$$\text{Standard deviation} = 2.53 \text{ g}$$

The client has called for a minimum fill weight of 94 g.

What is shown in Figure 20.25 left is that the filling process is not capable of meeting the client's fill requirements. Furthermore, at the other end, anything over 100 g is a costly giveaway.

Figure 20.25

The left curve shows the gram weights at each standard deviation. The right curve shows the change when a more accurate weighing system is installed.



By installing a more accurate weigh cell, the lowest and highest fill weights are eliminated. Now the 20 fill weights are:

100	97	100	103	98
97	103	102	99	100
100	99	98	101	102
99	100	101	101	100

Average fill weight = 100 g

Standard deviation = 1.7 g

The new filler easily meets the 94-g specification at 3σ and has reduced the give-away by 1.6 g.

SPC and Control Charts

The first step in applying SPC principles is to ensure that the process is capable of producing product within the required specification. Quality cannot be “inspected in,” quality must be produced.

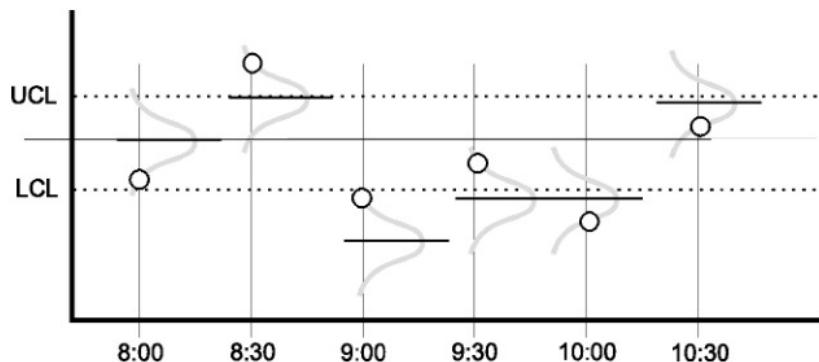
The next step is to ensure that the production process is stable and will reliably produce quality parts. As long as the machine is stable and running at a steady state, the measured attributes of samples removed periodically for quality assurance will fall within the boundaries of the established standard deviation. Data outside the established standard deviation will occur only when some changes have shifted production outside of the established steady state. (For example, a machine component coming out of adjustment, wear on bearings and other machine parts, changes in the materials being handled and so on.)

Histograms, (a bar chart arranged by frequency of an event occurring) Pareto charts (a bar chart arranged by the relative importance of a number of events that occur) and process analysis diagrams are useful tools to provide a visual basis for an investigation. Histograms focus attention on the most frequent occurrences. Pareto charts focus attention on the incidents that are the most serious. (The Pareto rule of thumb is that 20% of occurrences will cause you 80% of your headaches.) Process analysis documents the entire material and process flow. Some problems that come to light may originate several process steps ago.

To become aware of changes that might be taking place requires keeping a continuous record of the product characteristics using SPC control charts. Sampling is done at predetermined times based on the nature of the product and the production speed. Most usually, a group of three or more specimens is drawn, the measurements made and their average is plotted on the control charts.

X-bar charts are a data record of values as they are grouped around the average value; in other words, the bell curve excepting that the actual curve is not drawn in. An R chart records the range of values for every particular specimen group that was drawn for assessment. X-bar and R charts are usually drawn together so that any correlation between the two can be seen. The charts will have X-bar and the designated upper and lower control limits.

Figure 20.26
A lack of understanding of standard deviation principles can lead to costly errors.



A good understanding of sampling and understanding statistical distributions is a key factor in not committing the type of errors illustrated in Figure 20.26.

- 8:00 The operator weighs a box from production and finds it is holding 95.1 g of product. The lower limit is 95 g, so to be safe the operator increases the machine's fill weight. In fact, the machine is properly adjusted; this particular package happened to be at the lower end of the distribution curve.
- 8:30 The operator hasn't realized it yet, but a fair percentage of product is over the UCL. At 8:30, the operator weighs another package and discovers it's considerably overweight. The fill weight is drastically reduced.
- 9:00 Between 8:30 and 9:00, all fills are below the LCL. Not knowing what is going, on the operator increases the weight a little.
- 9:30 Finally, at 9:30, the operator thinks the fill weight is finally correct, so no adjustments are made. In fact, the distribution curve is partly below the LCL limit and so half the packages are under-filled.
- 10:00 Now the operator is cursing the machine. It was perfect at 9:30, and now it's filling below LCL again. Actually, the machine hasn't changed at all ... the distribution curve is in exactly the same place as it was at 9:30. The operator increases the fill again.
- 10:30 At the end of the day, everyone is wondering what's wrong with the machine.

X-Bar and R Charts

A basic tool in tracking down problems is to find significant correlations between data sets. Figure 20.27 illustrates a normal X-bar chart while Figures 20.28 to 20.33 illustrate examples of patterns that indicate that a problem exists or that there is a forewarning that the process is drifting out of control and that remedial action is advisable.

CHAPTER 20

Figure 20.27

A normal X-bar chart with a random distribution of attribute points about the mean. A single point outside the standard distribution would indicate a lack of stability and should be investigated.

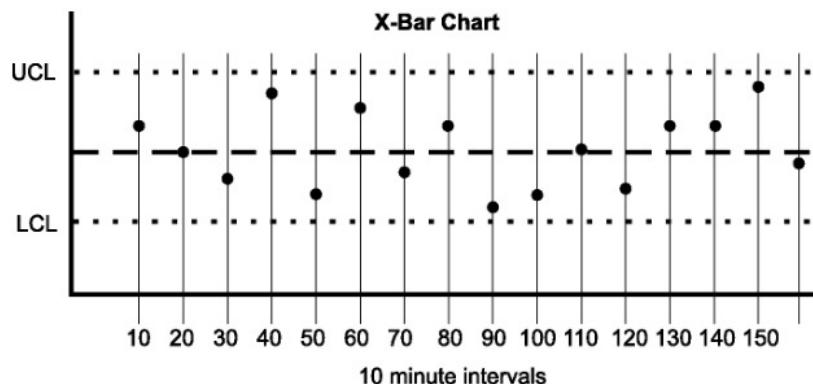


Figure 20.28

A run of seven or more points to one side of the center-line calls for an investigation.

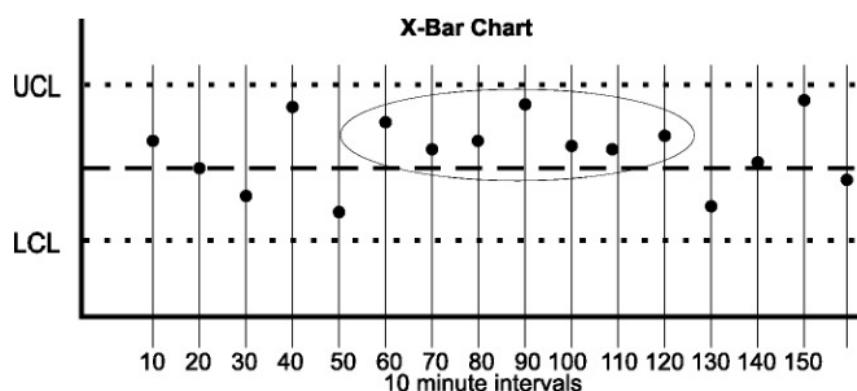


Figure 20.29

A directional trend is a warning that the machine is drifting out of control.

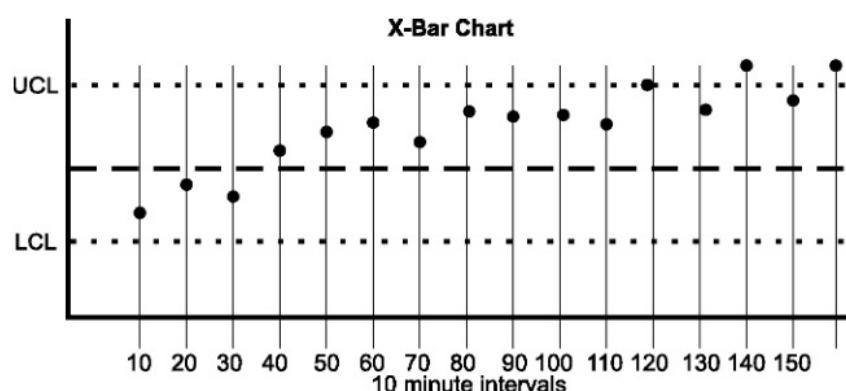


Figure 20.30

Cycles are patterns that repeat; a sure sign of instability. In this example, each cycle is preceded by a point beyond the control limits.

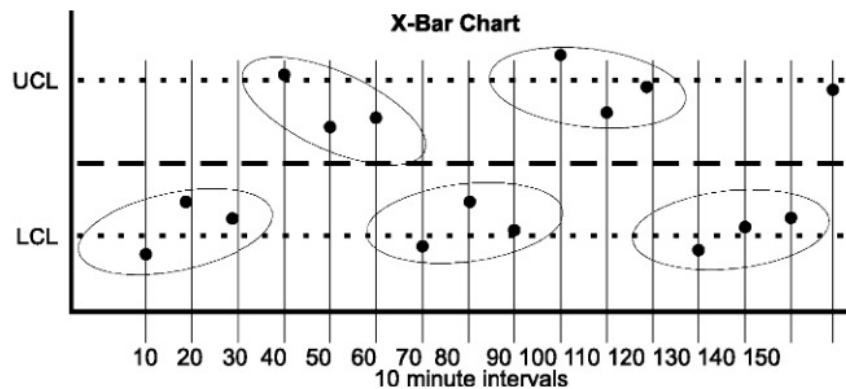
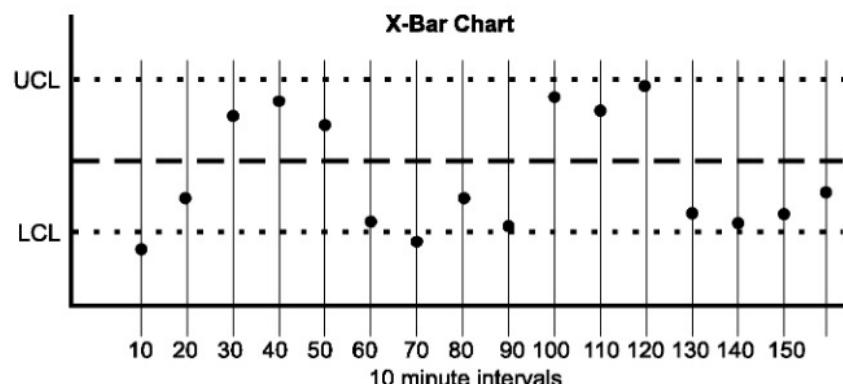
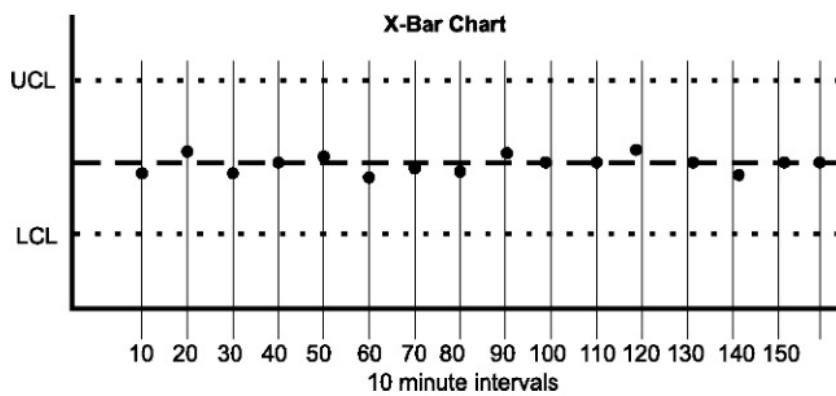


Figure 20.31

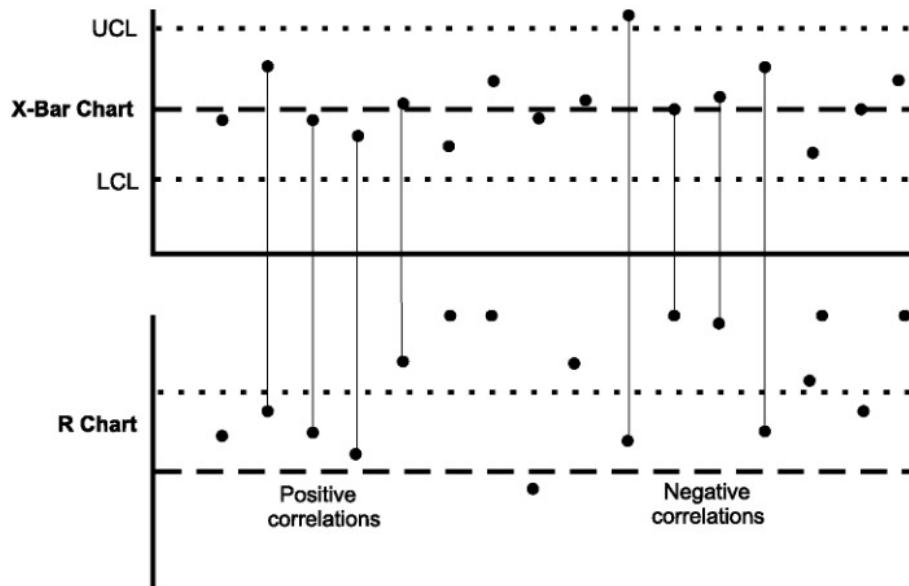
Mixtures usually indicate that there are two processes working at different levels.

**Figure 20.32**

Stratification may happen when improperly calculated control limits or chart scales are used. It is also possible that the specimens in any given sample group are constantly averaging out to the median line.

**Figure 20.33**

Correlations between the range of values in the sample and the deviation are possible. In a positive correlation, the X-bar and range points tend to follow each other up and down. In a negative correlation, the points move in opposite directions.



REVIEW QUESTIONS

1. A buffer is a conveyor mechanism where an amount of manufactured product can be held. Describe two reasons for specifying a buffer for a production line.
2. For what applications are piston fillers used, and what specific features of a piston filler are particularly useful?
3. Why and where would you use fill-to-volume systems? Give examples.
4. Dry products can be classed into several different categories according to the product's nature. Each type would require a different filler system. Describe four product types and a filler that could fill each product.
5. Why and with what kind of product would you use fill-to-level systems?
6. What four options are available for increasing production? Describe a situation that would favor each option.
7. Why is the packaging machinery business essentially custom in nature?
8. Discuss the possible advantages and disadvantages of a rotary machine, compared with a straight-line machine.
9. What does "angle of repose" mean, and what does it suggest to you in terms of filler election?
10. A filler, a capper and a tamper-evident band applicator are all connected inline. Calculate the theoretical throughput of this production line if the machine speeds and station uptimes are as follows:

Station	Machine Speed	Efficiency
Filler	275 cpm	97.5%
TE applicator	260 cpm	99.7%
Capper	290 cpm	91.6%

11. What are the operating principles of an auger filler, a volumetric-cup filler and a vibratory-feed filler?
12. Bulk-and-dribble-type weighing systems largely have been replaced by net-weighing fillers. Describe the operating principle of computer-combining techniques used in net weighers, and explain why these are an advantage over bulk-and-dribble systems.
13. Where and why are bottom-up fillers especially important?
14. What are the limitations of a gravity-type filler?
15. What kind of product would be filled using a vacuum-volumetric filling machine?
16. How does container type affect your choice of filler?
17. Why is rapid changeover often a critical part of JIT, or "just-in-time," manufacturing?
18. Discuss how you balance inventory costs against the per-unit cost of changeovers that are optimized.

- 19.** New production lines sometimes need significant debugging time. Why is this so?
- 20.** What is the advantage of upgrading existing equipment? What advantages might be gained by purchasing used equipment?
- 21.** In a typical production line, how would you estimate the speed required from each operating station in the line?
- 22.** What is the purpose of an infeed starwheel and a timing screw?
- 23.** What steps would you take to implement a rapid changeover program for a packaging line?
- 24.** Define design speed, capacity, run speed and line output.
- 25.** Both diaphragm fillers and piston fillers fill to predetermined volumes. What might be some advantages of a diaphragm filler, compared with a piston filler?
- 26.** What are working time, available production time, overall running time and actual productive running time?
- 27.** Why is it desirable to have machines before and after a buffer to be capable of temporary increases in speed?
- 28.** A buffer can be useful for increasing production, but installing too many buffers can slow a production line down. Explain why.
- 29.** Define population, sample and specimen.
- 30.** Describe the attributes of a standard distribution.
- 31.** What does a standard deviation quantify?
- 32.** Approximately what percentage will be one sigma, two sigma and three sigma away from the mean?
- 33.** What information is recorded on x-bar and R charts?
- 34.** What are the critical considerations when evaluating and selecting a robot for a given task?

Assignment

Describe the most preferred approach to minimize cost per unit for a packaging line consisting of the following unit operations:

- 1.** A product infeed station
- 2.** A form/fill/seal station (any style of wrapped package)
- 3.** A package collation station
- 4.** A cartoning station
- 5.** A case-packing station

Note: Feel free to utilize buffer(s) at the most appropriate location(s). Changeovers can be considered for unit carton count but not for the size of the wrapped packages.

CONTENTS

Carded Display Packaging

Blister and skin packaging compared, pegboard displays.

Blister Packaging

Blisters-on-card; foldover, slide and clamshell designs; typical thermoforming temperatures for common blister packaging plastics; blister materials and caliper; paperboard backing cards; assembly.

Carded Skin Packaging

Process, applications, films, paperboard and porosity.

Chub Packages

Description, applications.

Fiber Cans

Definition, round and oblong shapes, applications, materials, spiral winding and convolute winding, proprietary systems.

Collapsible Tubes

Comparison of metal, extruded plastic, coextruded plastic and laminated tube types.

Plastic and Paper Bags

Definitions, sachet, bag, sack, paper-based bags, paper tests, plastic bags, woven sacks.

Barcodes

Responsible authorities, overview of types, the Universal Product Code, barcode scanners, printing and scannability.

Security Labeling

Retail losses, electromagnetic and radio frequency systems, benefits of electronic article surveillance and radio frequency identification tagging.

Durable Goods Packaging

Furniture, appliances, environment, suggested packaging practices.

Wood Packaging

Pallets, skids, boxes, crates, packaging wood groups, nailing.

Pharmaceutical Packaging

Introduction, product formulation, primary packaging, secondary packaging and temperature-controlled shippers, combination product device and packaging, packaging equipment and cGMP discussion, pharmaceutical regulations.

Creative Designs

Heated packages, shoulderless jars, double-chambered packages, squeezable toothpaste and valved containers, molded pulp containers and forms, case-ready modified-atmosphere red meat packaging, printing inks with a difference.

The greater part of this textbook focuses on the materials of packaging and the most common package forms made using those materials. Of course, many other mixed-material applications and many nonmaterial concerns occupy a packager's time. This chapter will discuss some of these.

CARDED DISPLAY PACKAGING

Carded display packaging offers maximum product visibility and self-service convenience, while at the same time providing reasonable product protection against contamination and shipping damage. The backing card discourages theft of smaller articles and offers tamper evidence, provides convenient space for product identification or instructions and is useful for retail display. Although staples, ties or other physical means can be used to attach the product to a backing card, blister and skin packaging offer additional protection by covering the product and are more adaptable to automated production.

“Blister packaging” uses a preformed plastic shape that holds the product and is heat-sealed to a backing card. “Skin packaging” places the product on a backing card and uses a vacuum to draw a plastic film into close conformity to the object. A heat-sealable coating bonds the film or blister to the backing card. (See Figure 21.1)

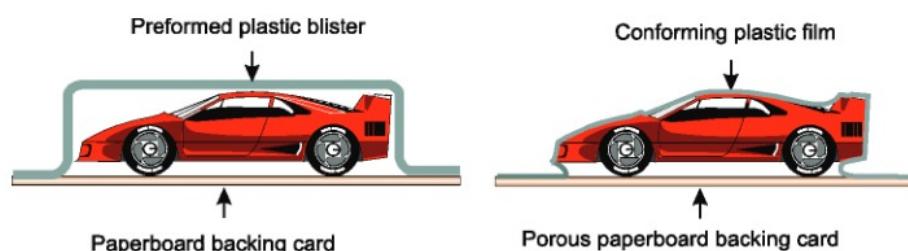


Figure 21.1
A paperboard-backed blister pack (left) and a skin pack (right).

Skin packaging is very useful for packaging hardware kits; companies may package many different (even custom) hardware kits using the same skin/backer and machine without the need for equipment changeovers. With either blister packaging or skin packaging, inks used to decorate the cards must withstand the temperatures involved.

The majority of carded packages are displayed on pegboards. A significant problem with suspended display packs is inadequate strength in the pegboard, or “butterfly,” hole area. The backing card should be able to hold several times the product weight and accommodate being readily removed and replaced on a pegboard without special care. Cards narrower than 50 millimeters (mm) (2 inches) are probably better displayed by other means. Where permitted by the manufacturing process, card corners should have a radius to reduce curling or ply separation.

Most retailers follow standard dimensions for spacing the hangers for carded display packages. The length and width of the backing card should be selected to provide maximum usage of available display space and should require minimum hanger relocation.

Package depth is controlled by product geometry and placement. Heavy blister and skin packages, with a center of gravity significantly in front of the backing card, will hang on an angle facing downward from the viewer’s eyes. Such designs tend to twist the pegboard hole against the hanging peg, often tearing the backing card.

Stores reset their in-store product placement, also known as planograms, one or two times per year. If launch timing is coordinated with these planogram adjustments, you can balance package size against shelf impact to minimize material usage.

BLISTER PACKAGING

Blister packaging is composed of a rigid, preformed thermoformed shape that is typically attached to a paperboard backing card. Usually, an adhesive bonds the plastic shell to the backing card. The most common blister package is the blister-on-card. (See Figure 21.2) A perforated backing card provides a convenient opening feature.

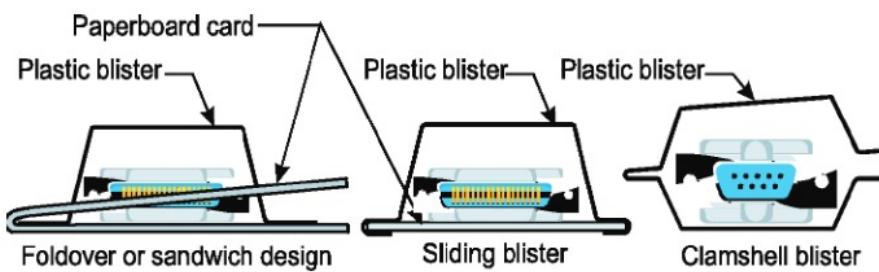
“Foldover,” or “sandwich,” cards effectively increase the backing card’s thickness. (See Figure 21.3, left) “Sliding designs” offer repeated or easy access to a product and do not require heat-sealable coatings. (See Figure 21.3, middle)

The advantages of “double blisters” and “clamshells” are the ability to view the product from all sides, hold an irregularly shaped product and keep a design’s center of gravity close to the package midpoint. (See Figure 21.3, right) Clamshell designs also can be used as a hinged storage container. Information usually is provided on a paper or card inserted into the blister along with the product. A negative of clamshells is that consumers find them difficult to open. This type of packaging normally is used for high-value products to prevent theft. Consequently, clamshells purposefully don’t have easy-open features and often require scissors or a knife to open.

Plastic blisters are produced by thermoforming: heating a plastic sheet to a temperature at which it can be shaped to a mold with the desired configuration. The key properties of blister material are cost, moldability, impact resistance, scuff resistance, low-temperature performance and clarity. Although nearly all thermoplastics can be thermoformed, most blister packages are made from:

**Figure 21.2**

The most common blister package is the blister-on-card. (Courtesy of Berlin Packaging.)

**Figure 21.3**

Examples of foldover, slide and clamshell blister design variations.

- Polyvinyl chloride (PVC).
- Polyethylene terephthalate copolymer (PETG).
- Polystyrene (PS).

Typical thermoforming temperatures are listed in Table 21.1.

Most blisters and clamshells are thermoformed from PVC. Its performance varies depending on formulation, and PVC characteristics should be verified for the application. PETG, recycled polyethylene terephthalate and amorphous polyethylene terephthalate have become more cost-competitive and offer superior stiffness. In some applications, PETG is considered to be the more environmentally-friendly choice. Although generally more expensive, PET can be used in thinner gauges than PVC to reduce its cost. As PVC has become less popular due to environmental concerns, PET and polypropylene (PP) have become more common. Styrenics have excellent clarity, but low impact resistance, unless an impact grade is used.

The blister material caliper varies, depending on the material, blister geometry and product nature. Most blister package materials are in the range of 0.12–0.18 mm (0.005–0.007 inch).

Table 21.1
Typical thermoforming temperatures for the most common blister packaging plastics.

Material	Thermoforming Temperature (Celsius)
polyvinyl chloride	139–176
polystyrene	143–176
polypropylene	148–199
polyethylene terephthalate glycol	129–162
polyethylene terephthalate	148–176

Paperboard is selected according to the weight of the product being packaged and must be suitable for the intended graphic presentation. Paperboard thickness for quality blister packaging should be about 500 micrometers (μm) (0.020 inch) and can go up to 800 μm (0.030 inch) for heavier or larger objects. Suitable paperboard thickness can be achieved by doubling a lighter sheet rather than by using a single heavy stock. This technique is particularly useful for reinforcing pegboard holes. Lighter boards would be used only for small items, items not displayed on pegboards or designs that incorporate structural integrity differently. Most paper backing for carded blister packs is flat and does not require the paperboard to have good folding properties.

The board surface must be receptive to the printing process and possess enough internal bond strength to resist ply separation under use conditions. Clay-coated newsback or its equivalent is a good choice for most hardware applications. Double-white-lined board stock would be used for applications where the back of the sheet will be printed or decorated. Solid bleached board stock is used where an overall high-quality appearance is necessary.

After printing, the card receives a heat-sealable top coating compatible with the blister material being used. Most PVC blisters are attached with a PVC-based heat-sealing material. Acrylic and ethylene-vinyl acetate formulations also are used. Heat, applied either from the blister side or the paperboard side, seals the blister to the board. A properly produced blister package will have a fiber-tearing bond between the blister and paperboard backing card.

In the packaging operation, the product usually is dropped into the open top of the blister. The paperboard card is placed over the blister and heat is applied to form the seal.

CARDED SKIN PACKAGING

A “carded skin package” is made by first placing the product on a flat paperboard sheet. Film mounted in a frame above the substrate card is heated until it softens and

is then draped over the product. A vacuum applied through the substrate card draws the film down to conform intimately around the product. The hot film activates an adhesive coating that has been preapplied to the paperboard, bonding the film to the board wherever contact has been made.

An alternative to blister packaging, skin packaging is more economical because it does not require special tooling or a mold. In addition, it uses less polymer material—the product becomes the mold. Plastic film is used rather than thicker sheet stock, a factor that increases in importance with larger parts. The process adapts readily to small or large production runs. Unlike blister packaging, skin packaging immobilizes or secures the product to the backing sheet. Skin packaging can be designed to hold several parts securely and in such a manner that each part can be inspected individually. Because the film “wraps around” the product due to the vacuum, it is more difficult for the consumer to separate the packaging film from the product than with blisters.

Skin-packaging films are usually polyethylene (PE) or ionomer (e.g., DuPont's Surlyn). Ionomers offer good clarity, abrasion resistance, exceptional toughness and rapid cycle times. This makes ionomer the material of choice for retail display applications, despite its premium price.

PEs are more economical but not as clear and are easily abraded or scuffed. PE requires more heat (and a longer cycle time) and has a higher shrinkage factor than other films. High shrinkage can curl board edges. The advantage of PE's economy is largely lost to the longer cycle times. Industrial applications where clarity and appearance are not critical use PE.

Since a vacuum needs to be drawn through the board to create the conforming skin, paperboards used in skin packaging must be porous. Clay-coated paperboard is rarely used since the clay seals the board surface. If a clay-coated or other non-porous board is selected for appearance reasons, it must be perforated to ensure that air can be withdrawn from the skin enclosure. But perforating makes it more difficult to reproduce a high-quality graphic image. This is a disadvantage of skin packaging. However, in some instances, the product is large enough or the geometry is such that perforations can be concealed behind the product.

Paperboards need to be stiff enough to provide a good display card and not curl or delaminate when the skin is applied. Thicknesses of 450–635 μm (0.018–0.025 inch) are the most common.

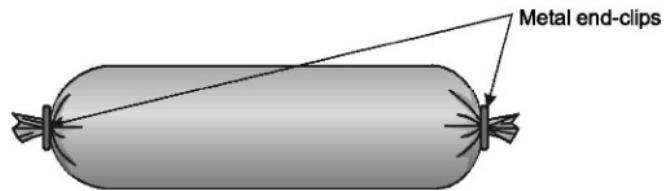
The heat-seal material must not seal the board's surface so completely that a vacuum cannot be drawn quickly. Heat-seal materials usually are formulated from ethylene-vinyl acetate.

CHUB PACKAGES

The term “chub packs” originated with the processed meat industry and describes short, chubby sausage-like forms. (See Figure 21.4) Modern chub packs are made on vertical form/fill/seal machines (see Chapter 15, Flexible Packaging Laminates) from a variety of laminated materials. The flat stock is unrolled, pulled over a forming collar and heat-sealed into a tubular shape. In its most common variation, one tube end is sealed with a metal clip, the product is pumped into the tube and the other end is similarly clipped shut.

Figure 21.4

A typical chub pack might hold a pound of breakfast sausage.



Chub packaging is versatile. Package sizes can range from miniature tubes to shapes measuring 150 mm in diameter and 1220 mm in length (6 inches in diameter and 48 inches long.) Virtually any pumpable paste can be filled into a chub pack. In addition to various ground and sausage meats, chub packs have been used to contain processed cheese, drywall compounds, explosive slurries, lard, frozen juices, icing, pastry dough and sandwich spread. Due to its economic efficiency, it is now being used for non-traditional products like soups.

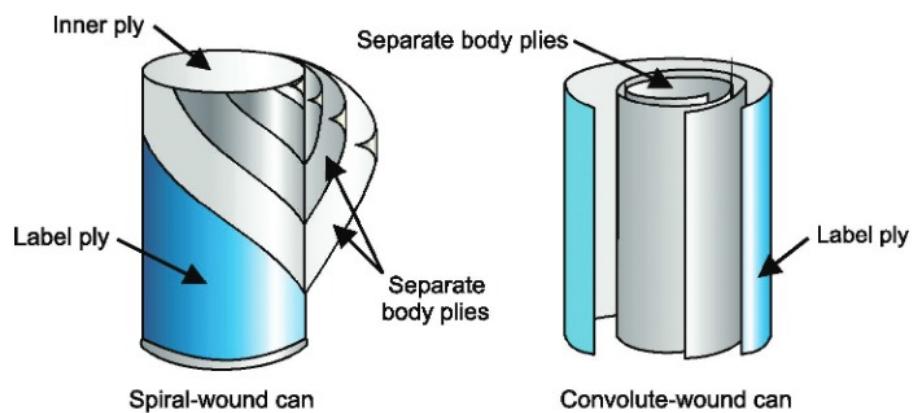
FIBER CANS

“Fiber cans” also are called “composite cans” and used in a wide range of product applications, from thick viscous products (e.g., caulk, grease) to dry powders (e.g., sweeteners or dehydrated beverages). In this discussion, the terms refer to cans made by winding overlapping layers of paper, sometimes with film, foil or other laminated materials, to produce an open-ended tube. (See Figure 21.5) Single-wrap containers produced from a sheet blank are not usually included when discussing fiber and composite cans.

The tube could be round, oblong or other cross-section. The tube ends are plugged or sealed with metal, plastic, composite or paperboard end pieces. Providing a liquid-tight seal is somewhat easier with a round cross-section tube than with an oblong tube, so round cans tend to be used for most liquid products and products requiring a hermetic end seal. Can shape is not as critical for dry products. Fiber cans are relatively low in cost, compared with similar metal, plastic or glass containers. The production machinery is simple enough that many users manufacture fiber cans in-house.

Figure 21.5

Construction of spiral-wound and convolute-wound fiber cans.



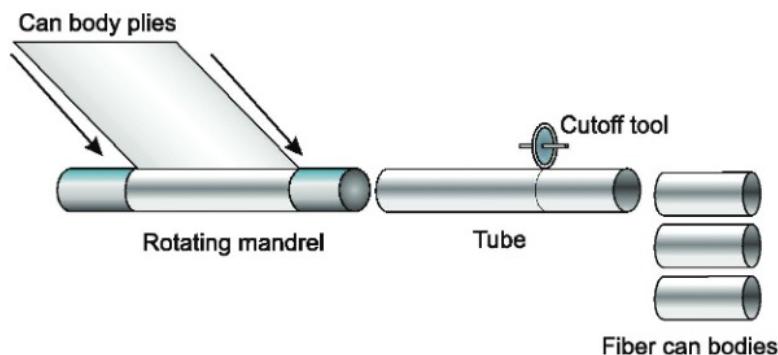


Figure 21.6
General layout of a convolute can-winding line.

The main body component of a fiber can is paperboard, usually a kraft or similar paperboard, selected for its stiffness and strength. Body plies might be plain kraft, while the innermost plies may be coated or laminated in advance to provide appropriate product-contact surfaces. Where high barrier is required, the inner material would be an aluminum foil laminate, while for lesser demanding barrier applications a polyvinylidene chloride-coated PP might be used. PE and other coatings are chosen if gas barrier issues are not a concern.

Although the details vary, can bodies are made by one of two basic processes: convolute and spiral-wound. In the convolute production method, sheets of paper and body materials are wrapped around the forming mandrel at right angles to form the body tube. (See Figure 21.6) The mandrel can be round, oblong or any other shape. In spiral-wound production, the body plies are brought in at an angle to the mandrel and spirally wound in staggered overlapping layers to form the body tube. (See Figure 21.7)

Either wet adhesives or heat-seal systems can be used to join the body plies. Typical wet adhesives are polyvinyl acetate/polyvinyl alcohol blends or dextrin. Synthetic blends offer somewhat better water resistance than dextrin, whereas dextrin is more economical. Hot melts and PE require heat to create the ply bonds but have significantly better moisture resistance.

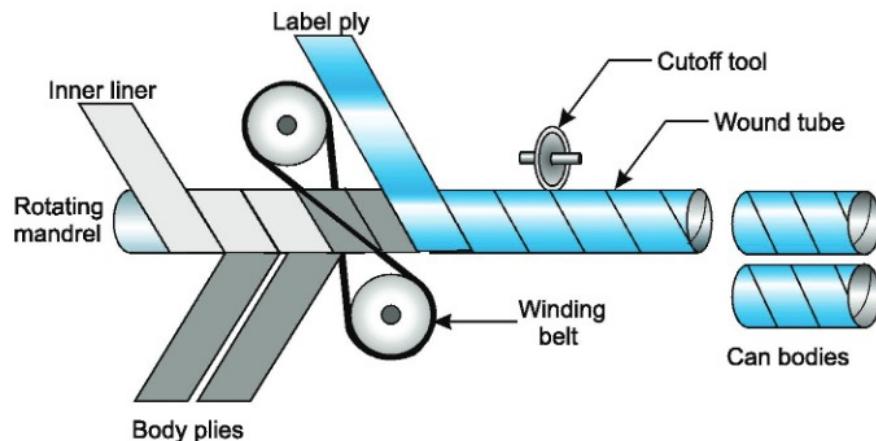


Figure 21.7
General layout of a spiral-wound fiber can line.

Metal can ends are applied by a double-seaming technique similar to that used for metal cans. Paperboard and plastic ends are used for less demanding applications. Fiber can size is given as the diameter and length in whole inches and sixteenths of an inch, identical to the procedure used for sizing metal cans. (See Chapter 8, Metal Cans and Containers)

COLLAPSIBLE TUBES

Collapsible tubes are used where controlled dosing is desired or for products that do not flow naturally. Tubes are used for a wide range of products, such as personal care, foods and building materials. Collapsible tubes can be made of impact-extruded metal, extruded and coextruded plastic or laminated stock. (See Chapter 8, Metal Cans and Containers; Chapter 11, Shaping Plastics; and Chapter 15, Flexible Packaging Laminates)

Metal tubes are made in a similar way to impact-extruded metal cans, with the bottom die forming the finish of the metal tube. The open end is then cut to length depending on the expected fill volume.

In extruded tubes, a continuous tube is extruded from a die that determines the diameter of the tube. Common diameters of extruded and laminate tubes include 35, 45 and 50 mm. The extruded tube is cut to length depending on the expected fill volume. Laminate tubes come in two main types, poly-barrier laminate (PBL) and aluminum-barrier laminate (ABL). Both start as flat web laminates, which are unwound and side-welded to form the tube body. As with extruded tubes, the finished tube is cut to length according to the expected fill volume. Specialty laminates also are available, substituting the aluminum barrier layer with vacuum-metallized films.

In the instance of extruded tubes and laminated tubes, the tube head is injection molded onto the tube body as shown in Figure 21.8. Each method produces a tube with different application properties as summarized in Table 21.2. For all tube types, common neck finishes include M8 and SPI 22-400 mm. Closures are applied in a separate station and come in a wide array of types, depending on the product application.

Figure 21.8
Heads are injection molded on laminated and extruded tube bodies. The molten injected plastic fuses to the preformed tube body.

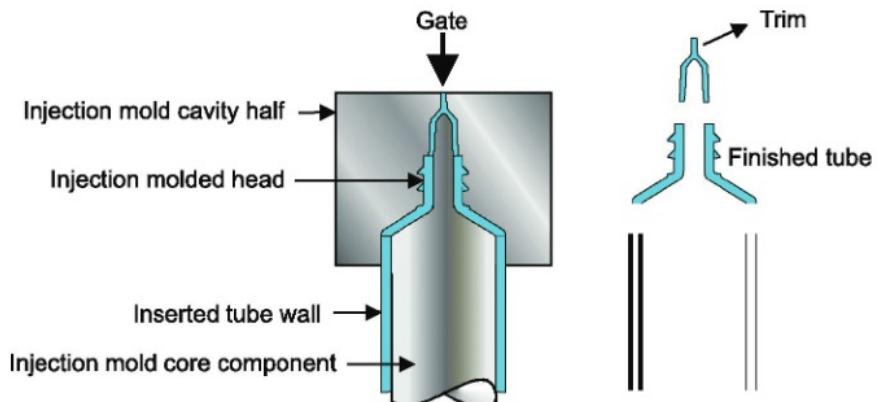


Table 21.2
Comparison of collapsible tubes made by different methods.

Property	Metal Tubes	Extruded Plastic	Coextruded Plastic	Laminated
Barrier	best	lowest	good	very good
Dead fold	best	poor	poor	fair

“Dead fold,” the ability of the tube to stay flattened when the product is ejected, is an important consideration for many pharmaceutical applications, where sucking air into a partially emptied tube might result in product contamination. Superior dead-fold characteristics and absolute barrier property make metal the material of choice for many pharmaceutical applications. Laminated tubes made with an aluminum foil layer are almost as good as metal for these properties. Coextruded and PBL tubes incorporating barrier layers (commonly ethylene vinyl alcohol) protect against product spoilage and flavor loss (for applications like toothpaste) but have poor dead-fold characteristics. However, in many cosmetic and other general applications, the lack of dead fold is viewed as a positive feature, since it allows for attractive display of the company graphic throughout the product’s life. But that makes it more inconvenient, or impossible, to dispense all the product.

Formed metal and extruded plastic tube bodies are commonly decorated using offset letterpress (dry offset), sometimes in combination with silk screen printing. These methods have limitations in producing process printing, so decoration requirements need to be considered when selecting tube type. Full or partial secondary pressure-sensitive labels can be applied to extruded tubes but add cost. Laminate tubes offer the advantage of having the ability to use combination decoration methods (offset, flexographic, rotogravure, silk screen, etc.) to achieve complex artwork. The use of metal in ABL and specialty laminate tubes also offers high aesthetics where metallic effects are desired, without the need for additional foil application. Protection, functionality, aesthetics and cost are all considerations when selecting the appropriate tube technology for product applications.

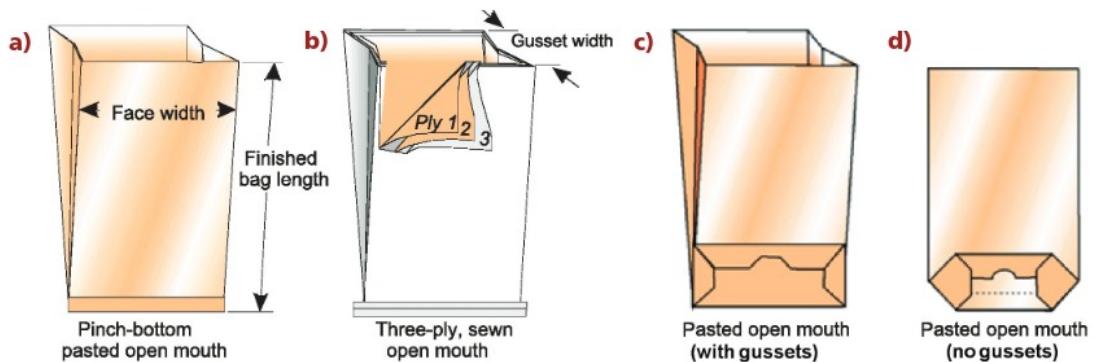
PLASTIC AND PAPER BAGS

Definitions

There is no distinct dividing line between sachet, pouch, bag or sack, and there are many regional variants on how the terms are applied. The dominant usage is:

Sachet

A small flexible container intended to hold single-serve portions, samples or any other small quantity of product. (Production of sachets and pouches is covered in Chapter 15, Flexible Packaging Laminates.)

**Figure 21.9**

Dimensioning conventions are the same for plastic or paper bags. They are given in this order: face width and finished bag length for flat constructions and face width, gusset width and finished bag length for gusseted bags.

Pouch

A relatively small flexible plastic packaging format for dry goods, liquids, moist or oily products. Common features include easy-open, resealable, screw cap or one-way valve.

Bag

A flexible container that opens or fills at one end that may subsequently be closed or sealed and is plastic or fiber-based. Bags can be made from single-layer plastic, plastic-based multilayer laminate and singlewall or multiwall paper constructions. Regardless of material, bag dimensions are given in order of face width and length, with the finished length being the dimension of the tube. For gusseted bags, the gusset width is the second dimension listed; the length dimension is always last. (See Figure 21.9)

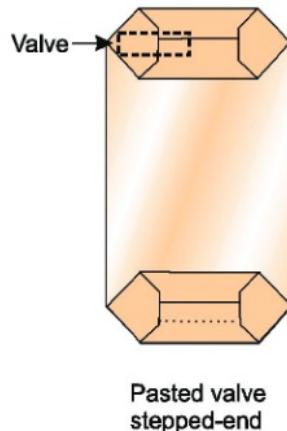
Sack

“Sack” often is used as a synonym for “bag” or as a heavy-duty bag as noted above. In some instances, sack refers to any bag made from natural or synthetic fibers.

Paper-Based Bags

The simplest paper bag is a flat paper tube with one end closed. Paper bag ends can be closed by sewing, folding and pasting or hot-melt gluing. The bag is filled through the open end and then may be closed or sealed. When filled and closed, the bags assume a pillow-like geometry. This geometry, while simple to produce, can form an unstable pallet load.

Squaring up the bag ends creates better load stability and stacking security on the retailer display shelf. It also provides a legible print surface area. A gusseted bag would use the closure geometry shown in Figure 21.9 (a, b and c), while a tube-form bag without gussets would use the geometry shown in Figure 21.9 (d). Valve-type multiwall bags, shown in Figure 21.10, are closed at both ends, with a sleeve (the

**Figure 21.10**

Valve-type multiwall bags are closed at both ends, with a sleeve (the valve) inserted in one corner. After the bag is filled through the valve, product pressure flattens it to close it.

valve) inserted in one corner, through which the bag can be filled. After filling, the product pressure flattens the valve to close. An extended sleeve can be folded and tucked or ultrasonically sealed, for a leak-proof closure.

Most multiwall paper bags use between two and four paper plies with weights from 65–100 grams per square meter (g/m^2) (39–60 lb. for 3,000 sq. ft. ream size) kraft paper. The outer ply may be bleached for better appearance, and any of the plies could be coated, laminated or impregnated to provide specific additional properties.

Multiwall bag plies are numbered from the inside of the bag to the outside in the United States; that is, the ply touching the product is "Ply 1." (See Figure 21.9, b) Note that this is opposite to flexible-packaging laminate convention that lists laminate construction from the outside face inward. Outside the United States, plies are numbered from outer to inner (product contact).

Major markets for multiwall bags include cement, building materials and other minerals, grain products, seed, agricultural products and foodstuffs, industrial chemicals, polymer resins and related materials. Large paper bags can be used as secondary packaging to hold small bags, such as sugar, salt and cookies.

Paper-based bags also include one-ply paper bags such as takeout, grocery, and shopping bags. These bags are intended to be used briefly and then recycled. Typically, the bags are recyclable and, in some cases, compostable. Grocery and shopping bags often have attached handles.

Physical Property Tests

Tensile Strength*

The measure of the ultimate force required to break a strip of material at a constant rate of extension. Tensile strength is reported in units of pound/inch width or kilonewtons per meter.

Elongation*

The distance a material stretches before breaking during a tensile test. Elongation is reported as a percentage.

Tensile Energy Absorption*

The tensile energy absorption (TEA) test is the integrated measurement of tensile strength and elongation. It's a measurement of material toughness and represented by the area under the stress/strain curve. Increasing TEA values enhances the bag's ability to absorb shock during filling and handling. TEA is reported in units of foot-pounds per square foot or joules per square meter.

Tear Strength*

The measure of the force required to propagate an initiated tear. Tear strength is reported in units of grams or millinewtons.

**Tests should be conducted in both machine and cross-machine (transverse) directions.*

Porosity

Porosity is a measure of substrate permeability. A paper's porosity is reported as the time in seconds for 100 milliliters (ml) of air to flow through 2.54 mm (1 square inch) of paper (seconds/100ml/in²). Porosity is most critical for filling pasted-valve bags. Powdered and lower density products require greater porosity for efficient filling. Greater porosity allows more air to travel through the sample quickly. For example, the filling of valve-style bags is slowed by the time required for air to escape from the bag so a high-porosity paper would be preferred.

Drop Tests

Drop tests are used to determine the structural integrity of a bag compared to a known fitness-for-use requirement or to compare the strength of bags of different constructions. A representative product filled with the net weight should be used for the drop test. Flat face drops are a general indicator of overall bag strength. Butt drops impart major stresses in the bag's circumferential dimension. Edge (gusset) drops tend to stress the bag length direction. A drop height of 2–4 feet is most common.

Coefficient of Friction

Coefficient of friction (CoF) can be static or dynamic. Static CoF is the ratio of the horizontal force compared to the vertical force to create movement between two samples of a substrate. Dynamic CoF compares the vertical and horizontal forces to maintain movement of the substrates. Alternatively, a slide-angle type test can be used to measure the frictional properties of a substrate. The tangent of the slide angle correlates to static CoF. Table 21.3 gives the static CoF for selected slide angles.

Water-Vapor Barrier

Water-vapor barrier properties of paper-based bags are achieved by inclusion of an extrusion-coated paper ply or with a polymer film. A bag's closures are a critical area where barrier properties are required, so final evaluation should be done on the completed bag, filled with the product and sealed, or closed, for shipment. Water-vapor barrier properties are best determined by placing bags into conditioning cham-

Table 21.3
The static coefficient of friction for selected slide angles.

Slide Angle	Static CoF
17	0.30
22	0.40
26	0.50
31	0.60
35	0.70
39	0.80

bers with controlled temperature and humidity and monitoring the gain or loss of water by periodic weighing of the bags.

Plastic Bags

Plastic bags can be made from various low-density or linear low-density polyethylene (LDPE/LLDPE) grades and blends. The typical thickness of a heavy-duty plastic bag ranges from 100–150 μm (0.004–0.006 inch). For more high-performance applications, metallocene PE might be used entirely or as a blend. Coextrusion can provide such properties as custom heat-seal layers or differential CoFs between the inside and outside of the bag. Laminated constructions for high-barrier and other special qualities are based on the same material criteria discussed in Chapter 15, Flexible Packaging Laminates.

Cross-laminated plastic film (e.g., Valeron from Valeron Strength Films) provides the highest performance and extreme toughness. Other plastic bag materials include woven polypropylene (WPP) and Tyvek (DuPont trade name), a strong, ultra-clean material having a porosity similar to paper and sometimes used for critical chemical packaging.

Woven Sacks

WPP sacks are prevalent in many market segments because of their structural and barrier benefits. Commodity products like rice, beans, etc. are packed in woven bags that are extrusion-coated but not laminated. Consumer products such as pet food, feed and bird seed are packed in laminated woven bags, which include a printed biaxially oriented PP outer layer. Woven poly sacks can be closed on existing bag machinery. WPP can be used to manufacture many of the same styles of bags that are made of paper.

Flexible intermediate bulk containers (FIBCs) are an alternative to corrugated or rigid plastic gaylords for many types of bulk goods. Frequently referred to as a “bulk bag,” “tote” or “Super Sack,” their heavy-duty WPP construction can accommodate

filled weights of up to 2,000 kilograms (kg). Lift loops, or straps, are incorporated at each top corner to allow easy loading and unloading for transport without special equipment.

All FIBCs are sewn together from multiple sections of WPP fabric. The most common is a four-panel design comprising the four sides of the bag, plus top and bottom panels. A U-panel design uses a single panel that comprises two opposing sides and the bag bottom (similar to a sling), to which the remaining two side panels and top panel are attached. A circular, or tubular, design bag is made from a seamless tube of WPP fabric for the body, to which top and bottom panels can be attached. The sewn seams can include a variety of design features to reduce sifting through the stitching, such as the addition of felt strips or filler cord or folding the fabric at the seam over onto itself and sewing through the folded material.

FIBCs typically are designed to be filled from the top and discharged from the bottom. Various design inlet and outlet spouts can be incorporated to facilitate product filling and discharging and to allow secure closure for transport and storage. FIBCs can incorporate liners for improved barrier properties.

Importantly, FIBCs frequently are used for industrial commodities and intermediate chemicals that often are emptied in flammable or explosive manufacturing environments where electrostatic discharge is a serious safety concern. All FIBCs fall into one of four categories (Type A, B, C or D) with regard to their ability to reduce or eliminate static discharge:

- **Type A.** Bags are made from standard WPP fabric and offer no protection from static discharge. Not safe for use in flammable and explosive environments.
- **Type B.** Bags are made from resins that can reduce brush (contact) discharges, i.e., “nuisance” discharges. Not safe for use in flammable or explosive environments.
- **Type C.** Bags utilize conductive threads woven into the WPP fabric. Bags must be grounded via a lanyard before emptying to prevent static discharge. When properly grounded, bags are considered to be safe to use in flammable or explosive environments.
- **Type D.** Also commonly known as “CROHMIQ” bags. Bags are made from proprietary CROHMIQ blue™ or CROHMIQ white™ fabric, which is designed to prevent the buildup of electrostatic charges on the bag surface, thus preventing the possibility of a static discharge. Bags are considered to be safe to use in flammable or explosive environments without the use of a grounding lanyard.

BARCODES

A “barcode” is a machine-readable symbol whose value is encoded in a sequence of high-contrast rectangular bars and spaces. GS1, an organization headquartered in Brussels, Belgium, oversees global standards for automatic identification, including the Universal Product Code (UPC) and European Article Numbering (EAN) systems, the standard machine-readable barcode systems used on retail packages. GS1 has many members including user companies and national organizations such as GS1 Canada, GS1 Germany and GS1 US, formerly the Uniform Code Council (UCC). Barcode readability standards are maintained by ANSI.

Many barcode systems are available. Some record only numerical data; others can reproduce the entire ASCII character set. Fixed-length codes have a specific number of characters that can be encoded, and the scanner looks for this number. Variable-length codes have no specific number of characters.

- **UPC-A.** The UPC is the common retailing code in North America. It is a two-part, fixed-length, machine-readable code used for individual items, or stock-keeping units, sold to consumers. It can be run 200% of size or, more commonly, truncated to 80% of size. UPC-A should meet the retail scanning guidelines of ANSI C grade.
- **Global Trade Item Number (GTIN), formerly SCC-14.** The GTIN is a 14-digit, machine-readable ITF-14 (formerly called Interleaved 2 of 5) barcode used primarily to provide information on goods packed in corrugated containers. It would be scanned at manufacturing warehouses and distribution centers and ties unit to case configuration to pallet load. An ANSI D grade allows it to be effectively printed on natural corrugated and other substrates that lack contrast.
- **SSCC-14.** This machine-readable code uses UCC/EAN 128 symbology and is applied as a secondary barcode on shipping containers or as the primary barcode for variable or serial information. The compact format allows for added information such as weight and count to be included in the scanned information.
- **GS1-128, formerly UCC/EAN-128.** Capable of encoding all 128 ASCII characters, this international, machine-readable, variable-length code provides the maximum amount of scannable information, including expiration date, lot number, origin, etc. However, this code may not read well when applied to natural kraft or corrugated. Printing the code on labelstock will ensure a readable code for shipping containers.
- **Code-39.** This is a machine-readable barcode where each character is made up of nine elements (four bars and five spaces). Separate characters are defined by inter-character gaps. Code-39 is a variable-length code in that no fixed number of characters makes up a code. Standard Code-39 can encode 44 different characters, while an expanded version can encode the entire 128-character ASCII set.
- **Two-dimensional barcodes.** The definition and uses of 2-D codes are covered in Chapter 1, Perspective on Packaging.

Barcode standards are continuously evolving. Check www.gs1.org for current information.

The UPC

The UPC found on retail packages started in the early 1970s as a 12-digit, machine-readable, fixed-length numeric code that uniquely identifies retail products. A five-digit group (manufacturer's identification number) identifies the manufacturer or organization controlling the product label. A second five-digit group (item code) identifies individual items within the company or organization controlling the product label. These main identification numbers are bracketed by two more digits: a number-system digit and a scan-check digit.

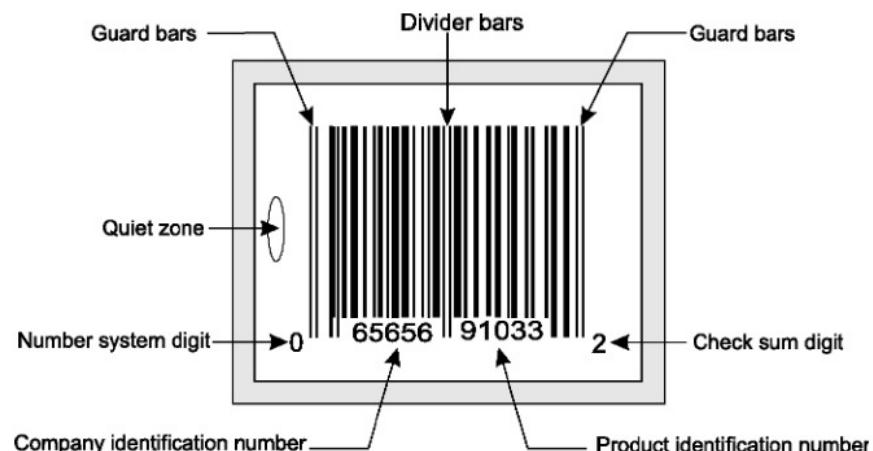


Figure 21.11
A representation
of UPC components.

The company identification number, assigned by GS1 or its representatives, and the product identification number are the central components of a UPC. (See Figure 21.11) Guard bars at either end of the code tell the scanner where the code starts and ends; a pair of divider bars separates the company and product halves of the code.

The check character or check digit at the end of the UPC is a value used for performing a mathematical check to ensure the accuracy of the scanned message. The number system digit identifies particular categories of scanned product. All barcode values also are presented in human-readable form underneath the machine-readable bars in the event that manual entry or verification is required.

The “quiet zone” is a specified area that must be kept clear of any printing or features that the scanner might mistake for a barcode element. This might include text, graphic designs, the package edge, creases and seams. For some barcode applications, the quiet zone is framed by a printed frame or “bearer bars.” These ensure that printing plate pressure is even across the barcode. Bearer bars are particularly recommended when printing on corrugated board.

Barcode Scanners

UPC barcode scanners use a helium-neon (red) laser (emitting at 660 nanometers) to determine the contrast between the reflected light from the dark bars and light spaces. The scan determines the ratio of bar width to space width. Using a ratio allows the scan to cross the code at any angle and also allows codes to be enlarged or reduced slightly as required by particular packaging applications.

The scanner does not see color as such, but rather the presence of red reflected light (space) or its absence (bar). When a black bar is printed on a white surface, the scanner detects red light reflected from the white spaces and no light reflected from the black bars. A black bar printed on a red background also would be scannable. In summary, colors can be used in barcodes providing that a high enough contrast, from the scanner’s point of view, can be maintained.

- White, yellow and red are seen by the scanner as a “space.”
- Black, blue and dark green are seen by the scanner as a “bar.”

Light greens are combinations of yellow (space) and blue (bar). These colors should be avoided or at least thoroughly tested for scannability.

Foils and metal surfaces reflect incident light away from the scanner and would be seen as a bar. An opaque white patch can be printed under the barcode to eliminate this problem. Alternatively, the code printing can be reversed and white spaces can be printed over the reflective surface, leaving the bare metal to represent the bars. Clear plastic films also require an opaque patch to be printed under the barcode symbol.

Printing and Scannability

Accurate scanning requires precise printing, and print, or bar, gain will affect scannability since gain reduces the size of the space between the bars. Reduction of space width can seriously affect the bar-to-space width ratio and result in a misread. All printing processes have some gain, but older flexography, in particular, requires care to ensure good scanning. Since gain tends to be greatest in the printing machine direction, it is best to locate UPCs so the bars are aligned in the machine direction. Gain in bar length is not as detrimental as gain in bar width.

Each press has its own printing characteristics. For purposes of barcode printing, each press needs to be “fingerprinted” to determine its printing attributes on any particular ink and substrate. Fingerprinting is used to determine the amount of gain inherent in the process for the purpose of producing a high-quality barcode film master. Film masters for barcode symbols will be size reduced to make up for subsequent gain during the printing on that press.

SECURITY LABELING

The National Retail Federation estimates North American retailers lose \$50 billion annually to theft. Product diversion to unauthorized retail channels and product counterfeiting add to the losses. Retailers have struggled to reduce these losses by various means. Initially, this meant careful watch with mirrors and keeping theft-prone goods in locked display cases. Early electronic devices were cumbersome.

Technological advances have reduced the cost of “electronic article surveillance” (EAS) tags, and the devices themselves have become almost paper-thin and the size of a commemorative postage stamp. As more retailers are asking their suppliers to include EAS tags in their products (source coding), the problem of tagging merchandise is shifting from the retailer to the package supplier. In short, the reduction of shoplifting losses has become a packager’s problem.

Two basic technologies are currently in use: Sensormatic systems employ acoustomagnetic technology, while Checkpoint systems use radio frequency technology. Both technologies revolve around a label or tag attached to the merchandise. If the tag is not deactivated at a checkout counter, it will respond to a signal sent when the article is moved between sensor gates at the exit and trigger an alarm.

In the acustomagnetic system, the sensor gate emits low radio frequency 58 kilohertz (kHz) pulses. The EAS tag has a built-in resonator that will begin to vibrate at 58 kHz, identical to the transmitted frequency. A receiver inside the sensor gates listens for a response in the 11 milliseconds between emitted pulses. If it receives a signal at least four times, it will set off an alarm.

A magnetized strip next to the resonator ensures that the resonance response is at precisely 58 kHz. A device at the checkout counter can deactivate the label by demagnetizing the strip or altering its magnetic properties so it resonates at some other frequency.

Radio frequency identification (RFID) technology revolves around a circuit that is etched from aluminum foil and laminated to a paper carrier. The RFID circuit is tuned to resonate to an 8.2 megahertz (MHz) transmitted signal. The deactivation device generates an RF field that alters the tag's resonance frequency.

EAS devices are small enough that they can be incorporated into the backs of price tags or pressure-sensitive labels. They can be laminated into multilayer constructions, attached to the inside of a folding carton, attached to the product itself or simply dropped into the package with the product. In these applications, the EAS tag is not visible to the prospective shoplifter. Depending on the situation, all merchandise or a selected percentage can be tagged.

Discouraging shoplifting is only one of the benefits of EAS and RFID tagging. RFID, in particular, has proven beneficial in product tracking, from source to end-use customer, and in inventory control.

DURABLE GOODS PACKAGING

The packaging of durable goods such as appliances and furniture is directed more at containment and protection than marketing and graphic display qualities. Corrugated board, often doublewall, is the main structural material, sometimes in conjunction with wood battens, skids or platforms. Internal securement and protective forms can be made from any of the expanded plastics or cellulose-based materials. Surfaces that can be polished or abraded are wrapped or covered with a nonabrasive isolating material. Rule 41 of the Uniform Freight Classification (rail) and Item 222 of the National Motor Freight Classification (truck) define requirements for packaging of almost any durable goods product. An example of furniture packaging is shown in Figure 21.12.

Do not assume the appliance or furniture item will be shipped in its normal use position or that directional arrows will be respected. Couches, desks and long dressers frequently are upended to make use of carrier vehicle space. Packages can end up on their sides, faces or ends to utilize equipment and space more effectively. The product needs protection from all directions.

Wherever possible, provide handling holes or grips. A heavy item without good gripping points is more likely to be dragged, rolled and otherwise abused. Strategic placement of gripping points also tends to control package orientation.

Suggested good appliance and furniture packaging practices are:

- Cover all woodwork and polished surfaces with a protective nonabrasive material.

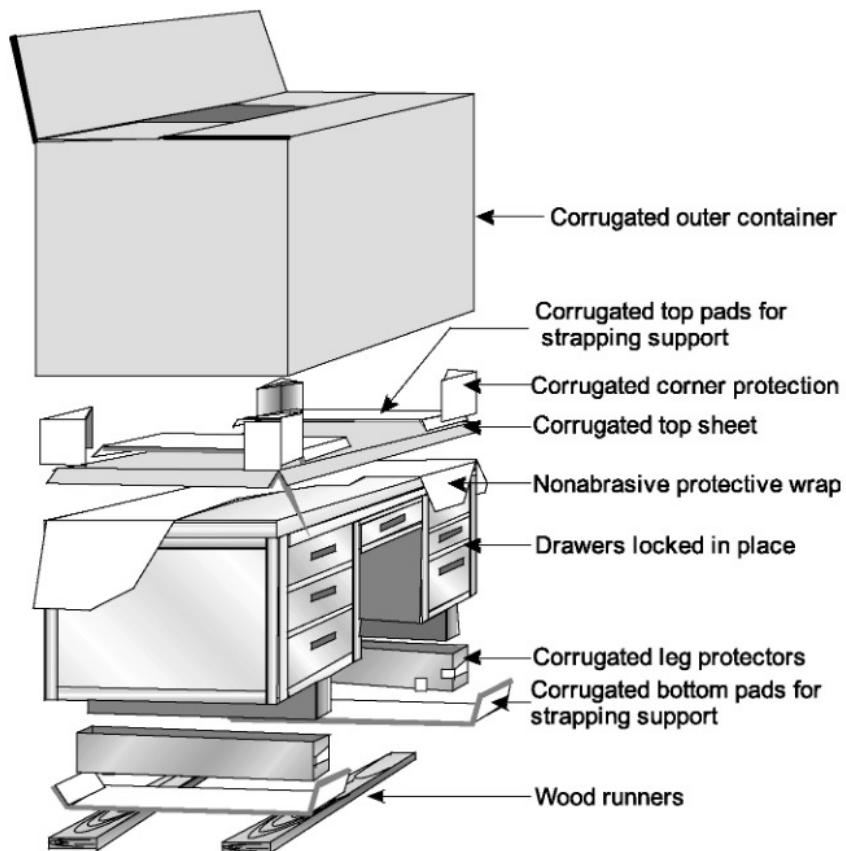


Figure 21.12
An example of a furniture package.

- Protect all edges to at least 75% of their length with inner protective forms.
- Protect all corners and projections with protective forms.
- The outer package should provide at least 20-mm (0.75-inch) clearance between the package and the goods for all surfaces.
- Base, plinths and legs should not be used as bearing surfaces. Suspend pieces off their legs or bases. A separate skid or resting surface attached to the base or legs is another alternative.
- Contain all hardware separately and secure it firmly to an appropriate component. Wrap loose shelves, legs and other finished pieces in protective material and fasten in place. Secure all drawers, doors and other moving parts. Non-marring tape is convenient.
- Corner drops are common. If the object being packaged does not have a great deal of diagonal rigidity, brace the container to provide additional needed support.
- The final package should be tight, with no opportunity for movement of the principal object, subassembly items or interior packaging.
- Designs should be verified with suitable preshipment test procedures.

Table 21.4

The four structural wood groups. The densities in kilograms per cubic meter (kg/m^3) are given for selected woods. For comparison, balsa, the least dense wood, is $40 \text{ kg}/\text{m}^3$ while lignum vitae, the densest wood, is $1,400 \text{ kg}/\text{m}^3$.

Group 1	Group 2	Group 3	Group 4
Aspen	Douglas Fir (545)	Ash (most) (560)	Beech (750)
Basswood (469)	Hemlock (465)	California Black Oak	Birch (650)
Cedar (335)	Southern Yellow Pine	Soft Elm (629)	Hackberry
Cypress	Tamarack	Soft Maples (530)	Hard Maples (740)
Firs (most) (358)	Western Larch	Sweetgum	Hickory (800)
Pine (most) (415)		Sycamore	Oak (750)
Redwood		Tupelo	Pecan
Spruce (480)			Rock Elm (735)
Poplar (465)			White Ash

Group 1 woods are lower-density woods of both coniferous and deciduous species. These woods have moderate nail-holding ability and are relatively free from splitting. They have low to moderate beam and shock strength. Species in this group are easily cut and fastened and are the most economical.

Group 2 woods are all medium-density coniferous species. They are heavily grained woods, with the springwood being much harder than the summerwood. While stiffer and better at holding nails than Group 1 woods, Group 2 woods have a greater tendency to split or to deflect nails from their intended path.

Group 3 woods are medium-density hardwoods. Their structural properties are similar to Group 2 woods, with the important exception that they are less likely to split when nailed or impacted. Group 3 woods are useful for box ends and cleats and when rotary cuts are used to make wire-bound boxes and plywood panels.

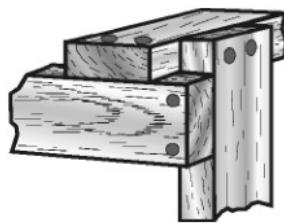
Group 4 woods are high-density hardwoods and have the greatest stiffness, nail pullout resistance and shock resistance. As the heaviest and hardest of the commonly used wood species, they are more difficult to work with. Driving nails, for example, takes some effort, and there is some tendency to split.

WOOD PACKAGING

A small amount of wood is used for upscale and novelty packaging. For these applications, wood usually is selected for its aesthetic properties. Most often, these applications would include attractive close grains and good color and be absent of resinous materials and objectionable odors.

Figure 21.13

A three-way corner joint eliminates the need for weak end-grain nailing.



Wood packaging applications are mainly in pallets, skids, boxes and crates. For these applications, structural properties such as stiffness and fastener-holding ability become of paramount importance. Although all woods are chemically similar, the amount and nature of the cellulose fiber component result in a broad range of properties. The amount of cellulosic material in a wood species is related to its density. It follows that a denser wood species likely will be stiffer and able to hold a nail better than a soft, low-density wood. This consideration has led to a general division of wood species into the four structural groups shown in Table 21.4.

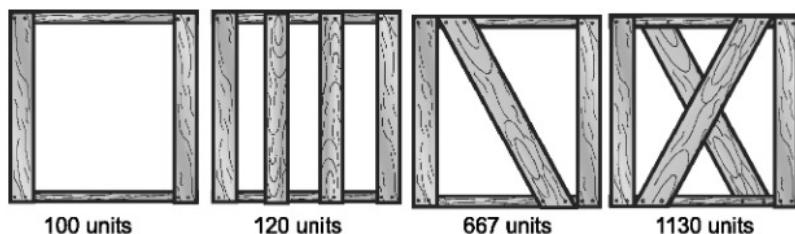
Sturdy wood constructions start with the selection of good quality wood; well-seasoned, dry and free of excessive warp, knots, splits and dry rot. Assembly should follow good nailing practice:

- Drive nails through the thinner piece into the thicker wherever possible.
- A nail should have twice the length in the thicker piece than in the thinner, or at least 40 mm (1.5 inches).
- Never nail into the end grain. Nail withdrawal resistance from the end grain is very low. Figure 21.13 illustrates the proper method of making a three-way corner that avoids end-grain nailing. “Toe” nailing is only marginally better than end-grain nailing.
- Design containers so that nailed joints are in shear since this offers the greatest resistance to nail withdrawal.
- Clinch nails where the joined pieces are less than 75 mm (3 inches) thick.
- Avoid placing nails closer than the thickness of the board from the end or half the thickness from an edge.

Good crate and box designs make extensive use of diagonal members to increase the structure’s rigidity. Figure 21.14 illustrates the effect of perpendicular and diagonal bracing.

Figure 21.14

The rigidity of a structure is most significantly improved by diagonal bracing members.



ASTM D6039, Standard for Crates, Open and Covered, is a guide to the design and construction of open and closed wood crates.

PHARMACEUTICAL PACKAGING: HUMAN DRUGS AND BIOLOGICS

Introduction

It is essential that drugs be taken in the prescribed amount and at the prescribed time to achieve the desired effects. Furthermore, a high degree of confidence is needed that the drug, as taken by the patient, is actually the one that was prescribed and that it has not lost or changed potency. Any departure from these conditions could result in ineffective treatment or more serious consequences since many drugs are potentially harmful or even toxic when improperly administered. Package design, production and distribution must ensure the delivery of the proper quantity of the proper drug to the patient.

Product Formulation

Pharmaceutical dosage forms are a mixture of drug substance, or active pharmaceutical ingredients, and excipients (inactive ingredients). The selection of the final dosage form of a product is based on many factors, including the route of administration, chemical stability, etc. Table 21.5, provided by IoPP's Drug and Pharmaceutical Packaging Committee, is a summary of the various dosage forms and associated routes of administration.

When considering primary package design, it is critical to understand the properties of the drug substance, its mechanisms of chemical degradation and the final dosage form. For example, is the active ingredient sensitive to moisture, light, oxygen or temperature, among others? Based on these factors, a material can be selected to protect the product accordingly. Once the material is selected, the other area to consider is the potential for product and package interaction. In general, the greater the contact between the product and the package, the greater the risk of an interaction. Certain types of drug dosage forms (such as injectable and inhalation products) have an inherently greater degree of concern for package interaction and, thus, should be more carefully scrutinized during package selection. Table 21.6, taken from the Food and Drug Administration's Guidance for Industry: Container Closure Systems for Packaging Drugs and Biologics, illustrates the level of concern for product/package interaction when taking both the product route of administration and the product dosage form into account.

Primary Packaging

Pharmaceutical package development is a critical part of the drug development and approval process. Drug applicants must submit information to the appropriate health authorities (e.g., Food and Drug Administration (FDA), European Medicines Agency

Table 21.5
Product dosage form factors.

<i>Route of Admission</i>		<i>Route of Absorption</i>	<i>Dosage Forms</i>	
Oral		Digestive Tract (enteral)	Solids	Tablet – Micro Tablet – Granules – Capsule – Gel Cap – Gummy
			Liquids	Solution – Softgel – Suspension – Emulsion – Syrup
		Buccal/Sublingual	Solids	Orally Disintegrating Tablet – Film – Lollipop – Chewing Gum – Oral Patch – Lozenges
			Liquids	Mouthwash – Toothpaste – Ointment – Oral Spray
		Respiratory Tract	Solids	Dry Powder Inhaler
			Liquids	Pressurized Metered Dose Inhaler – Nebulizer
Ophthalmic / Otologic / Nasal			Nasal Spray – Ear Drops – Eye Drops – Ointment	
Urogenital			Ointment – Pessary (Vaginal Suppository) – Vaginal Ring – Vaginal Douche	
Rectal (enteral)			Ointment – Suppository – Enema – Murphy Drip	
Dermal			Ointment – Topical Gel – Paste – Film – Cream – Lotion – Transdermal Patch – Transdermal Spray	
Parenterals / Combination Products			Syringes – Micro Needles – Intravenous Solutions – Micro Infusers – Injector Pen (Intradermal – Subcutaneous – Intramuscular – Intraosseous – Intraperitoneal – Intravenous	

Table 21.6
Examples of packaging concerns for common classes of drug products.

Degree of Concern Associated with the Route of Administration	Likelihood of Packaging Component/Dosage Form Interactions		
	High	Medium	Low
Highest	Inhalation aerosols and solutions; injections and injectable suspensions*	Sterile powders and powders for injection; inhalation powders	
High	Ophthalmic solutions and suspensions; transdermal ointments and patches; nasal aerosols and sprays		
Low	Topical solutions and suspensions; topical and lingual aerosols; oral solutions and suspensions	Topical powders; oral powders	Oral tablets and oral (hard and soft gelatin) capsules

*In this table, the term "suspension" is used to mean a mixture of two immiscible phases (e.g., solid in liquid or liquid in liquid). As such, it encompasses a wide variety of dosage forms such as creams, ointments, gels and emulsions, as well as suspensions in the pharmaceutical sense.

(EMA), Health Canada, etc.) regarding the packaging materials used to protect and preserve the drug (both drug substance and drug product) and show suitability of the material selected for the intended shelf life.

In addition, the packaging components and/or systems must be functional and cost-effective and meet all distribution and disposal requirements (e.g., cold chain, etc.). For example, pressure differentials experienced during air transport can lead to the seal on the end of a syringe's plunger to move into a nonsterile area and back into the sterile area after the pressure has returned to normal. In pharmaceutical packaging, the term "container-closure system" is used to describe both the primary packaging (i.e., product-contact material) and the secondary packaging components that protect the drug substance and drug product from point of packaging, through supply chain distribution and throughout the product's shelf life.

Different types of primary container-closure systems are used in the pharmaceutical industry for both drug substance and drug product. The type of dosage form and the route of administration typically drive the container-closure system selected. The qualification process to determine the suitability of the primary container-closure system is dependent on the complexity of the dosage form and the suitability of the packaging systems. This includes monograph testing to meet the appropriate pharmacopeia standards, such as the *United States Pharmacopeia (USP)*, *European Pharmacopeia* and *Japanese Pharmacopeia*.

Considerations on the qualification process should include external protection factors. This would include temperature, light and moisture; compatibility of the packaging system to the product due to interactions, such as absorption or adsorption; safety of the material selected and its material of construction through extractable and leachable testing; toxicology evaluation; and lastly, the performance of the packaging. Performance includes the packaging's ability to function in the manner the design intended, as well as the ability to deliver the product in the right amount per the approved dosing quantities or levels over the shelf life of the product.

Solid-dose products (tablets, capsules, etc.) typically are packaged in plastic bottles with closures and/or blister packaging. Glass container systems are less commonly used in solid-dose packaging due to the increased barrier and light protection properties of plastic packaging. However, glass container systems such as ampoules, vials and syringes are used for sterile injectable products. Form-fill-seal systems for powders, liquids, transdermal and solid-dose products—such as strip packs, sachets and pouches—using plastic, aluminum foil, paper/poly or paper/poly/foil laminate packaging are common in different parts of the world.

As product delivery systems and routes of administration become more sophisticated, primary container systems have become more complex. The increasing complexity has led to combination product regulations and requirements as the product and the device or the packaging become more intertwined. It is important that a drug product development effort considers the types of packaging systems early in the development process and has in place well-defined requirement specifications, design and development plans and, with the highly regulated pharmaceutical industry, proper documentation and qualification of the primary and secondary packaging and the associated manufacturing processes.

For further reading on pharmaceutical packaging, the following guidance documents are recommended:

- For product registration and filing requirements, the International Conference on Harmonization (ICH) M4Q (Quality section) of the Common Technical Document provides a harmonized structure and format for presenting CMC (Chemistry, Manufacturing and Controls) information in a registration dossier and it includes requirements for the container-closure section. (See <http://www.ich.org>)
- FDA Guidance for Industry on Container Closure Systems for Packaging Human Drugs and Biologics. (See <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/container-closure-systems-packaging-human-drugs-and-biologics>)
- FDA Guidance for Industry on Changes to an Approved NDA and ANDA. (See <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>)
- *Rules and Guidance for Pharmaceutical Manufacturers and Distributors 2017* (known as “the Orange Guide”). (<https://mhrainspectorate.blog.gov.uk/2016/12/02/the-2017-orange-and-green-guide>)

Secondary Packaging

Development of the secondary packaging for pharmaceuticals is the next step in protecting the drug product for its journey to the patient. In many cases, secondary packaging protects products from moisture, oxygen and light, including ultraviolet (UV) rays. It also supports communication and graphics design to differentiate strengths, product names and critical regulatory labeling information. Secondary packaging mockups with artwork often are submitted to the health authorities (i.e., FDA, EMA, Health Canada, etc.) for approval before product launch.

Although secondary packaging is not in direct contact with the drug product, it often is tested for its interaction with the drug product. For example, where labels are affixed to plastic vials, leachables and extractables testing is performed on the ink and adhesive to determine if any migration of the substances will occur during the life of the product. Secondary packaging also may be required for stabilities studies to determine the shelf life of the product. All secondary packaging materials should be tested for functionality (e.g., abrasion resistance, accelerated aging, etc.), as well as manufacturability and ability to withstand the distribution environment, before heading into manufacturing.

There are several types of secondary packaging based on the primary container-closure systems (e.g., syringe, vial, blister, etc.). For example, the typical secondary package for a syringe would be to place it into a tray with a lidstock, then slide the tray and instructions-for-use into a side-load carton. (See Figure 21.15) To minimize components, syringes can be placed in a top-load carton with glued flutes. (See Figure 21.16) When protecting a vial from distribution channels, the most common secondary package would be a top-load carton, with an insert. (See Figure 21.17)

Compliance packaging is a specialized type of secondary packaging, which helps promote adherence to medication dosing instructions. Poor adherence has a tremen-

dous cost in dollars and lives. Pharmaceutical compliance packaging is best described as packaging that supports or enables the consumption of the correct dose of the appropriate medication at the correct time for the prescribed duration of treatment. Compliance packaging contributes to this goal through:

- Ease of identification (to avoid taking the wrong medication).
- Clarity of instruction (to ensure medication is taken how/when it is prescribed).

Figure 21.15
Syringes are packaged in a side-load carton.



Figure 21.16
To minimize components, syringes can be placed in a top-load carton with glued flutes.



Figure 21.17
When protecting a vial from distribution channels, the most common secondary package would be a top-load carton with an insert.



- Visible evidence of medication dispensed (to avoid skipped or repeat dosage).

This category of packaging most commonly involves blisters or bottles but is not limited to that packaging and can use calendars, colored graphics and, sometimes, electronics for reminders/prompts and tracking features. With the incorporation of Internet and cell phone connectivity, extended families, healthcare professionals and caregivers can be notified of dosing history. The technology also can support automatic refills when appropriate. Compliance packaging is used most often to optimize the effectiveness of treatment, especially for chronic conditions.

The following industry organizations offer further information:

1. Healthcare Compliance Packaging Council
<http://www.hcpconline.org>.
2. European Healthcare Compliance Packaging Council
<http://www.hcpc-europe.org>.

All secondary designs are lab-tested for protection and line trials are completed when the manufacturing sites are determined. A limited number of guidance documents are available specifically for pharmaceutical packaging. Often, medical device packaging guidelines are adopted for pharmaceutical packaging because the packaging designs and applications are similar. The following guidance documents are recommended when developing secondary packaging.

1. Distribution Testing

- a. ASTM D4169, Standard Practice for Performance Testing of Shipping Containers and Systems.
- b. ISTA 3A, Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb.) or Less.

NOTE: ASTM D4169 and ISTA 3A are recognized consensus standards for sterile medical device packaging. (<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/detail.cfm?id=28714>)

- c. USP 1177, GOOD PACKAGING PRACTICES.

2. Printed Material Testing

- a. ASTM D5264-98, Standard Test Method for Abrasion Resistance of Printed Materials by the Sutherland Rub Tester.
- b. ASTM F1980-99e1, Standard Guide for Accelerated Aging of Sterile Medical Device Packages.
- c. ASTM D4332, Standard Practice for Conditioning Containers, Packages or Packaging.

3. Container Testing

- a. FDA Guidance for Industry on Container-Closure System for Packaging Human Drugs and Biologics. (<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>)
- b. USP 661, Containers Plastics (includes Extractables and Leachables).

- c. USP 671, Container Performance Testing.
- d. USP 1136, Packaging Unit-of-Use.

4. Stability Testing

- a. Product stability requirements, ICH Quality Guidelines for Stability Q1A-Q1F. (<http://www.ich.org/products/guidelines/quality/article/quality-guidelines.html>)
- b. Guidance for Industry Q1A(R2) Stability Testing of New Drug Substances and Products. (<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073369.pdf>)

5. Child-Resistant/Senior-Friendly Packaging

- a. ASTM D3475-20, Standard Classification of Child-Resistant Packages.
- b. ISO 8317:2005, Child-Resistant Packaging—Requirements and Testing Procedures for Reclosable Packages.

Temperature-Controlled Shippers

The essential principles and practices of transporting temperature-sensitive pharmaceutical products through the transportation environment are commonly referred to as “cold chain.” These products must be transported under temperature control to ensure product quality and safety are not adversely affected. The most common temperature range for temperature-controlled shippers is 2–8°C, although increasing quantities of products are shipped at controlled room temperature (15–30°C), as defined by the *USP*, and deep-frozen temperature ranges ($\leq-20^{\circ}\text{C}$, $\leq-60^{\circ}\text{C}$, $\leq-120^{\circ}\text{C}$).

The distribution environment can vary greatly, especially when transporting pharmaceutical products between climatic zones. Seasonal changes, mode of transportation, physical hazards such as shock and vibration and regional regulations and capabilities are variables that must be considered within the transportation environment. These variables should be evaluated on a case-by-case basis for the impact on the product and its packaging.

The principles of qualification for the transport of temperature-sensitive medicinal products must closely follow established guidelines and regulations for qualifying the manufacture of these same products. These include:

- Development of specifications, processes, systems and components.
- Written procedures.
- Approved protocols and reports.
- Justified test methods and acceptance criteria.

To perform operational qualification studies of temperature-controlled shipping packages, it is necessary to conduct laboratory testing to thermally challenge the packages and systems. These tests should be conducted using industry-standard or custom environmental temperature profiles, which are representative of the conditions the package will encounter during shipment. To develop custom thermal testing profiles for shippers, several factors must be considered, including temperature

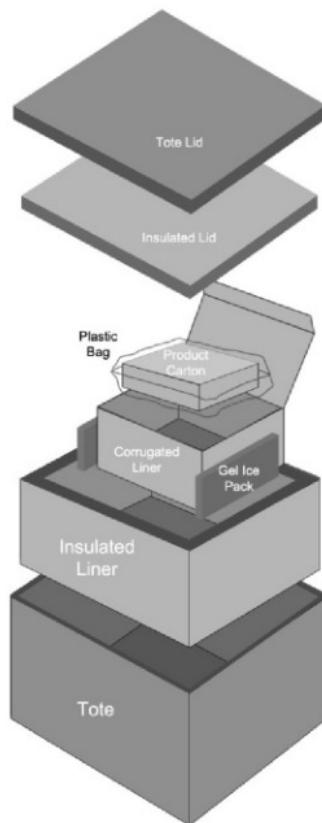


Figure 21.18
Packaging configuration of a controlled-temperature shipper.

conditions at the shipper's origin and destination and mode(s) of transit, as well as the total duration of transit.

Other environmental profiles, such as shock and vibration, need to be based on realistic expectations of transport conditions and developed using scientifically sound criteria. This is performed using field-testing/monitoring of actual shipments, review of published standards or other means. Sound rationale must be provided for the process used in selecting or developing temperature and physical profiles used in transport qualification testing.

The allowable minimum and maximum product loads for transport in the temperature-controlled shippers must be determined during qualification. The thermal mass of the product load has an impact on the stability of the system. The lower the thermal mass of the product load, the more reactive it is to ambient temperature variation. (See Figure 21.18)

Cold chain packaging shippers that have been confirmed through operational qualification are verified during performance qualification. The performance qualification serves to demonstrate that the temperature-controlled shipping system is effective and reproducible with the processes and procedures established. The relevant personnel and organizations participating in the cold chain process are trained in the procedures for material conditioning and handling, packaging and shipping. Updates to the processes and procedures are made as needed based on the outcome of performance qualification execution.

Combination Product Device and Packaging

In 21 CFR 3.2(e), the FDA defines “combination products” as therapeutic and diagnostic products that combine drugs, devices and/or biological products. These combinations of two or more different types of regulated products include:

- Drug and device.
- Biologic and device.
- Drug and biologic.
- Drug, device and biologic.

The combinations mentioned above could be:

1. Physically or chemically combined or mixed products to create a single entity.
2. Co-packaging of two or more separate products in a single package or kit.
3. Products packaged separately but approved and labeled for intended use only with specific combinations.

The container-closure systems selected for packaging combination products must meet all the technical and regulatory requirements of the individual components of the combination (device, drug, biologics). For the drug and biologics, this would include ICH stability in the final packaged system throughout its shelf life and compliance to compendia and individual country requirements. For devices, the packaging components should protect the shelf life of the combination product and have documentation on design control per ISO 13485, ISO 14971 and CFR 820. An area of increasing requirements is human factor engineering studies as part of the development of the combination product-device packaging.

Pharmaceutical Packaging Equipment Design and Qualification

Regulations are translated into company procedures that assure safety, cleanliness and process control during manufacturing and packaging operations. Documentation is required to show that materials received from suppliers match the acceptance criteria established for the end pharmaceutical product. Instructions for assembling drug product and packaging into a salable unit are required and changes to these documents are tightly controlled to ensure that the safety and efficacy of the drug product are not compromised.

The pharmaceutical industry specifies packaging equipment that meets its unique regulatory expectations. These expectations, as defined by the current Good Manufacturing Practices (cGMP) of the respective health authorities of the approving countries, drive equipment and facility design, testing, validation, maintenance, personnel training and documentation.

Equipment manufacturers must take special measures to assure that equipment is designed to be cleanable and sanitary. The design expectation for cleanliness varies

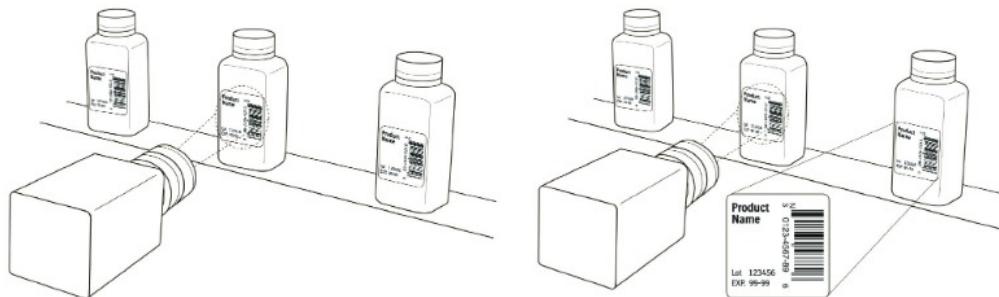


Figure 21.19
Example of electronic verification systems for printed material.

even within these parameters and depends on the nature of the products being packaged, e.g., equipment for aseptic or sterile products has very high cleaning and sanitization standards, while the expectations for oral solid dosage forms or topical ointments are less stringent. Cleanliness standards can extend to requiring that equipment is designed to allow for visual inspection during batch changeover to check for the presence of stray product and packaging components.

Modern pharmaceutical packaging equipment sourcing also must support robust equipment commissioning and qualification. The industry-standard approach is defined within the *Baseline Guide Vol. 5: Commissioning & Qualification, 2nd Edition*, published by the International Society for Pharmaceutical Engineering (ISPE). This approach requires a risk-based approach to equipment specification and design, as well as commissioning and qualification.

Following qualification and startup in production, strict regulatory requirements compel packagers to maintain control of their equipment once it is qualified. These requirements include documenting preventive and corrective maintenance and training of maintenance personnel and operators.

Special attention should be paid to computerized control systems such as programmable logic controllers, human/machine interfaces and supporting systems. These computerized systems often play a key role in controlling critical-to-quality attributes, and as such, are required to be well-designed, documented and qualified through robust testing.

Many regulatory agencies also have strict requirements for controlling printed materials including labels, printed packaging components and patient information inserts. Printed materials often are designed to identify and differentiate products and strengths to reduce patient dosing errors. Full 100% reconciliation of printed materials is typically required in packaging operations, and modern equipment often features electronic verification devices such as barcode scanners or vision systems to verify that every single printed packaging component used is the correct item for that product and batch. (See Figure 21.19)

For further definition of best practices for pharmaceutical packing equipment specification and qualification, refer to ISPE's *Baseline Guide Vol 5: Commissioning & Qualification, 2nd Edition* available at ispe.org.

Pharmaceutical Regulations

The packaging and sale of drugs are strictly regulated, and these regulations are intended to assure a high level of safety and efficacy of the products delivered to patients. Enforcement of regulations is achieved via approval of products submitted to regulatory agencies for marketing and by inspections of manufacturing and distribution facilities. The primary responsibility for drug regulations falls under the jurisdiction of the FDA in the United States. Various other regulatory agencies exist and continue to evolve throughout the world. For example, many other governmental agencies enforce similar standards of quality in drug manufacture and packaging. Many of these agencies are increasingly involved in inspection activities and document submissions in their own right. For example, the roles of the Health Products and Food Branch in Canada and the EMA in Europe are growing in importance in the ever-more-global marketplace.

Although details vary, the spirit and intent of regulations are similar in many countries. Section 505 (b) of the U.S. Federal Food, Drug and Cosmetic Act establishes the basic regulatory framework:

Any person may file with the Secretary an application with respect to any drug subject to provisions of section 505 (a). Such persons shall submit to the Secretary as part of the application (1) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use; (2) a full list of the articles used as components of such drug; (3) a full statement of the composition of such drug; (4) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing and packing of such drug; (5) such samples of such drug and of the articles used as components thereof as the Secretary may require; and (6) specimens of the labeling proposed to be used for such drug.

Governmental agencies around the world regulate aspects of drug and pharmaceutical packaging and manufacturing, such as the Drug Enforcement Agency (DEA) for controlled substances and the Consumer Product Safety Commission (CPSC) for child-resistant and senior-friendly packaging. Regulating agencies include:

- U.S. Food and Drug Administration.
- U.S. Consumer Product Safety Commission.
- U.S. Customs and Border Protection.
- U.S. Drug Enforcement Agency.
- U.S. Transportation Security Administration.
- European Medicines Agency-European Union (EU).
- Pharmaceuticals and Medical Devices Agency-Japan.
- Korea Ministry of Food and Drug Safety.
- Taiwan Food and Drug Administration.
- National Drug Authority-Uganda.

- Therapeutic Goods Administration-Australia.
- Brazilian Health Surveillance Agency (ANVISA).
- Cooperation Council for the Arab States of the Gulf (formerly the Gulf Cooperation Council).

Brand and Product Protection

As pharmaceuticals are considered “high-value” products, special consideration must be taken to deter counterfeiting. To protect products, many companies use overt or covert methods to authenticate drugs at the packaging level.

Overt methods are those that end-users can readily see and authenticate. The use of holograms, color-shifting ink or any visible indicator on the package can be described as an overt anticounterfeiting technique.

The main benefit of an overt measure is that end-users can easily authenticate packaged products, thus giving them a reasonable sense of confidence that the product is legitimate. The downside is that a potential counterfeiter also is aware of the anticounterfeiting indicator and may reproduce it to fool the end-user into thinking the product is legitimate. As counterfeiters have continually adapted and become more sophisticated in their ability to reproduce overt anticounterfeiting identifiers, companies must continue to develop more sophisticated overt techniques to stay ahead.

Covert methods typically cannot be easily seen or authenticated by the end-user. Such methods are designed to be used by the pharmaceutical company itself or by other special personnel who know how to find and identify the feature(s). These techniques are particularly useful in investigating potentially counterfeited products in the supply chain. The use of special taggants, micro-printing, invisible ink or very small but deliberate printing errors on the package are examples of covert anticounterfeiting techniques.

Covert methods have the benefit of being hard to detect and/or reproduce by potential counterfeiters and, as such, tend to be more reliable indicators of legitimate product. The downside of covert anticounterfeiting methods is that very few people in the supply chain will have the knowledge or the proper equipment to effectively identify those features. Many companies apply both overt and covert features to their packaging to achieve the broadest assurance of product authenticity throughout the supply chain.

Another concern for pharmaceutical products is product diversion and theft. Diversion and theft occur at every level of the pharmaceutical supply chain—manufacturing, packaging, storage and shipment. Pharmaceutical companies must take precautions to ensure that product cannot be extracted easily from the legitimate supply chain. To reduce the potential for product theft, stakeholders employ security cameras and special garments that inhibit one’s ability to hide stolen product and implement handling procedures to ensure product does not linger in unsecured areas for longer than necessary.

In the United States, drugs that have a high potential for abuse (and, thus, diversion) are classified as controlled substances under the Controlled Substances Act (Title 21 USC § 801). These types of drugs that have an accepted medical use are classified as “Schedule II” through “Schedule V” by this act, with the schedule a drug

receives based on its potential for abuse. Scheduled drugs must meet additional documentation, transit, handling and storage requirements beyond those of non-scheduled drugs to prevent product theft. Drugs defined as Schedule II must meet the highest set of requirements, including the use of vaults for product storage throughout the distribution and supply chain down to the pharmacy. In recent years, the principles of Good Distribution Practices across the industry have become increasingly critical to pharmaceutical supply chain security.

In the effort to find a comprehensive plan to reduce the potential for drug counterfeiting and diversion, many countries have introduced regulations for serialization. In the United States, the Drug Quality and Security Act (DQSA) was enacted by Congress on November 27, 2013. Title II of DQSA, the Drug Supply Chain Security Act (DSCSA), outlines the current regulatory requirements for serialization to enhance prescription drug security during the next decade. The scope of the DSCSA can be broken into four phases: lot-level product traceability, unique product identification, wholesaler verification and full supply chain traceability.

For lot-level product traceability requirements, the manufacturers, repackagers and wholesale distributors must provide transaction information, transaction statements and transaction history with lot-specific information in electronic or paper format.

For unique product identification requirements, manufacturers are required to affix serialization information (GTIN, serial number, batch/lot number, expiration date) in human-readable text and machine-readable barcode symbology (GS1ECC200 DataMatrix code) at each saleable level. The serialization information must be printed at the unit level (e.g., folding boxes, bottle labels, sleeves, dose packs, etc.) and shipper/case level (e.g., shipper label, etc.) for prescription drug packaging. Data element sequence in a barcode symbology should follow the GS1 requirements. For shipper label, partial shipper and pallet label layout requirements, Healthcare Distribution Alliance (HDA) Guidelines for Bar Coding in the Pharmaceutical Supply Chain should be followed as a reference document. Serialization information must be stored for six years after the transaction date (DSCSA Title II, SEC. 202, Subchapter H, SEC. 582 (b) (1) (A)(ii) and (2) (A)). In the event a product is recalled, determined to be illegitimate or suspected to be illegitimate, manufacturers, repackagers, wholesale distributors and dispensers are required to notify FDA and other trading partners not later than one business day and within 48 hours.

For wholesaler verification requirements, manufacturers are required to communicate serial numbers to wholesalers to verify saleable returns before being reintroduced to the supply chain.

For full supply chain traceability requirements, manufacturers, repackagers, wholesale distributors and dispensers must be able to exchange serial number data in an EPCIS format.

The EU also has adopted legislation to protect patients from the threat of counterfeit medicines. The Falsified Medicines Directive (Directive 2011/62/EU), known as the EUFMD, was published on July 1, 2011, and took effect on January 2, 2013. This law required the implementation of serialization on the secondary packaging of all prescription drugs with limited exceptions, beginning in February 2019. The serialization is required to be applied as a GS1 2D DataMatrix code that contains the GTIN, serial number, lot and expiration date. In some markets (such as Portugal) where a national drug registration number is key to product identification, that number is included as well. This information must be included as human-readable in-

formation next to the code to allow the pack to be identified if the code is unreadable.

The data relating to the serialized packs in the EU must be submitted to the European Medicine Verification System (EMVS). The EMVS acts as a hub, rather than an EU-wide repository. Each EU member state was required to establish its own National Medicine Verification System (NMVS) that stores the serialization data related to the packs that are meant for their market. The EMVS passes submitted serialization data to the relevant NMVS.

The EUFMD requires that every pack be scanned at the point of dispensing to the patient to verify the serial number. If the number is valid, it will be marked in the system as dispensed, and the patient receives the medicine. If the number is not found or in an invalid state, the manufacturer is sent an alert, and the pharmacist will not dispense the pack to the patient. The system also can be used to verify suspicious packs at any point in the supply chain.

Serialization requirements are quickly becoming global with requirements in place or emerging in many markets.

However, the downside of the above is there is no globally harmonized process to meet all the requirements from different regions and countries.

- 1.** Title United States Code (USC) Controlled Substances Act.
<http://www.deadiversion.usdoj.gov/21cfr/21usc/index.html>
- 2.** Guidance for Industry—Standards for Securing the Drug Supply Chain—Standardized Numerical Identification for Prescription Drug Packages.
<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM206075.pdf>
- 3.** WHO Technical Report Series, No. 957, 2010, *WHO Good Distribution Practices for Pharmaceutical Products*.
<http://apps.who.int/medicinedocs/documents/s18678en/s18678en.pdf>
- 4.** DQSA.
<https://www.govinfo.gov/content/pkg/PLAW-113publ54/pdf/PLAW-113publ54.pdf>
- 5.** DSCSA.
<https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa>
- 6.** HDA.
<https://www.hda.org/>
- 7.** GS1.
<https://www.gs1us.org/>
- 8.** European Union Falsified Medicines Directive 2011/62/EU.
http://ec.europa.eu/health/files/eudralex/vol-1/dir_2011_62/dir_2011_62_en.pdf

Tamper-Evident & Child-Resistant Packaging

To ensure product safety and effectiveness, tamper-evident (TE) packaging also should be employed on many drug products. TE packaging is broadly defined as product packaging that leaves noticeable evidence that the product has been accessed. TE packages typically employ the use of seals or other barriers that must be breached to access the package contents. These barriers should be noticeable to the end-user

when they have been breached or removed and should not be easily repairable for someone who wishes to illicitly access the contents, steal or adulterate the product inside and then repair the barrier in a way that would be unnoticeable.

TE packaging is a requirement for over-the-counter drug products (in the United States) and should be considered for prescription drug products. EUFMD requires individual packs to be TE. Examples of TE packaging include those that must essentially be destroyed to access the product such as ampules; form-fill-seal containers, blisters and pouches; induction seals; shrink bands on bottles; frangible tape-sealed cartons; TE labels on cartons; glued carton flaps, etc. Many national regulatory organizations, including the U.S. FDA, have requirements or guidelines on how and/or where TE packaging should be used.

Child resistance is another feature that is employed on many pharmaceutical products. While the standards for testing and requirements for child-resistant (CR) packaging can vary from country to country, the U.S. standards for CR packaging were developed because of the Poison Prevention Act of 1970 (Title 15 USC § 1471–1477). In the United States, a package is deemed CR if it meets the requirements set forth in 16 CFR Part 1700—Poison Prevention Packaging. This regulation not only defines the testing procedure for CR packaging, it also identifies which types of products are required to use it.

Under the regulation, any package meeting the definition of a CR package must undergo use testing by at least 50 children and at least 100 adults. This testing is to ensure that the package cannot be opened by the vast majority of children and that it can be opened (and in the case of reclosable packages, reclosed properly) by adults. It is important to note that in the United States, the CPSC administers and oversees the Poison Prevention Packaging Act.

1. 21 CFR Part 211.132 Tamper-evident packaging requirements for over-the-counter (OTC) human drug products.
<http://www.gpo.gov/fdsys/pkg/CFR-2001-title21-vol4/pdf/CFR-2001-title21-vol4-sec211-132.pdf>
2. 16 CFR Part 1700 – Poison Prevention Packaging.
<http://www.gpo.gov/fdsys/pkg/CFR-2012-title16-vol2/pdf/CFR-2012-title16-vol2-part1700.pdf>

CREATIVE DESIGNS

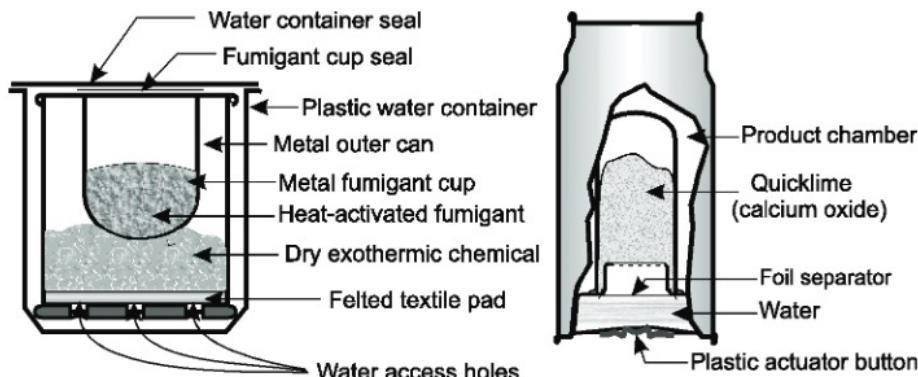
It is easy to conclude that most packages are represented by variations on rectangular boxes or Boston round bottles. But the most creative part of packaging is problem-solving, whether that problem is technical or creative. This section examines a few of the more unusual packaging designs.

Heated Packages

Figure 21.20, left, shows a package designed to provide a timed release of insecticide fog for fumigating buildings. The packaging system is composed of a metal fumigant cup inserted into an outer metal can that has holes punched in its bottom. A felted

Figure 21.20

Self-heating fumigant and beverage can packages. Both are activated by allowing water to come in contact with an exothermic chemical.

**Figure 21.21**

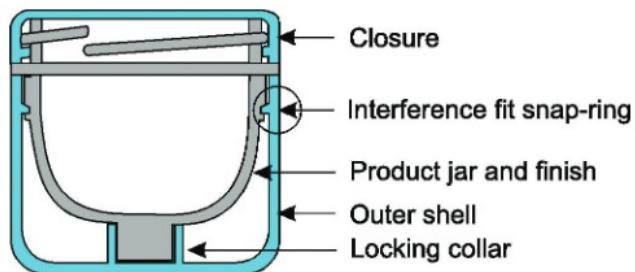
A plastic self-heating container of tea from Italy (left) and a metal self-heating can of coffee.



textile pad blocks the holes enough so that an exothermic chemical in the bottom of the outer can does not fall through, and when in use, controls the ingress of water. The system is activated by pouring water into the plastic water cup. Water seeps through the bottom holes of the metal outer can through the felted textile pad. The reaction between the water and the chemical develops enough heat to vaporize and provide a controlled release of the insecticide retained in the fumigant cup.

Self-heating packages have been developed for a variety of heated-food applications. A self-heating instant coffee (or other beverage) container is activated by pushing a button that ruptures the thin, foil separator membrane, allowing water to make contact with the quicklime. (See Figure 21.20, right) The coffee will be heated to about 60°C (140°F) in 3 min. In Japan, sake is heated by a similar method. Figure 21.21 shows a plastic and a metal self-heating beverage container.

Self-chilling cans are made by replacing the exothermic chemical with an endothermic chemical.

**Figure 21.22**

A two-piece cosmetic jar body designed to provide a smooth, uninterrupted exterior surface.

Shoulderless Jars

Ideally, the inside of a skin cream jar would have straight walls with no undercut. This can be done only if the closure threads are placed around the exterior of a straight-walled cylinder, which would result in a closure larger in diameter than the jar. For aesthetic reasons, some designs call for a perfectly smooth match between the closure exterior and the jar body. One way of achieving this is shown in Figure 21.22. The injection-molded product jar has a smooth-walled bowl to hold the product. Commonly called a double-wall jar, the package provides a high-end look, but comes under scrutiny for excess plastic use and consumer misrepresentation on content size. The closure threads are on the jar. The product jar is snapped into an outer shell that provides the smooth surface that will give an exact uninterrupted match with the closure. The locking collar and the bottom extension of the product jar have a matching series of vertical serrations to stop the inner product jar from turning inside the outer shell when the closure is rotated.

Double-Chambered Packages

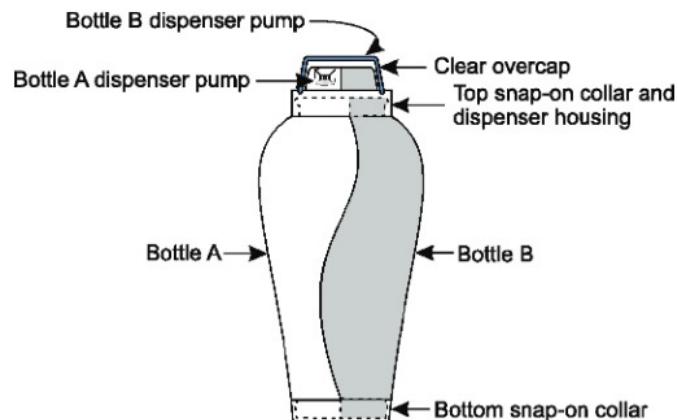
Packages that have two separate chambers have been designed for various applications. Several designs incorporate threads in the base, in effect making the bottom of the jar a closure. A second jar can then be screwed into the bottom of the first jar. Additional jars can be added to produce a “stack” of jars. The dual-bottle package shown in Figure 21.23 is composed of two blow-molded bottles that fit together along a curved side and are held together by adhesive and top and bottom snap-on collars. The upper collar is part of the dispenser pump housing. The pump outlets face in opposite directions.

A similar concept, but assembled from glass, has been used to market a specialty liquor.

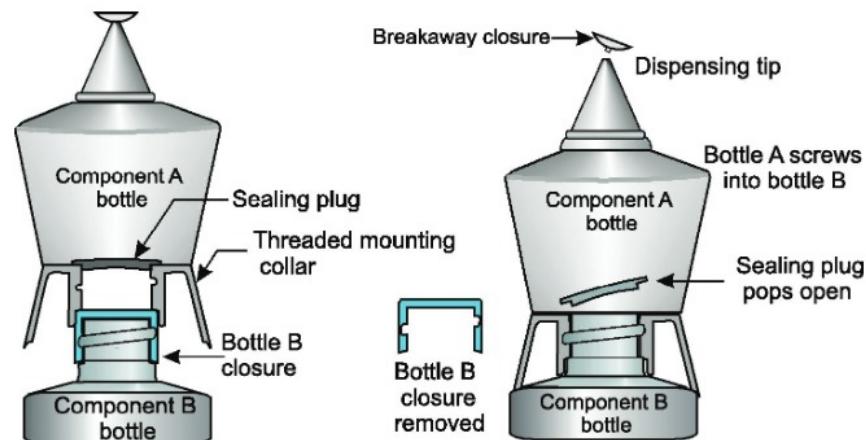
In another variation, the pump draws a metered amount of product from the two separate containers but delivers it through one exit nozzle. This is a useful system for products that must be mixed immediately before use.

Two standard collapsible tubes can be inserted into a larger third tube to provide simultaneous ejection of two components. While simpler than pumps, evacuating the last bit of product can be a challenge.

Hair-coloring kits often have components that must be mixed immediately before use. One common approach is based on having the first component bottle screw into the bottom of the second component bottle. (See Figure 21.24) A plug in the bottom

**Figure 21.23**

A dual-bottle package with dispensing pumps. (After a Lever Ponds design.)

**Figure 21.24**

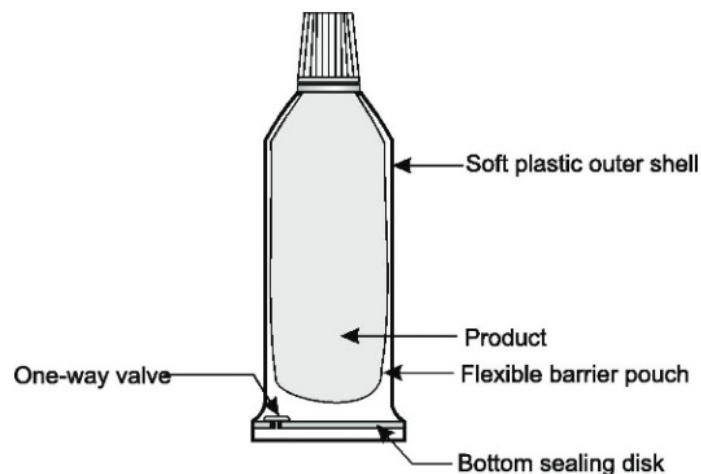
A two-bottle system, typically used for hair-coloring preparations, allows the mixing of two components just prior to use.

of the upper bottle is forced open as the first bottle is screwed in, allowing the two fluids to mix. Since the product is intended for single-use, the upper bottle has a break-away applicator tip rather than a threaded closure.

Other common dual compartments include a syringe, used for two-part epoxy; a two-chamber single-use thermoform that keeps two products separated until folded and squeezed; and tandem flexible pouches.

Squeezable Toothpaste and Valved Containers

Dental creams have been offered in a wide selection of package formats, including aerosol cans and more recently in a complex paste-pump. Despite these innovations, the convenience and low cost of a simple squeeze tube make it a mainstay in the category. The system shown in Figure 21.25 combines the convenience of a squeeze tube with the aesthetic appeal and stand-up advantage of a bottle. The paste, in a high-barrier laminated bag, is sealed into a soft plastic outer shell. When the shell is squeezed, air pressure forces paste out of the bag. When pressure on the outer shell is relaxed, a one-way valve opens to the outside to allow the pressure inside the shell to equalize back to atmospheric.

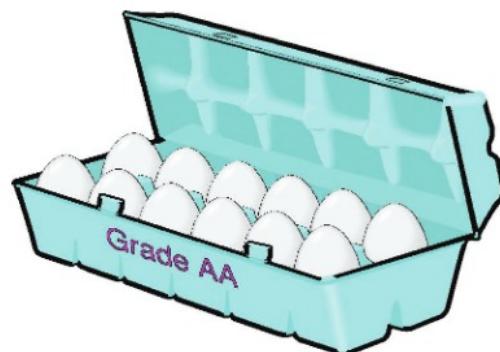
**Figure 21.25**

A flexible product bag inside a valved, squeezable outer shell.

Simple, small one-way valves have been applied to many package types for various purposes. For example, fresh-ground coffee releases significant amounts of carbon dioxide immediately after grinding. Where flexible packaging is done directly from the grinder, a small one-way valve allows internal outgassing pressure to vent the package, while preventing entry of outside air and a shorter shelf life. In another application, a microwavable pouch has a pressure-release valve that allows the venting of excess steam during heating.

Molded Pulp Containers and Forms

Molded pulp refers to three-dimensional packaging articles that are manufactured by pouring a slurry of cellulose fiber and water into a mold made from a fine screen material. The fiber generally comes from low-cost mechanical pulp or recycled feedstock. As in papermaking, the water runs through the screen, usually helped by the application of a vacuum, leaving the matted cellulose fiber caught on the screen. In the basic molding process, the completed form travels through a drying oven to remove the remainder of the water. Familiar applications of molded pulp forms made by the basic method are the common egg tray, corner protectors and berry boxes. (See Figure 21.26)

**Figure 21.26**

Egg trays are most typically molded by the basic process and incorporate recycled fiber.



Figure 21.27
A precision-molded protective form for a camera lens.

In the more advanced (but slower) precision molding process, the part is molded similarly, but drying takes place between heated matched mold surfaces. Precision molding provides a more exactly dimensioned, smoother and denser surface.

Precision forming is used to make disposable dishware products. More recently, significant inroads have been made in protective packaging, such as shown in Figure 21.27. Higher grade pulps, including bleached pulps, are used for many of these applications. Plant-based packaging, introduced by Procter & Gamble for its Gillette Fusion ProGlide razor, is based on bamboo and bulrush and cuts plastic use 75%.

Case-Ready Modified-Atmosphere Red Meat Packaging

Modified-atmosphere packaging is an attractive option for increasing the shelf life of many food products, including red meats such as beef. However, the absence of oxygen, while improving shelf life, gives the myoglobin a deoxygenated deep purple color. This does not present a problem with commercial beef, but the North American consumer is not accustomed to seeing purple beef in the supermarket display case. This problem has been overcome by a modified-atmosphere trayed beef package with a barrier lidstock that peels away leaving a permeable film over the tray. In the back of the store, the beef cuts are all purple. However, when the retailer strips the high-barrier film away from the permeable film, the beef reverts to its oxygenated bright red color in a few minutes. This system enables central processing and packaging.

Printing Inks with a Difference

Not all packaging innovations involve the package's physical design. Thermochromic inks that change color with temperature have been used to indicate when a microwavable product is ready. Another application features a graphic of a wolf on a beer bottle label. When the label is cold, only the wolf's glowing red eyes can be seen. As the bottle warms (presumably as the contents are consumed), the rest of the wolf's image becomes visible.

Doctors occasionally need to conduct certain procedures (for example, when using a video endoscope) in dimly lit rooms. At the same time, they need to be able to read labels on catheters and other medical supply packages. One line of devices used under these conditions improves readability under dim light by using phosphorescent ink for the essential information.

Additional uses for special inks include single-time color-change relating to product quality and evidence of poor distribution or storage; tactile inks for adding texture and depth; and UV inks which are invisible to the consumer but machine-readable, for eye marks, counterfeit taggants and lot codes.

REVIEW QUESTIONS

- 1.** Explain the structural difference between a blister package and a skin package.
- 2.** What plastic material is most commonly used for thermoforming the blister of a blister package? Name two other materials that are also used.
- 3.** What two materials are used for the film component of a skin package? Which is the preferred film for consumer retail applications? Why?
- 4.** Explain why clay-coated boards are not normally used for skin packaging. What disadvantage arises from this fact?
- 5.** What are the two processes used to make fiber can bodies?
- 6.** Why are metal collapsible tubes preferred for many pharmaceutical applications?
- 7.** What decorating advantages might be gained by specifying a laminated tube?
- 8.** Compare the barrier qualities of the four collapsible tube constructions.
- 9.** List three design features that would be applied to a bottle for a semisolid product.
- 10.** Discuss aspects of neck design and its relationship to product, filling and distribution.
- 11.** What problem might be encountered if a bottle design has deep circumferential rings molded around the body?
- 12.** What is the “quiet zone” on a barcode?
- 13.** What does a scanner actually measure when it scans a code? Why was this particular method chosen?
- 14.** The divider bars in a UPC (EAN) code separate two major digit groups. What do the two groups represent?
- 15.** What would happen if you printed red bars on a white background?
- 16.** What three colors are recognized as a bar by a UPC scanner?
- 17.** What problems must be overcome when printing a barcode on a metal can? And on a clear plastic bag?
- 18.** What two significant advantages could be gained with effective EAS tagging?
- 19.** For the purpose of structural applications, woods are classed into four groups. What is the basis of this classification system?
- 20.** What is the design advantage of a three-way wood corner construction?
- 21.** Why do most large wood crates make extensive use of diagonal members?
- 22.** Name the three main avenues of degradation when discussing drugs.
- 23.** What is “gang printing,” and why is this method of printing generally disallowed for pharmaceutical packaging applications?

- 24.** What does the term “validation” describe?
- 25.** Why are recycled and regrind plastics not allowed for direct-contact applications in many drug packages?
- 26.** What are the advantages and disadvantages of precision molding, compared with the basic method of molding pulp forms?
- 27.** Concerning paper bags: a) What is the convention for dimensioning a paper bag? b) How are multiwall paper bag plies listed?

Assignment

You are launching a range of personal care products, including a body wash, soap bar, facial cream and an herbal supplement. Describe the types of packaging options you could use for each product, detailing selection criteria, shelf display and any potential risks associated with your choices.

THE PACKAGE DEVELOPMENT PROCESS

22

CONTENTS

Managing the Packaging Function

Importance of a strong product/package combination, market failure, complexity, different needs, packaging as a system, positioning of packaging in different sized companies, packaging as a coordinated activity.

Project Scope

Graphic changes, repositioning, changing existing structures, new products in established marketplaces, introduction of new products, understanding where familiarity is needed.

Package Development Process

Package design functions as a central clearing point, generation of ideas, idea sources, packaging-objective statements, new product risks, launch as a team effort. Project planning charts, quantifying packaging objectives, the general design process. Package design briefs, typical responsibilities, facts to be assembled, importance of a design brief. Developing and screening alternatives.

Specifications

Machinability, performance, aesthetics, classifications of defects, user experience.

Writing a Specification

Measuring quality, material specifications and performance testing, specification format, specification identification.

Redesign of an Oil Bottle and Shipping System

Case study: project concept and organization, information development, development and testing of alternatives (resin and design), development and testing of shrink-wrapped trays, development and testing of pallet loads, solving a shipping problem.

An Example of Graphic Design Development

Establishing possible product positions, examples of positioning by point-of-difference statements

Package Designer's Checklist

List of the facts the package designer needs to compile for a product launch. Package design brief example, summarizing what the package should achieve.

MANAGING THE PACKAGING FUNCTION

The Successful Package

Throughout this book, the word “system” has been used to link a package to other essential activities that are part of the packaging universe. The relationship between the package, product and purchaser is one of these systems. Most purchasers tend to view package and product as a single entity, so having a superior product is not enough. The message of the product’s superiority, convenience, sustainability or other benefit must be clearly communicated to the prospective purchaser. Sadly, many excellent products never reach their market potential for lack of a suitable package. (See Figure 22.1)

On the other hand, an occasional spectacular package is developed for a product that does not live up to the promise the package makes or implies. It is true that such a package will stimulate at least one sale, but an inferior product, once exposed, will not generate a second purchase. Success will be short-lived.

The goal for long-term success is, therefore, to have a strong product showcased in an effective package. Many examples show how excellent package designs have lifted ordinary products into the unusual, and in some instances, created a whole new product category. Many of these designs probably started with the questions, “How can this be made easier?” or “How can I get rid of this problem?” or even, “There must be a better way of doing this.” In highly competitive markets, the package can make the difference between a successful product and market failure.

The growth of e-commerce has put new emphasis on “unboxing,” the experience of receiving and opening a package. If there’s any doubt about how much consumers enjoy unboxing, just search YouTube. It offers a choice of more than 100 million unboxing videos. To deliver a positive unboxing experience, package designs need to project quality and generate a sense of excitement with a bit of a suspenseful reveal without being frustrating to open. Case in point are cell phone

packages. Simple yet elegant designs fulfill expectations and work equally well whether the unit is purchased in-store or online.

Sources differ on the exact number, but as many as 30,000 to 40,000 consumer products are launched every year. Few of these generate respectable sales, and indeed, the failure rate of launches is very high. Katrina Carl, Mark Oliver Inc., suggests that about 58% fail because the customer cannot recognize any significant differences between the new product and competing products. A further 32% fail because of poor product positioning. It is perhaps significant that product performance accounts for only 12% of launch failures.

Indeed, many so-called “new” products are relaunches of products that have failed in the past. The “newness” is, more often than not, a repositioning or restaging, a package redesign or both.

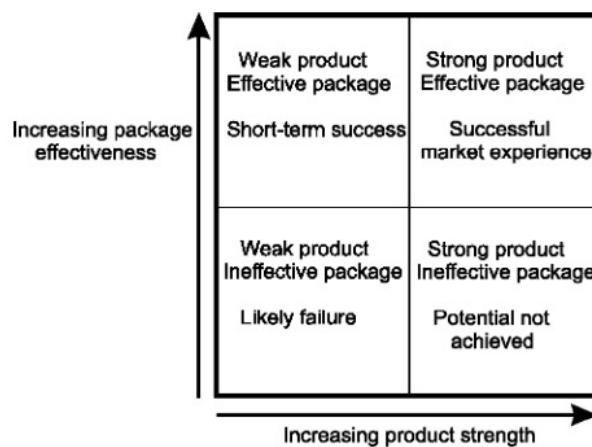
Package Development Has Many Stakeholders

It would be convenient to be able to draw a tidy flowchart of the steps needed to develop a package, accompanied by another block diagram detailing who was responsible for each activity. However, this is not possible. There are about as many ways of developing and managing the packaging function as there are companies. Plus, in today’s ultra-competitive marketplace, many development steps are done in parallel rather than sequentially to prevent delays in the launch of the product/package and ensure material is available when needed.

Packaging is an extraordinarily complex endeavor that must be viewed holistically as a part of a larger system within which every activity has some impact or demand on the package. Thus, purchasing, receiving, warehousing and materials handling, production, marketing, shipping, distribution and sales each has its own particular demands on the package. Often, these demands are not mutually compatible:

- Purchasing wants a good price, quality and reliable suppliers.
- Product development wants a package that contains, protects and preserves.

Figure 22.1
A good product and a good package ensure long-term success.



- Production wants trouble-free operation on existing equipment along with the largest processing window.
- Warehouse staff wants to stack pallets as high as possible.
- Shipping wants packages that will withstand every shipping hazard.
- Marketing wants a unique seven-sided package printed in 11 colors.
- Sales wants a package that will impress retailers into providing more shelf space.
- Legal wants protection against all real and imaginable possibilities.
- The retailer wants the highest margin and highest possible sales turnover for every square meter of store space.

To complete the picture, add environmental and sustainability concerns, and most importantly, the needs of consumers.

No part of the product production system can be altered without affecting other parts. The purchase of a faster packaging machine may require tighter packaging specifications. A small change in package size may have a detrimental impact on pallet building and transport efficiencies. A change from corrugated distribution boxes to shrink-wrapped trays may require an increase in a plastic bottle's compression strength. The most economical package to purchase may be the most difficult to fill. A unique design having superior shelf impact may require extensive production machinery retooling. The packaging challenge is to meet consumer or customer expectations along with all of the individual system requirements, including the company's long-term strategy and profit objectives.

How the packaging process is managed is primarily a function of the company's philosophy and its view of packaging's role in the enterprise. Company size and packaging cost relative to total cost are other important factors. In a small company, packaging responsibility may be a part of some other officer's job, typically a purchasing agent or the production supervisor. Time constraints or lack of in-depth knowledge usually forces a heavy reliance on the package supplier.

As company size or knowledge of expenditures on package material increase, a full-time packaging specialist may be appointed to oversee packaging activities. This person may report to the production manager, marketing or other departments. The person may have total responsibility for organizing, coordinating, directing and implementing the packaging process, or he or she may work under the direction of a committee or senior manager. Companies with professional packaging staff and facilities may be less dependent on suppliers but still may rely heavily on supplier expertise for packaging ideas and designs.

Packaging responsibilities at very large companies are typically divided among various departments. Package development, quality control and testing, graphic design and package purchasing are typical divisions. The management and inter-relationships of the individual departments vary. If a single universal statement is to be made, it is that product and package must be developed in a closely coordinated fashion, with all parties contributing, rather than developed separately (i.e., "Here's the product—now figure out a package.").

PROJECT SCOPE

Package development can take from a month to several years. The simplest situation is one where graphics are changed on an established product line to shift the demographic/psychographic appeal, add a seasonal or holiday note or announce a promotional offering. These changes invariably involve copy or artwork. Whatever the change, the product parentage remains obvious, and because the change affects only the graphics, most of the work centers on the marketing function. With few exceptions, new suppliers do not have to be located, production line changes are not needed and material compatibility or shelf-life studies are not necessary. (See Table 22.1, Situation 1)

Repositioning is primarily a graphics change, assuming that the package's physical structure does not need significant alteration. The usual challenge is to reposition the product to appeal to a new demographic/psychographic market while retaining the identity or equity of the original product. Obviously, this is a riskier undertaking.

A second situation is somewhat more complex and might involve changing the package's physical design. (See Table 22.1, Situation 2) The package size might have changed, the new graphics may include a hologram or the design may have been altered to accept a promotional/bonus item. Regulatory updates also may cause structural and graphics changes. One example is adding a Nutrition Facts label. Now, the changes affect more than just the marketing and graphics functions. Production needs to check if such a package can run on existing machinery and, if not, what changes are required. Procurement needs to make sure the supplier can run the change. If so, what are the tooling costs, cost impact and turn-

Table 22.1
Package development projects vary in complexity depending on the project's scope. Project complexity increases as you go down the table. (More people have to be involved and more problems need to be resolved.)

	Product	Physical Design	Materials	Graphic Design
Situation 1	same	same	same	change
Situation 2	same	similar	same	similar
Situation 3	similar	same	same	similar
Situation 4	same	different	same	different
Situation 5	same	different	different	different
Situation 6	all new	unknown	unknown	unknown
Situation 7	same	similar	same	different

around time? In addition, package size changes need to be evaluated to determine the impact on shelving and regulatory compliance.

Formulation changes, changes in the package's physical design or changes to different packaging materials (See Table 22.1, Situations 3, 4 and 5) might trigger the need for product/package shelf-life tests, material compatibility studies or material specification changes. The number of stakeholders who must be involved increases, too. The impact on production, warehousing, shipping container size, distribution, customer acceptance, sourcing and other parts of the system will need to be determined.

Situation 6 in Table 22.1 illustrates the most complex packaging project—a truly all-new product. No consumer is going to have this item on a shopping list. There is no history of consumer attitude toward the product, nor is there any existing marketplace experience (competitors) on which to base package design directions. At the beginning of such a project, there is, at best, only a general feel for the demographic/psychographic audience and a limited idea of what the package material should be and what form the package should take.

Finally, Situation 7 in Table 22.1 provides a look at how private labeling differs from an in-house project.

Packaging form is sometimes dictated by technical necessity, similar existing product lines, the shipping environment to be encountered or the consumer's pre-conception of what the packaged product should look like. For example:

- There is no technical reason why a breakfast cereal or a detergent could not be offered in a round, spiral-wound paperboard container. In its early years, Quaker Oats Co. selected that format for its breakfast cereal. Today many consumers would not recognize the product if it were not in its familiar container.
- Canadian smokers expect cigarettes to come in rigid paperboard slide boxes; U.S. consumers prefer a soft pack. Using either nation's packaging form in the other country would be going against established consumer perceptions.

Notwithstanding, some package designs have successfully challenged convention. The Pringles potato chip canister and L'eggs ladies' hosiery pack (that originally came in a rigid plastic package shaped like an egg) are examples of packaging that challenged established designs. Such moves must be made cautiously with some evidence that consumers will respond to the unfamiliar form.

Some product fields are relatively insensitive to material or package format. Spices and condiments, for example, are offered in a wide assortment of containers:

Spiral-wound paperboard composites	Plastic bottles
Aluminum cans with plastic end pieces	Ceramic decorator jars
Impact-extruded aluminum cans	Glass bottles
Round and rectangular steel cans	Flexible pouches

PACKAGE DEVELOPMENT PROCESS

An Overview of the Package Development Process

The figures in this section offer generalized models for the package development process. It is important to understand that the model does not have an orderly information flow from left to right or top to bottom. Rather, information flows continuously among the respective bodies; it passes or is coordinated through the “package design function” several times during its course. (In this text, “package design function” does not imply major technical and graphic activity by a specific design department. Rather, it implies important milestones at which some person or body must give serious thought to some aspect of the final package.)

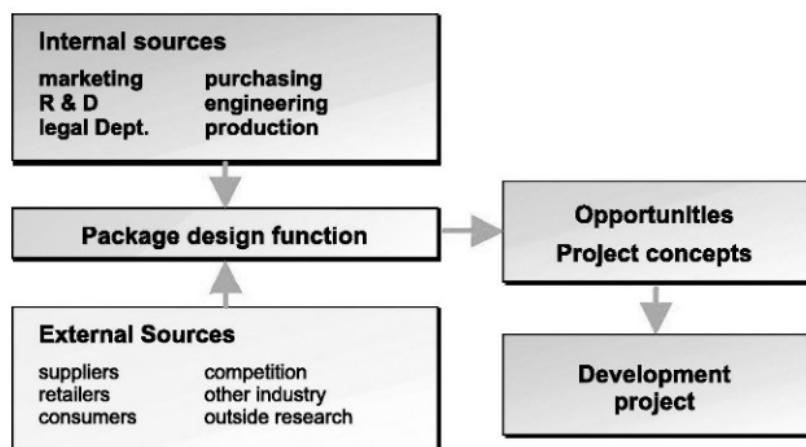
It is obvious that the package design function, whatever its form, acts as a central clearing point and a vital communication channel through which ideas are assembled and evaluated and a consensus established and approved to continue to move forward.

Generating Ideas

Ideas for change can come from many sources inside or outside the company. (See Figure 22.2) Some companies have specific product and package development departments. Such departments continuously scan the field for product ideas and work on new product and package concepts. Some projects might be internally motivated. For example, company growth may be stagnant or declining due to competitive pressures, and management may have been brainstorming for a major new market offering. The following are some ways in which companies generate new product ideas:

- Many concepts, particularly in the fashion industries, are developed in the marketing department or consumer insights department. Perhaps some color trend can be applied to cosmetic offerings. A competitor’s success or consumer perceptions of some issue can motivate new product ideas.
- Another example would be a retailer or brand owner wants to cross-sell or cross-

Figure 22.2
Ideas for change can come from many sources.



merchandise, e.g., light bulbs with ceiling fans or floor lamps or coolant with a threading machine.

- Company R&D laboratories generate new technologies that can be used to create products with market possibilities. This is an important source of ideas for technology areas. Alternatively, technologies and product ideas can be licensed or purchased from outside sources or sourced through an open innovation process.
- Suppliers are often good sources of ideas. Most suppliers are actively involved in getting that little edge on the competition, and their efforts often lead to cost-cutting innovations or new possibilities.
- Techniques used in other industries or countries may be observed. For example, can some technique used in the cosmetics industry be used to enhance a food product? Is a business product finding increased home use?

Whatever the origin, management must judge project and package ideas in view of manufacturing expertise and limitations, corporate goals and financial capabilities. In a dynamic field such as packaging, there are literally thousands of options available at any point in time.

Any package change or development must have clearly stated objectives. Change simply for the sake of change is not a valid reason for altering a package. The following are some examples of specific, quantified objectives for new or revised packaging:

- To successfully launch a new product, with success being identified by specific sales targets and business.
- To revitalize a dormant brand and raise sales to a specified level.
- To increase sales by providing a new convenience or utility to the consumer.
- To respond to environmental concerns, whether voluntarily or mandated.
- To respond to newly identified customer or consumer needs.
- To reposition an existing product in response to changing market conditions.
- To reduce costs by changing to more efficient packaging, processing or supply.
- To maintain market share by responding to a competitor's initiative.

Lack of a specific reasoned objective means the design probably won't be focused on the elements needed to realize some benefit. In other words, if you don't know where you're going, any road will take you there. Changes or designs made under such circumstances are just as likely to be detrimental as beneficial.

The objective of all business, of course, is to create profitable long-term sales. Every proposed option must be tested against that prime objective. New product developments are notoriously risky and expensive undertakings. It is said that of 100 concepts developed to a working stage, only 10 are actually offered to the consumer. Of these 10, only one or two will be on the market two years later.

The most effective way of decreasing risk is to do your homework up front. Marketing analysis, product mapping studies, focus group sessions, exhaustive development trials and market tests are costly, but their costs are minimal compared with the costs of a failed product launch.

A new product/package launch represents a team effort, with each team member wanting something different from the package. All stakeholders, including the final customer/consumer, must be consulted and actively involved in screening out the insignificant many from the significant few. The significant few are the real business opportunities.

The Package Design Brief

The ideas generated in the project initiation phase are not enough to form the basis of a full development program. Perhaps the most important first task is to expand and quantify the project objectives. The next task is to generate a comprehensive catalog of all possible information related to the product launch.

Among others, the various departments and groups listed under “Information Development” in Figure 22.3—and further expanded in Figures 22.4 through 22.7—will contribute information according to their needs and expertise. Compiling the required information for the brief is an excellent example of the kind of interdisciplinary, interdepartmental role a packaging professional may be expected to fill.

The information is compiled in a comprehensive document, sometimes called the “package design brief” but also referred to as a “packaging checklist” or “requirement.” The brief summarizes what the proposed package design is supposed to achieve:

- In what marketplace.
- With what product.
- By what means.
- Against what competition.
- Targeted to what group.
- In conjunction with what other activities.

The objective is to document as many facts about the proposed launch as possible, making each stakeholder aware of all the project details. The design brief ensures that all needs are met and any necessary compromises are acceptable. A checklist for compiling the project details and a hypothetical design brief form may be found at the end of this chapter.

The design brief can be compared to a musical score in that it ensures that all participants are playing the same tune. The brief is not a static document. As a project evolves, information on the initial brief may change and new information may be added. The important thing is that everyone involved with a project should clearly understand the objectives and the means by which they will be achieved. It is vital that input be sought from everyone involved in the launch.

Finding out after several months of intensive package design work that the hot new material has not been cleared by the Food and Drug Administration (FDA) is costly. Input from suppliers should be sought as early as possible in any project. They are aware of new technologies on the horizon and knowledgeable about the arts and tricks that will keep costs in line and quality at its peak. In fact, with today’s ever-growing need for speed to market, suppliers often assume much of the responsibility for package development.

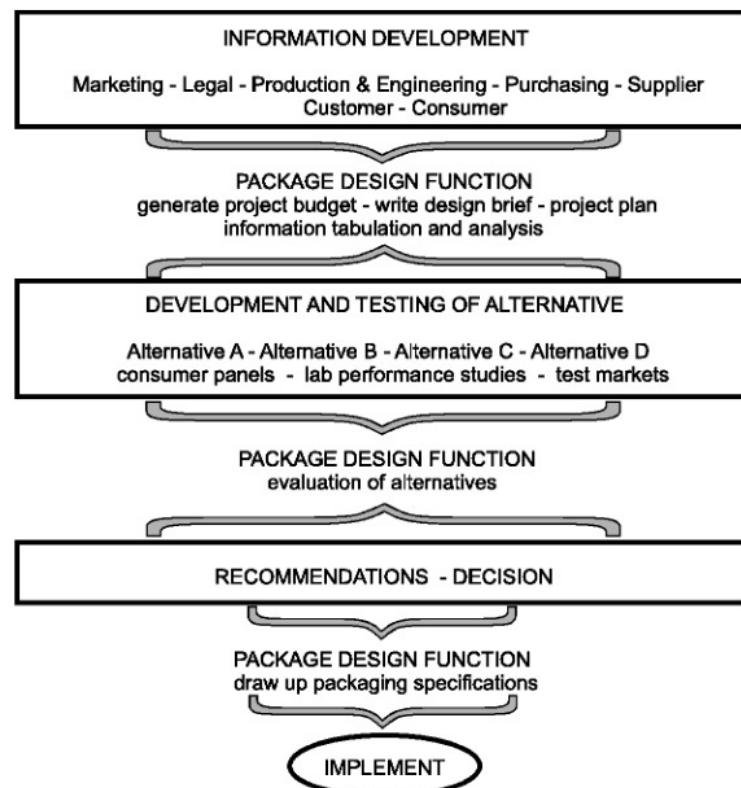


Figure 22.3
The general package design process.

Figure 22.4
Package design: technical responsibilities.

PRODUCT SPECS	PACKAGE SPECS	INFORMATION	PERFORMANCE
protection required form required handling characteristics hazards	material requirements testing requirements storage data field conditions	ingredient lists instructions legal claims government	trials and tests field evaluations hazards

Figure 22.5
Package design: manufacturing and engineering responsibilities.

EQUIPMENT	PACKAGE	STAFF	SCHEDULE
available capacity new machines product performance package performance production methods layout required modifications production costs	production trials size specification storage specification receiving specification pallet patterns rejection criteria shipping tests plant hazards inspection	quality control machine operators handling staff occupational hazards	supplier plant seasonal

Figure 22.6
Package design: marketing responsibilities.

CONCEPT	MARKET FACTORS	INFORMATION	MARKET TESTING
Product form arrangement features Package type unit size or sizes artwork and copy features	identification buying habits product exposure market practice competition seasonal factors distribution positioning targeted customer	use instructions storage instructions safety recipes pricing environmental sustainability	customer consumer

Figure 22.7
Package design: legal, purchasing and traffic responsibilities.

LEGAL	PURCHASING	TRAFFIC
brand names trademarks patents net weight ingredients tamper evidence child resistance NDC/DIN number government	company-supplier liaison materials availability package type alternatives graphic art alternatives cost estimates prototype samples supplier identification specification agreements quality control standards government approvals delivery schedules	freight classifications rates gross weights distribution costs customer practice shipping hazards coding handling and warehousing

Not all the facts will be readily available at this early stage. Depending on the nature of the launch, some consumer focus-group studies may be conducted to better quantify market potential or product parameters. The group responsible for the package design function assembles and coordinates this information for presentation to management.

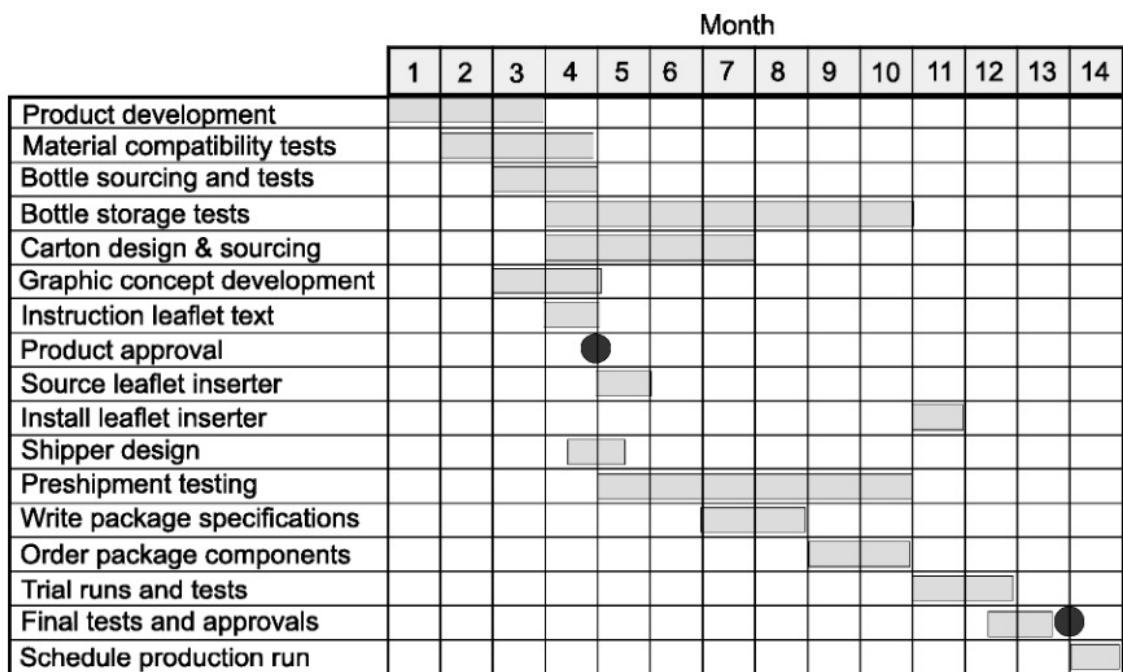
The Development Timetable

Assuming favorable management response to the project concept, a timetable is developed, which lists activities, milestones and critical decision points. Gantt charts, or critical path charts, are popular project scheduling and tracking methods.

The simplified Gantt chart in Figure 22.8 shows only the most general details. Gantt charts clearly identify activities that can start only after the completion of other activities and enable staff and resource allocation planning over the project time period.

Development and Testing of Alternatives

Based on the information provided in the package design brief, the package design group will generate ideas of how the product might be packaged. Some organizations conduct wide-open brainstorming sessions, at which all ideas,

**Figure 22.8**

Example of a Gantt chart. A more complete chart would include time allocations for legal clearances, closure sourcing, accompanying promotional activities and so on.

regardless of their apparent practicality, are considered. From these, choices are narrowed to those most likely to succeed. Others use a strictly logical and practical step-by-step scientific approach. Increasingly, suppliers provide the design function.

Even when the supplier isn't developing the design, supplier selection often begins in parallel with package development or is pre-determined due to preferred customer contracts, which are common today to ensure materials are available when needed.

Eventually, the possibilities are narrowed to a few options, all of which, on the surface, appear good. Samples may be made and laboratory evaluations are used to detect the not-so-obvious flaws or problems in the approaches. These steps often are performed by the supplier. Product compatibility tests, shelf-life studies and simulated shipping tests are three of the most important types of laboratory evaluation. This part of the program also may include pilot product runs and consumer test panels or markets. Laboratory evaluation data often are useful when writing the package specifications.

If the data are positive, the project may proceed to the last phases: recommendations, final decisions, drawing up the specifications and implementing the design. As often as not, new information may send a project back to an earlier position. A whole new set of package alternatives may need to be explored, developed and tested.

SPECIFICATIONS

If supplier selection hasn't already been determined due to contractual obligations or occurred in parallel with package development, the last step prior to actual production is to identify suitable suppliers and negotiate delivery of a supply of packages and packaging components of adequate quality. "Quality" is often defined as "conforming to requirements." Requirements fall into three broad categories:

- Machinability.
- Performance.
- Aesthetics.

Machinability

When a package is introduced into a production line, it essentially becomes a part of the machine. While the tolerances of a machine's moving parts are fixed within a small range, the tolerances of cartons or bottles introduced into the production lines can vary by several orders of magnitude. Production problems are encountered when a package tolerance goes beyond what the machine can handle. For example, the centrality of a plastic bottle finish must be within the very small range within which the liquid filling tube moves. If the filler is one that employs a vacuum to assist filling, the finish land area must be flat and free from parting lines or other irregularities. At the capping station, any ovality of the finish may give a false torque reading and result in a leaking closure.

The requirements that need to be established are those dimensions and values that will provide the most trouble-free production on the intended line (usually referred to as a package's "runnability"). As has been noted in Chapter 20, Packaging Machinery, faster machines tend to require tighter specifications. A packaging engineer working on a package design should be fully aware of equipment capabilities.

Performance

These are values that pertain to containment, preservation, protection and provision for efficient transport and use of the product. Performance may include such values as chemical compatibility, barrier qualities, shock (drop) resistance, stacking strength, water resistance, openability, dispensability and vibration/friction. Other factors to consider include equipment specifications and readability of barcodes.

Aesthetics

Maintaining an acceptable appearance in the eye of a prospective customer is an important merchandising factor. Cleanliness is an issue with all packaging. The acceptable ranges of a graphic's color and overall appearance must be established along with the acceptable levels of print blemishes, poor registration, scuffs and other defects inherent to the printing process. Aesthetics also include the placement accuracy of labels.

In well-run companies, “requirements” are documented in the company’s specifications, purchase orders, drawings or written requirements. This is essential for defining and communicating corporate expectations of quality. Without such written definitions, suppliers and in-house staff will adopt the quality standards that are most convenient to them.

When dealing with suppliers, the production of a quality package rests on good communication, as formalized in the incoming packaging material specification. This specification:

- Communicates your exact needs to your supplier.
- Provides your supplier with a basis for judging its production.
- Provides your staff with a basis for accepting packages and components.
- Allows for supplier bids on a fair and consistent basis.
- Serves as the contractual benchmark when there is dispute.
- Serves as a benchmark for package improvement.

Great care should be taken to establish the correct tolerance level for every critical package performance factor. Too broad a tolerance can cause machine or aesthetic problems. On the other hand, unreasonably tight tolerances may limit the number of potential suppliers and significantly increase costs.

A complete product specification system is not a single document, but rather three groups of documents. (See Figure 22.9) The documents describe all the materials and activities that will result in the efficient production of a product possessing the characteristics that have been identified as representing the appropriate quality.

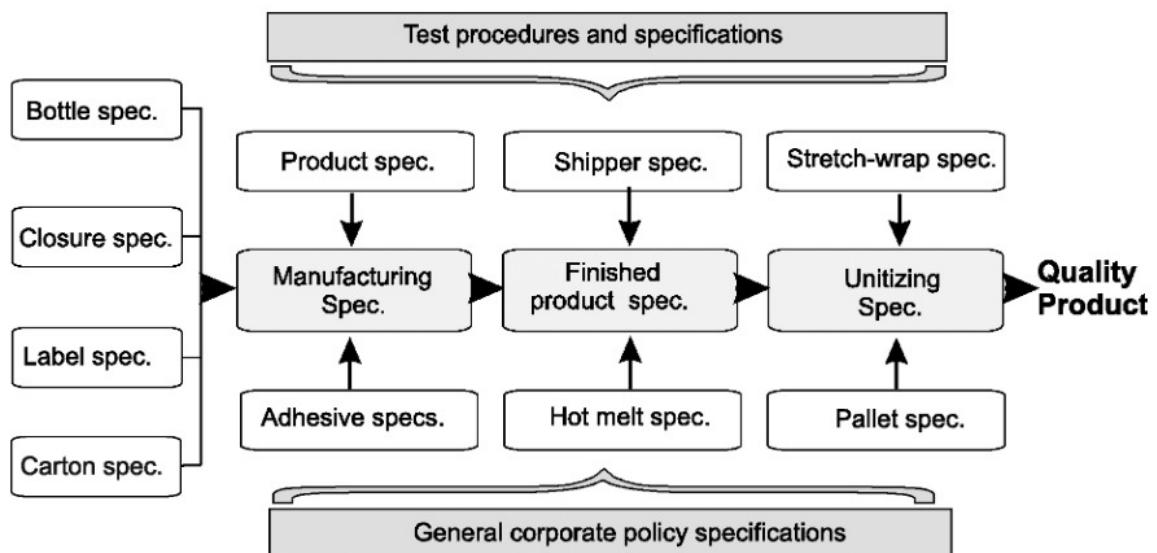


Figure 22.9

A product manufacturing specification is a set of documents that defines a quality product and all of the materials and activities that will result in a quality product.