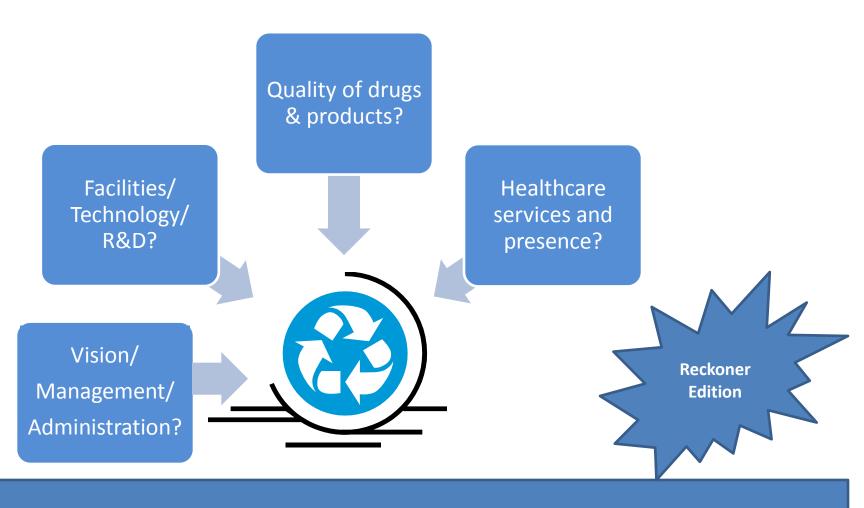
Pharmaceutical networks as ASSETs (during the 2020 crisis)



A Tool for Pharma networks

K.S.Venkatram , AOEC & SSHGIEC 2015-2020

Pharmaceuticals as ASSETs

(An ASSETs Guide)

By,

K.S.Venkatram

AOEC & SSHGIEC, 2015

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•	Name of the organization:

- Year established: Status: Manufacturer/Distributor/Retailer
- Head office at:
- Regional offices in:
- Manufacturing plant(s) situated in:
- Evolution of the organization since inception:
- Classification of the organization:
- System of medicine: Allopathy/ Ayurveda/ Homoeopathy/Other

Role in healthcare:

- Are specialty generic drugs manufactured and supplied?
- Overview:
- Are super generic drugs manufactured and supplied?
- Overview:
- Are bulk drugs manufactured and supplied?
- Overview:
- Are trial medicines manufactured and supplied?
- Overview:

- Are healthcare products manufactured and supplied?
- Overview:

Are healthcare accessories manufactured and supplied?
 Overview:

• Any accreditation (today or planned):

Any quality level adhered to in GMP/GCP/GDP (today or planned):

- Does the organization supply to retail chain(s)? Yes/No
- Overview of retail chain(s) being supplied drugs:

- Does the organization supply drugs directly to some Chemists & Druggists? Yes/No
- Overview of Chemists & Druggists being supplied drugs:

NOTE regarding terms or abbreviations used in this handbook/guide:

- Pharmacies term used to refer to Chemists and Druggists and vice-versa
- GMP abbreviation stands for Good Manufacturing Practices
- GCP abbreviation stands for Good Clinical Practices
- GDP abbreviation stands for Good Dispensing Practices
- SMART stands for Specific, Measurable, Achievable, Realistic & Time oriented practices
- KCDA stands for Karnataka Chemists & Drugs Association

Part 1 (Value addition?)

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Is an organization ready for the millennium?

- There are 5 or more areas that an organization must focus on, to be ready for the millennium i.e.
- 1. Fundamental Business Vision and Strategic Positioning. AOEC can **help transform a healthcare establishment** into an ASSET that can provide holistic services.
- 2. Standards compliance / Accreditation. AOEC can help one do an initial survey and plan for ISO 9001:2008 compliance/NABH or NABL accreditation/both via gap analysis which is available in a separate quality management handbooks.
- 3. Operational Efficiency and Effectiveness. AOEC can help one **plan for and implement** Disaster Management via this reference guide.
- 4. Continual Performance Management for sustained success through ISO 9004:2009 compliance. AOEC can help one **implement this compliance** today via its quality management handbooks.
- 5. Leading edge Service Evaluation and Review Techniques that make it easy to assess and improve an establishment's healthcare model. AOEC can help one **develop a technique** today via its quality management handbooks.
- We proceed to review what can make a healthcare model continually excellent.

A good Healthcare model demonstrates

Better Availability/ Demonstration of unique value

Improved Acceptability for quality and competence

Being Continually Excellent in Healthcare

Overall Accountability / Transformability in services

Qualified GMP, GCP & GDP/ Intelligence/ Affordability

In an increasingly competitive and changing world, establishments like Chemists & Druggists (pharmacies) help promote organizational readiness in healthcare providers or even act like relief bridges that help people avail of medical services like supply of medicines, healthcare accessories, nutritional products, etc with over the counter intelligence in preventing medication errors, backup orientation for consuming medicines, and sometimes even help discuss response to treatment.

- Designing Pharmaceutical -> Chemist & Druggist (pharmacy) environments that can act as relief bridges
- The mandatory need for a pharmaceutical and its links to act as a relief bridge is that
- 1. There must be a well-defined RADIUS of services keeping in mind the size of the organization, type of business of the organization and its activities
- 2. There must be a management culture to ensure ethical practices in marketing,
- operations, and facility management. There must be a management culture to understand and manage cost & time ratios that affect Quality of healthcare
- 3. There must be a process to control and reduce complexity of processes and their interactions in or at the links
- 4. There must be a process to accelerate competence of personnel for adeptness

5. There must be Service Evaluation and Review techniques for the links

AOEC's concept of Service Evaluation and Review techniques

- 1. Setting up of a Help Desk for pharmaceuticals (at the KCDA for example) to know more about the functioning of the pharmacies in associated region(s)
- 2. Implementing Customer Satisfaction Surveys (PERT feedback) at pharmacies as a day to day operations imperative
- 3. Ensuring holistic Customer profile details or Critical Path Management Feedback are available from pharmacies (whenever relevant)

ISSUES:

It is expected that surveillance or gathering feedback remains difficult to implement at all pharmacies, as our country (India) has a mixture of educated & uneducated people purchasing medications or healthcare products from them.

As a start we can implement these methodologies in pharmaceuticals and links that want to be considered as ASSETs.

Establishments with more than back-office readiness

Having a plan for adept, emergent, continually available and accessible medical supplies has been a common thing of the past.

However AOEC can transform a pharmaceutical and its links into an ASSET that not only demonstrates availability, ethical practices and effectiveness in meeting demand, but also helps assess vital issues affecting consumers, and manage other situational needs like threats, emergencies, disaster mitigation or disaster management while saving lives or reducing chances of uncontrollable incidences.

With this new transformation, a pharmaceutical and its links can additionally achieve different levels of conservation to preserve the environment.

The ASSETs Guide considers different scenarios before stating that its self-assessment can improve the Quality of services.

About the scenarios considered

The establishment being supplied drugs, healthcare accessories and other healthcare products could be:

- 1. One of the most well-known and well-networked Chemist and Druggist retail chains (for a region) owing to its presence, use of IT and technology
 - 2. One of the crucial Chemist and Druggist retail chains (for a region) owing to its capacity or location
- 3. One of the Chemist and Druggist retail chains supplying drugs for disease incidence control and/or disaster management (for a region)
- 4. One of the many available Chemist and Druggist retail chains (for a region)

The ASSETs Guide states that self-assessment can improve the Quality of services, if the pharmaceutical regularly finds out whether its retailers or supply chain endpoints (like Chemists and Druggists or pharmacies) assess and manage non-conformities in 2 areas

A. Business Curves or Patterns in services

- 1 Gap analysis for managing business interests
- 2 Gap analysis for managing customers
- 3 Gap analysis for choice of method or procedure for customer
- 4 Gap analysis for achieving quality of services in all supply
- 5 Gap analysis for managing personnel
- 6 Gap analysis for managing facility, and environment (on a 24/7 basis)
- 7 Gap analysis for any data analysis and evaluation of services
- 8 Gap analysis for any ad-hoc or formal report generation
- 9 Gap analysis for communication with supply chain links

B. Back-office services

- 1 Gap analysis for Organizational structures
- 2 Gap analysis for Management system
- 3 Gap analysis for Documentation requirements
- 4 Gap analysis for Quality of services
- 5 Gap analysis for Purchasing
- 6 Gap analysis for Services to the customer
- 7 Gap analysis for Customer related processes
- 8 Gap analysis for Control of nonconforming work
- 9 Gap analysis for Improvement, Corrective actions and Preventive actions
- 10 Gap analysis for Control of records
- 11 Gap analysis for Internal Audits
- 12 Gap analysis for Management reviews

The ASSETs guide Part 1,2 & 3 includes all this and more information. You can place your order for the same by either calling AEOC on the mobile number 9342867666 or by emailing AOEC at ksvenkatram@yahoo.co.in or venkataoec@gmail.com.

- To function like an ASSET, the Guide states that a pharmaceutical's clinical and dispensing practices need to be intelligently self-assessed for the following 3 macro-processes:
- a. Customer Relationship Management
- b. Internal Supply Chain Management
- c. Supplier Relationship Management
- With this background
- ASSET 'strategies' can help work towards a virtue that the Chemist and Druggist (pharmacy) can provide services with a 80/20 rule, where at least 80% of the time the customer can get medicines for all kinds of needs like
- 1. Prescription coverage
- 2. Specific drugs/medicines
- 3. Contingencies based medicines (where certain supply chain coordination may be needed)

4. Incidences based medicine (where the Chemist and Druggist can help provide medicines/drugs "for accidents/need based treatment/ post treatment/ post surgery coverage"), where in all cases a profile methodology can help a customer get "continual supplies SMARTLY" via a plan for both readiness and quality improvement

What follows in the next few sections?

The details that follow can be projected as self-assessment information that a Chemist and Druggist or pharmacy fills in, whenever a pharmaceutical (interested in GCP & GDP) likes to know if its retailers or supply chain endpoints are functioning properly.

Laying of this foundation can help organizations like the KCDA, IPA, OPPI or IDMA setup a Help Desk that pharmaceuticals can contact to get information about a region's Chemists and Druggists (or pharmacies) like their quality control accountability, or their adherence to norms related to preparedness, readiness and mitigation for synergetic healthcare services.

Pricing for Auditors

S. No	Standard Description	Qty	Preference	Price (in Rs)
1a	Guide + single license for 1 pharmacy	1	CD-ROM	xxx
1b	Guide + single license for 1 pharmacy	1	Printed Copy with CD-ROM	

Pricing for small-sized or exclusive Pharmaceuticals

S. No	Standard Description	Qty	Preference	Price (in Rs)
1a	Guide + single license for 1 pharmacy	1	CD-ROM	xxx
1b	Guide + single license for 1 pharmacy	1	Printed Copy with CD-ROM	

Pricing for large-sized Pharmaceuticals

S. No	Standard Description	Qty	Preference	Price (in Rs)
1a	Guide + single license for 1 pharmacy	1	CD-ROM	XXX
1b	Guide + single license for 1 pharmacy	1	Printed Copy with CD-ROM	

Your Chemists and Druggists as ASSETs

(Unified assessment information to be filled in by the pharmacy)

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Understanding the Chemist and Druggist

- Name of the establishment:
- Year established: Status: Owned/Associated unit/Part of retail chain
- Classification of the establishment:
- Role in healthcare:
- System of medicine: Allopathy/ Ayurveda/ Homoeopathy/Other
- Evolution of the establishment since inception:
- Is there a medical practitioner available in the facility:
- Is there separate consultation along with the supply of medicines:

Understanding the Chemist and Druggist

- Is the facility part of a retail chain:
- Is the facility purely for an associated healthcare provider:
- Are medicines only sold or sold & supplied to other providers:
- Marketing relied on to sell drugs, and products:
- Any accreditation (today or planned):
- Any quality level adhered to (today or planned):
- Does the facility use IT and advanced technology :
- Number of customers per day category (>200, 100-200, <100):
- Are contractual agreements used in running the facility:

Gap Analysis or Selfassessment based on SMART Convergence (Part 2)

Being Continually Excellent in Healthcare

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Key considerations

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Gap Analysis for Business Curves or Patterns in services (Basic Edition for I-catalog synergy)

This section includes questions that review whether the retailers or supply chain endpoints operate for continual quality management. Your team can iterate through these questions to understand the current lacunae and thereon bridge the gaps.

Gap Analysis for Business Curves Management practices

What is business curves management for sustained success about?

A Chemist and Druggist's environment is ever-changing and not deterministic for risk management and resources utilization. The issues affecting the health of people are also not within our control, so the need for healthcare is a complex relationship and needs autonomous reinforcement.

In this scenario, a reputable healthcare organization is one that can deliver services of good quality and continual excellence. To achieve sustained success and quantum emergence in its service model, a healthcare organization will need to meter/create/improve upon/genetically makeup or create concepts/ strategizations/conditioning for critical success factors in an autonomic way over the long-term.

Planning for and implementing **ISO 9001:2008** and **ISO 9004:2009** is a good way of ensuring a Chemist and Druggist performs for sustained success or continual excellence. **AOEC's handbook/guide with a section on Business Curves Management can help a Chemist and Druggist also deliver for quantum emergence.** To help understand where you are positioned today, there are few questions of common importance that follow on the next few pages.

Gap Analysis for managing business interests

- 1. Does your organization maintain and improve the quality of supplies on a regular basis? Yes/No/Partially
- 2. Does your organization improve its quality of interactions with customers on a case to case basis? Yes/No/Partially
- 3. Does your organization improve its quality of supply of medications / other healthcare specific products to customers on a case to case basis? Yes/No/Partially
- 4. Does your organization improve the customer's understanding of prescription specific / over-the-counter medications & healthcare specific products? Yes/No/Partially
- 5. Does your organization think as important that the customer normally consult a medical practitioner for any prescription specific / over-the-counter medications & healthcare specific products? Yes/No/Partially

Gap Analysis for managing business interests

- 6. Does your organization need its personnel / staff to be aware of the inventory of supplies on a regular basis? Yes/No/Partially
- 7. Does your organization need its personnel / staff to be aware of the medical information associated with much-in-demand medications & healthcare specific products on a regular basis? Yes/No/Partially
- 8. Does your organization work to limit complaints and incidences faced by customers in its manner of conducting sales of medications & healthcare specific products on an every time basis? Yes/No/Partially
- 9. Does your organization work to limit legal liability for any sale of medications & healthcare specific products on an every time basis? Yes/No/Partially
- 10. Does your organization effectively address concerns and complaints that do arise on its sale of medications & healthcare specific products on an every time basis? Yes/No/Partially

Gap Analysis for managing business interests

For any sale recently, were there any adverse drug reactions? Yes/No

- For any sale recently, were there mistakes or omissions in information gathering about sensitivity to any drugs? Yes/No
- For any sale recently, were there any incidences of medication errors? Yes/No
- For any sale recently, were there any incidences of medications being altered due to unavailability? Yes/No
- For any sale recently, were there any other management issues at the facility? Yes/No What were these issues?
 - 11. Does your organization effectively reject and return with identification outdated/counter productive/ duplicate supplies on an every time basis? Yes/No/Partially

Does your organization follow safe practices for disposing unwanted drugs? Yes/No/Partially

12. Does your organization implement or outsource a Call Centre to help customers, partners or supply chain links connect to your business on a 24/7 arrangement by making calls that indicate needs or by recording messages that indicate status for availability, rejected stock etc? Yes/No/Partially

- 1. Does your organization rely on certain well-informed staff to supply prescription or treatment specific medications or healthcare specific products on an every time basis? Yes/No/Partially
- 2. Does your organization have a methodology to tell a customer whether to-bepurchased medications or healthcare specific products are not right for them (due to side effects, being counter productive, or due to known unsuitable combinations)? Yes/No/Partially
- 3. Does your organization have a methodology to tell a customer whether to-bepurchased medications may not be in right dosage (when there is no prescription or when there is an older prescription)? Yes/No/Partially
- 4. Does your organization have a methodology to tell a customer whether the customer must cross check with the practitioner (when there is no prescription, or when there is a spelling mistake/bad handwriting in prescription, or when there is an out of stock / no longer available condition, or when the customer needs to know more)? Yes/No/Partially

- 5. Does your organization have a methodology to tell a customer whether medications or products must be consumed/used according to specific conditions, or as per directions for consumption? Yes/No/Partially
- 6. Does your organization have a methodology to help in a customer's untreated but preliminarily triaged condition, if the customer is injured due to an accident, incapable of action, or unfamiliar with need for treatment (specifically if the customer is from a far off area, another city, state or country)? Yes/No/Partially

The triage system categorizes a customer's need for different conditions such as:

- a. Category 1: Critical / Is being rushed to a hospital needs resuscitation
- b. Category 2: Serious / Needs medical treatment immediately and is waiting for an ambulance
- c. Category 3: Urgent / Needs medical treatment within an hour
- d. Category 4: Simple / Needs care when possible
- e. Category 5: On prescription medications
- f. Category 6: Self-medication

Additional details for emergency or disaster management

The Chemist and Druggist will need to implement a methodology to manage situational needs of such customers as per a triaged system:

- a. The Chemist and Druggist may need to help contact an emergency department of the nearest suitable hospital
- b. The Chemist and Druggist may need to help contact the customer's physician or a medical practitioner to help stabilize the customer's condition
- c. The Chemist and Druggist may need to help in any associated disaster preparedness if the customer is from such a site
- d. The Chemist and Druggist may need to help contact any blood bank
- e. The Chemist and Druggist may need to help save time or prevent further incidences by identifying safety practices

- f. The Chemist and Druggist may need to detail any wrong medication taken or wrong course of action followed to help a medical practitioner counter any side effects or control further incidences
- g. The Chemist and Druggist may need to cross check antibiotic policies to ensure the medication being given does not cause complications or does not act counter productively
- h. The Chemist and Druggist may need to store important life saving medications separately, so they can be retrieved without any loss of time or productivity
- i. The Chemist and Druggist may need its staff to participate in training or orientation programs to act in emergencies or in situations that need life saving

This is an emerging role, early efforts to develop this vision in Chemists & Druggists (or pharmacy) environments may help people in different situations.

Gap analysis for choice of method or procedure for customer

The Chemist and Druggist may need to decide as to what method or procedure should be adopted for a customer. The policy is to select a methodology from one of the following:

- 1. Provide medication or healthcare products only
- 2. Provide medication or healthcare products with record keeping
- 3. Provide medication or healthcare products with scheduling for further supply
- 4. Provide medication or healthcare products with PERT feedback or CPM reviews
- 5. Provide supplies and help healthcare providers via angelic themes such as
- a. Zero Day Effectiveness where the customer can depend upon the Chemist and Druggist completely for the entire period during which the medications or products are needed.

Zero Day Effectiveness could need the Chemist and Druggist to learn more about or become more familiar with the customer's need and to then plan for supply management, staff training / education, complexity or problem reduction like packaging of medications for uneducated people's or aged people's easy consumption, any out of stock condition, past expiry date incidences, incidences like medication or product not from manufacturer but possibly duplicate, scenario where the customer is with an old prescription so can be affected by less popular choices or limited availability issues etc.

Gap analysis for choice of method or procedure for customer

- b. Obtaining of relevant information on a 3-6 monthly basis, as to whether due process has been followed by customer consuming the medication or using the healthcare product, and whether this makes a difference in causing a sense of relief, an improvement in health or improved well-being etc.
- c. Obtaining of relevant feedback on a 3-6 monthly basis, as to how has the medication or healthcare product helped the customer given that it may have caused a sense of relief, an improvement in health or improved well-being etc.
- d. Obtaining of requests for need-to-know-more about medications or healthcare products on a 3-6 monthly basis from incidence prone customers, who are interested in the kind of diagnosis needed, or in how a medication or healthcare product can provide a sense of relief, an improvement in health or improved well-being etc for different body constitutions or conditions.

Channelized requests or feedback from Chemists & Druggists can help build a **forward lifetime concept** to help patients/customers avail of medications or products more effectively. This information can be used for sales or can be passed on (1) **to supply chains** for preventing stock outs in normal circumstances, contingencies or during disaster control, (2) **to pharmaceuticals** as unofficial feedback or as a request for review of formulation of policy of coverage, or branding or labeling, (3) **to medical practitioners** expecting to prescribe this medication or product and also for results in cases where the customer does not report back periodically or stops treatment but continues prescription etc.

Customer Profile (Unifying healthcare)

A pharmacy could define/revise a form to collect profile information from customers depending upon possible response, time available, vulnerability or severity noticed in health condition.

Pharmacy Id:	Customer Id:		
Customer's Name:			
Place of residence:			
Region:	City:		
State:	Country:		
Sex:	Age:		
Nationality: Country	of origin:		
Education: Uneducated/High school/College/Graduate/Post graduate/Studying/Others			
Nature of occupation: Unemployed/Employed/Self-employed/Business/Retired/Others			

Do you work or study in less safe environments? Yes/No/Not applicable

Nature of work or study environment:

Do you travel frequently? Yes/No

Last country visited:

Date visited:

Any incidences during travel? Yes/No/Not applicable/Do not know/Cannot comment

HEALTH EVALUATION

Your constitution? Healthy/ Occasionally unwell/Recovering/Chronic condition/Do not know Weight: Normal/Under-weight /Over weight/Do not know

Blood sugar: Normal/Low/High/Under control/Do not know

Blood pressure: Normal/Low/High/Under control/Do not know

Any other Life-changing condition:

Diet: Vegetarian/Non-vegetarian/Both/Others

Do you suffer from any food allergies? Yes/No/Do not know

Do you suffer from any drug or medicine related allergies? Yes/No/Do not know

Do you suffer from pollen, smoke or dust allergies? Yes/No/Do not know

Do you know about your vulnerability or susceptibility to certain diseases? Yes/No/Do not know Do you have more information about this?

NEEDS EVALUATION

Do you use medication or healthcare products regularly? Yes/No

Are you on prescription medicines? Yes/No

Are you currently under treatment? Yes/No/On prescription medicines

Can you read prescriptions or statutory healthcare information? Always/Yes/No/Not applicable

Do you use medications or healthcare products purely on the advice of doctors or practitioners? Always/Yes/No/Not applicable

Nature of medications or healthcare products that you consume on advice of doctors or practitioners:

Nature of medications or healthcare products that you consume as self-medication or as self-guided care:

Can you use associated statutory information or warnings to contact doctors or practitioners when suffering from contra-indications? Always/Yes/No/Not applicable

Do you have a family physician? Yes/No/Not applicable Name of physician:

Details:

Do you need references? Yes/No/Not applicable

REFERRALS				
Name of practitioner:	Details:			
Name of practitioner:	Details:			
Name of practitioner:	Details:			
DETAILS OF CHRONIC DISEASE OR MAJOR / RECENT INCIDENCES				
Do you know about the nature of your problem? Yes/No/Not applicable/Do not know				
Is clinical diagnosis available? Yes/No/Not applicable				
Nature of your problem:				

Care availed for problem: Not under treatment/Under treatment/Was treated but there is a reoccurrence/Was treated but cannot revisit that doctor or practitioner

Issues faced? Do not have medical records/Do not know enough/No expert opinion available/Suffered contra-indications/Medications costly/Medications not available/Fewer alternate medicines

System of medicine availed of specifically for problem? Allopathy/Ayurveda/ Homoeopathy/ Mix/ Others

OTHER DETAILS

System of medicine availed of most often? Allopathy/Ayurveda/ Homoeopathy/Mix/Others

System of medicine availed of sometimes? Allopathy/Ayurveda/ Homoeopathy/Mix/Others

System of medicine that has not worked? Allopathy/Ayurveda/ Homoeopathy

Any alternatives recommended by experts?

Are you under any trial for medications or healthcare products or plan of care?

Do you alter medications sometimes? Only on the advice of an expert/Self-guided/On the basis of availability/On the basis of costs/Other reasons
Issues faced:

VOICING OUT

Do you discuss your conditions or responses regularly with experts? Yes/No/Not applicable Do you want to discuss your condition or responses with experts? Yes/No/Not applicable Options available?

Do you discuss your condition or responses with other peer groups of people suffering from the same diseases or illness? Yes/No/Not applicable

Do you want to discuss your condition or responses with other peer groups? Yes/No/Not applicable Options available?

Do you rely on any source of information or marketing function to know more about the drugs and products available for your condition (so you become a more aware consumer)? Yes/No/Not applicable

Options available or improvements needed?

Do you wish to send your profile information and feedback to different sections of the healthcare industry via your Chemist & Druggist (or pharmacy)? Yes/No/Not applicable
Options available?

Customer Satisfaction Survey (PERT feedback)

A pharmacy could define/revise a survey form to collect customer satisfaction information from customers

Pharmacy Id:	Customer Id or Name:	
1. Your opinion about the enquiry/customer information gathering:		
Very Good		
Good		
Satisfactory		
Poor		
Not applicable		
2. Quality of consultation if availed of on-s	ite:	
Very Good		
Good		
Satisfactory		
Poor		
Not applicable		

3. Customer or Patient Guidance System/Connectivity arrangements:
Very Good
Good
Satisfactory
Poor
Not applicable
4. Promptness/ Behavior/ Empathy shown by staff:
Very Good
Good
Satisfactory
Poor
Not applicable

5. Time taken for need assessment and confirmation of availability:

, , , , , , , , , , , , , , , , , , ,
Very Good
Good
Satisfactory
Poor
Not applicable
6. Did you have a prior reservation? If yes, did you need any rescheduling due to non-availability?
Yes
No
Not applicable
7. Waiting time for completion of sale?
Less than 5 minutes
More than 15 minutes
Not satisfactory

8. Your opinion about the look of the facility:

	Very Good
	Good
	Satisfactory
	Poor
	Not applicable
	9. Quality of facilities (Air-conditioning/ventilation, lighting, fire-safety, stores control etc): Comfort
	level?
_	
	Very Good
	Good
	Satisfactory
	Poor
	Not applicable

10. Any other consultation/dispensing aspect (like preferential packaging or time stamping to help consumption):

12. Any suggestions for improvement?

Gap analysis for achieving quality of services in all supply

Does the organization define structural goals in its quality management system?

- a. To discover problems, deficiencies, inconsistencies with how certain medications or healthcare products are being sold to stop these issues from becoming complaints. Yes/No/Partially
- b. To re-educate staff or correct behavior after only one event rather than after persistent or repetitive events. Yes/No/Partially
- c. For most regular customers, to ensure all relevant information is known or obtained to help choices being made. Yes/No/Partially
- d. For uneducated or aged regular customers, to ensure relevant packaging of medications on the basis of color codes that identify their purpose. Yes/No/Partially
- e. To ensure due process for consumption of vital medications, life saving/life support healthcare products is known to staff and potential or existing customers. Yes/No/Partially
- f. To ensure legalities are followed at all times during supply sourcing, dispatch or selling. Yes/No/Partially
- g. To ensure record keeping is done regularly to help any quality assurance process or auditing process. Yes/No/Partially

- 1. Does human resource planning support the organization's current and future ability to meet the needs of customers? Yes/No/Partially
- 2. Does the organization maintain an adequate number and mix of staff to meet the needs of customers? Yes/No/Partially
- 3. Are the job specifications and job descriptions well defined for each category of staff? Yes/No/Partially
- 4. Does the organization verify the antecedents of a potential employee with regards to criminal/negligence background? Yes/No/Partially
- 5. Is there a documented procedure for recruitment? Yes/No/Partially
- 6. Is recruitment based on pre-defined criteria? Yes/No/Partially

- 7. Is every staff member joining the organization provided simple induction training? Yes/No/Partially
- 8. Does the induction training include orientation to the organization's vision, mission and values? Yes/No/Partially
- 9. Does the simple induction training include awareness on employee rights and responsibilities? Yes/No/Partially
- 10. Does the simple induction training include orientation to service standards of the organization? Yes/No/Partially
- 11. Is every staff member made aware of organization wide policies and procedures, as well as relevant department/unit/service programme's policies and procedures? Yes/No/Partially

- 12. Does a documented training and development policy exist for the staff?
 Yes/No/Partially
- 13. Does the organization maintain the training record? Yes/No/Partially
- 14. Does training also occur when job responsibilities change or when new medications/ healthcare products are introduced? Yes/No/Partially
- 15. Are feedback mechanisms available for assessment of training and development programmes? Is the feedback used to improve the training programme? Yes/No/Partially
- 16. Are staff trained on the risks within the organization's environment?
 Yes/No/Partially

- 17.Can staff members demonstrate and take action to report, eliminate or minimize risks? Yes/No/Partially
- 18.Is the disciplinary policy and procedure based on the principles of natural justice? Yes/No/Partially
- 19.Is the disciplinary procedure in consonance with the prevailing laws?
 Yes/No/Partially
- 20 Is there a provision to make appeals in all disciplinary cases? Yes/No/Partially
- 21.Does the redressal procedure always address the customer grievance?
 Yes/No/Partially
- 22.Does the redressal procedure always address the staff grievance?
 Yes/No/Partially

- 23. Are health problems of employees taken care of in accordance with the organization's policy? Yes/No/Partially
- 24.Are occupational health hazards adequately addressed? Yes/No/Partially
- 25.Are personal files maintained in respect of all staff? Yes/No/Partially
- 26.Do personal files contain personal information regarding the staff's qualifications, disciplinary background and health status? Yes/No/Partially
- 27.Do personal files contain all records of in-service training and education?
 Yes/No/Partially
- 28. Do personal files contain results of all evaluations? Yes/No/Partially

• 29. Is there a process of identifying, credentialing and privileging of staff permitted to supply medications / healthcare products without supervision? Yes/No/Partially

- 1. Does a safety committee coordinate development, implementation and monitoring of a safety plan and policies for the facility? Yes/No/Partially
- 2. Are fire alarms, burglar alarms, sensors and other safety devices installed across the organization and are they inspected periodically? Yes/No/Partially
- 3. Does the organization have non-smoking zones? Yes/No/Partially
- 4. Are facility inspection rounds to ensure safety conducted once a day? Yes/No/Partially
- Are facility inspection rounds to ensure storage conditions are as per guidelines of the manufacturers? Yes/No/Partially
- 5. Are inspection reports documented and are corrective and preventive measures undertaken? Yes/No/Partially

- 6. Is there a safety education programme for staff? Yes/No/Partially
- 7. Are facilities appropriate to the scope of services of the organization? Yes/No/Partially
- 8. Does the establishment and facilities operate to ensure safety of staff and visitors? Yes/No/Partially
- Are up-to-date drawings maintained to support details of site layout, floor plans and fire-escape routes? Yes/No/Partially
- 9. Are internal and external sign postings largely understood by the community? Yes/No/Partially
- 10. Is potable water and electricity available around the clock? Yes/No/Partially

- 11. Are alternate sources of electricity and potable water provided as a backup for any failure/shortage? Is there a plan for water management? Yes/No/Partially
- 12. Does the organization regularly test these alternate sources? Yes/No/Partially
- 13. Is the provision of space in accordance with the available literature on good practices (Indian and international standards) and directed by government agencies? Yes/No/Partially
- 14. Are there designated individuals responsible for the maintenance of all facilities? Yes/No/Partially
- 15. Is there a documented operational and maintenance plan (inclusive of preventive and breakdown planning)? Yes/No/Partially
- 16. Are maintenance staff contactable for emergency repairs? Yes/No/Partially

- 17. Are response times monitored right from reporting to inspection and thereon implementation of corrective actions? Yes/No/Partially
- 18. Does the organization plan for devices/appliances/equipment in accordance with its services and strategic plan? Yes/No/Partially
- 19. Are devices/appliances/equipment selected, purchased/rented, updated or upgraded by a collaboration process? Yes/No/Partially
- 20. Are devices/appliances/equipment inventoried and proper logs maintained as required? Yes/No/Partially
- 21. Do qualified and trained personnel operate and maintain device/appliance/equipment and utility systems? Yes/No/Partially
- 22. Is there a documented operational and maintenance (incidental, preventive and corrective) plan? Yes/No/Partially

- 23. Is there a maintenance plan for water management? Yes/No/Partially
- 24. Is there a maintenance plan for electrical systems? Yes/No/Partially
- 25. Is there a maintenance plan for heating, ventilation and air-conditioning? Yes/No/Partially
- 26. Is there a documented procedure for device/appliance/equipment replacement and disposal? Yes/No/Partially
- 27. Do qualified and trained personnel operate and maintain the device/appliance/equipment? Yes/No/Partially
- 28. Are the devices/appliances/equipment periodically inspected and calibrated for their proper functioning? Yes/No/Partially

- 35. Does the organization have plans and provisions for early detection, abatement and containment of fire, and non-fire emergencies (disasters) within the facilities? Yes/No/Partially
- 36. Does the organization have a documented safe-exit plan in case of fire and non-fire emergencies? Yes/No/Partially
- 37. Are the staff trained for stock saving & life saving roles in case of such emergencies? Yes/No/Partially
- 38. Are mock drills held at least once a year? Yes/No/Partially
- 39. Is there a maintenance plan for fire-management related equipment? Yes/No/Partially
- 40. Does the organization identify potential emergencies on a periodic basis? Yes/No/Partially

- 41. Does the organization have a documented disaster management plan? Yes/No/Partially
- 42. Does the organization have plans for handling community emergencies, epidemics and other disasters? Yes/No/Partially
- 43. Are provisions made for the availability of medical supplies, healthcare products, equipment and materials during such emergencies? Yes/No/Partially
- 44. Are the staff trained for disaster management roles in case of such emergencies? Yes/No/Partially
- 45. Is the disaster management plan tested at least twice a year? Yes/No/Partially
- 46. Are hazardous materials/ bio-medical waste materials identified within the organization? Yes/No/Partially

- 47. Does the organization implement processes for sorting, labeling, handling, storage, transporting and disposal of hazardous material/ bio-medical waste material? Yes/No/Partially
- 48. Are requisite regulatory requirements met in respect of radioactive material? Yes/No/Partially
- 49. Is there a plan for managing spills of hazardous materials/ bio-medical waste materials? Yes/No/Partially
- 50. Are staff educated and trained for handling such materials? Yes/No/Partially

- 1. Have information needs of the organization been identified? Are they
 appropriate to the scope of services being provided by the organization?
 Yes/No/Partially
- 2. Do documented policies and procedures exist to meet the need for information?
 Yes/No/Partially
- 3. Are these policies and procedures in compliance with the prevailing laws and regulations? Yes/No/Partially
- 4. Are all information management and technology investments in accordance with the documented policies and procedures? Yes/No/Partially
- 5. Does the organization contribute to external databases in accordance with the law and regulations? Yes/No/Partially

- 6. Are formats for data collection standardized? Yes/No/Partially
- 7. Are necessary resources available for analyzing data?
 Yes/No/Partially
- 8. Are documented procedures laid down for timely dissemination of data?
 Yes/No/Partially
- 9. Are documented procedures laid down for storage and retrieving of data?
 Yes/No/Partially
- 10. Do appropriate staff participate in selecting, integrating and using data?
 Yes/No/Partially

- 11. Does every record of sale/ stock have an unique identifier? Yes/No/Partially
- 12. Does an organizational policy identify those authorized to make entries in a record of sale/ stock? Yes/No/Partially
- 13. Are entries in a record of sale/ stock named, signed, dated and timed always?
 Yes/No/Partially
- 14. Can the author of an entry be identified always? Yes/No/Partially
- 15. Are contents of a record of sale/ stock identified and documented?
 Yes/No/Partially
- 16. Does the record of sale/ stock provide a complete up-to-date and chronological account of services rendered? Yes/No/Partially

- 16. Is there a provision to ensure within 24-hours, the availability of the supply of medications/ healthcare products for continuity of care? Yes/No/Partially
- 17. Does the record of sale contain information regarding the customer's name, medical practitioner's name, and sale details? Yes/No/Partially
- 18. Does the record of sale contain details of any customer specific alterations to the prescription or details of the care identified by the medical practitioner? Yes/No/Partially
- 19.Do documented policies and procedures exist for maintaining confidentiality, security and integrity of records, data and information? Yes/No/Partially

- 20.Are documented policies and procedures in consonance with the appropriate laws? Yes/No/Partially
- 21.Do documented policies and procedures incorporate safe-guarding of data/information/record against loss, destruction and tampering? Yes/No/Partially
- 22. Does the organization have an effective process of monitoring compliance for the laid down policy and procedure? Yes/No/Partially
- 23. Does the organization use developments in appropriate technology for improving confidentiality, integrity and security? Yes/No/Partially
- 24.Is privileged health information (used for purposes identified or as required by the law) not disclosed without the customer's authorization? Yes/No/Partially

- 25.Is there a documented procedure on how to respond to patients/physicians and other public agencies that request for access to information in the record of sale/ stock in accordance with the local and national laws? Yes/No/Partially
- 26.Are documented policies and procedures in place for retaining a customer's record of sale, data and information? Yes/No/Partially
- 27. Are laid down policies and procedures in consonance with the local and national laws and regulations? Yes/No/Partially
- 28. Does the retention process provide expected confidentiality and security?
 Yes/No/Partially
- 29.Are the destruction of records, data and information of sale/ stock in accordance with the laid-down policy? Yes/No/Partially

- 30. Does the organization regularly carry out review of its records? Yes/No/Partially Are records of sale/ stock reviewed periodically? Yes/No/Partially
- For records of sale/ stock, does the review use a representative sample based on statistical principles? Yes/No/Partially
- Are records of profiles reviewed periodically & due action taken? Yes/No/Partially
- Are records of feedback reviewed periodically & due action taken? Yes/No/Partially
- Are records of satisfaction surveys reviewed periodically & due action taken?
 Yes/No/Partially
- Are the reviews conducted by identified auditors? Yes/No/Partially
- 31. Does the review focus on the timeliness, legibility and completeness of the records of sale/ stock? Yes/No/Partially
- 32. Does the review process include records of both old and existing customers? Yes/No/Partially

Gap analysis for any data analysis and evaluation of services

- 33. Does the review point out and document deficiencies in records? Yes/No/Partially
- 34. Does the organization undertake appropriate corrective and preventive measures within a defined period of time and are these documented? Yes/No/Partially

What are the expectations of a customer in case of a healthcare provider (like a Chemist and Druggist or pharmacy)?

1. Compliance for patient perspectives like

- a. Right to information
- b. Considerateness, respect and care while meeting needs
- c. Right to privacy and safety
- d. Right to choose and be heard
- e. Right to any available consumer education

2. Acceptability of services offered like

- a. Need based accessibility
- b. Recognition and re-establishment of patient practitioner relationships
- c. Good quality supplies with safe facilities
- d. Recognition of patient frequency/ preference as to whether supplies provided are effective, can be more right for timely purchasing, are of good quality and have overall efficacy (i.e. Zero Day Effectiveness, due process details, feedback, need to know more)

- Can reports be generated for:
- Total number of Sales: Yes/No
- Total number of Referral cases: Yes/No
- Total number of New customers: Yes/No
- Total number of Existing customers: Yes/No
- Total number of Trials based customers: Yes/No
- Total number of Enquiries: Yes/No
- Total number of Defective sales: Yes/No
- Any productivity problem : Yes/No
- Any Attrition rate problem: Yes/No
- Any issues in Equipment Management/Engineering: Yes/No
- Any issues in Supply Chain Management: Yes/No
- Any issues in Materials planning/management: Yes/No

- Any issues in House-keeping: Yes/No
- Any issues in Waste Management: Yes/No
- Any issues in Communications procedures: Yes/No
- Any issues in Customer/ Public Relations Department: Yes/No
- Any issues in Security & Safety services: Yes/No
- Any issues in Transport services: Yes/No
- Any issues in Disaster Management: Yes/No
- Any issues in Financial Management/Budgeting: Yes/No

- Any issues in Interactions between staff/coordination: Yes/No
- Any issues in decision making (for quality levels): Yes/No
- Any issues in (On-the-job) Learning/Training: Yes/No
- Any issues in maintaining quality levels or reducing issues on hand: Yes/No
- Any issues in information collection, management and dissemination practices for continual excellence in services: Yes/No
- Any issues in designing an Information Centre/ Resource Centre/ Call Centre to assess and support needs for agility in practices: Yes/No

- 1. Do those responsible for governance lay down the supply chain vision, mission and value system? Yes/No/Partially
- 2. Do those responsible for governance approve the strategic and operational plans and organization's budget for the supply chain? Yes/No/Partially
- 3. Do those responsible for governance monitor and measure the performance of a link in the supply chain against the stated mission Yes/No/Partially
- 4. Do those responsible for governance identify contact staff for links in the supply chain? Yes/No/Partially
- 5. Do those responsible for governance support sustainable marketing strategies, safety initiatives and quality improvement plans for the supply chain? Yes/No/Partially
- 6. Do those responsible for governance support trial/ market specific campaign activities in the supply chain? Yes/No/Partially

- 7. Do those responsible for governance address the supply chain's social responsibility? Yes/No/Partially
- 8. Do those responsible for governance inform the supply chain links about the quality and performance of supplies? Yes/No/Partially
- 9.Is the management conversant with ethics, laws and regulations and do they know its applicability? Yes/No/Partially
- 10. Does the management ensure implementation of these requirements?
 Yes/No/Partially
- 11. Does the management regularly update any amendments in the prevailing laws being considered? Yes/No/Partially

- 12. Is there a mechanism to regularly know about licenses/ registrations/ certifications in the supply chain? Yes/No/Partially
- 13. Are the scope of services of each link of the supply chain defined and utilized effectively? Yes/No/Partially
- 14. Are administrative policies and procedures for each link in the supply chain maintained properly? Yes/No/Partially
- 15. Does the contact management programme for each service, location of business site, link in the supply chain have effective leadership? Yes/No/Partially
- 16. Are contact management staff/ supervisors involved in quality improvement?
 Yes/No/Partially
- 17. Do contact management supervisors make public the vision, mission and values of the organization in the supply chain? Yes/No/Partially

- 18. Do supervisors establish the organization's ethical management?
 Yes/No/Partially
- 19. Does the organization disclose its ownership? Yes/No/Partially
- 20. Does the organization honestly portray the services it can and cannot provide?
 Yes/No/Partially
- 21. Does the organization honestly portray its affiliations and accreditations?
 Yes/No/Partially
- 22. Does the organization accurately bill for its services based upon a standard billing and inventory system? Yes/No/Partially
- 23. Does the person heading the organization/department have requisite and appropriate administrative qualifications? Yes/No/Partially

- 24. Does the person heading the organization/department have requisite and appropriate administrative experience? Yes/No/Partially
- 25. Does the organization prepare strategic and operational plans including shortterm and long-term goals commensurate to the organization's vision, mission and value systems in consultation with various links in the supply chain? Yes/No/Partially
- 26. Does the organization coordinate the functioning with the links & external agencies and does it monitor the progress in achieving the defined goals and objectives? Yes/No/Partially
- 27. Does the organization plan and budget for its activities annually?
 Yes/No/Partially
- Are the performances of the supervisors reviewed for their effectiveness?
 Yes/No/Partially

- 28. Is the functioning of any joint venture reviewed for its effectiveness?
 Yes/No/Partially
- 29. Does the organization document supportive rights and responsibilities to perform in different roles? Yes/No/Partially
- 30. Does the organization document its service standards? Yes/No/Partially
- 31. Does the organization have a formal documented agreement for all outsourced services? Yes/No/Partially
- 32. Does the organization monitor the quality of its outsourced services?
- Yes/No/Partially
- 33. Does the organization ensure appropriate proactive risk management across its services? Yes/No/Partially

- 34. Does the organization provide resources for proactive risk assessment and risk reduction activities? Yes/No/Partially
- 34. Does the management implement systems for internal and external reporting of system and process failures? Yes/No/Partially
- 35. Does the management ensure appropriate corrective and preventive actions are taken to address supply chain related incidents? Yes/No/Partially
- 36. Does the management ensure the supply chain management system is monitored and audited periodically for effectiveness? ? Yes/No/Partially
- 37. Does the management package a flowchart that illustrates how its medications/healthcare accessories/healthcare products sourced from the manufacturer's shop floor, or distributor's storehouse reach its retail chain, a step that can reduce supply of spurious drugs or sale of spurious drugs or other unethical practices? Yes/No/Partially

Gap Analysis for Governance, Management and Quality in services (Basic Edition for I-catalog synergy)

This section includes questions that review whether retailers or supply chain endpoints operate for continual quality management. Your team can iterate through these questions to understand the current lacunae and thereon bridge the gaps.

1. Has the organization determined , planned and developed organizational structures needed for any service realization? Yes/No/Partially

This guide states that the planning of any service realization can be achieved by developing and implementing a Business Curves Management system, where there is scope for all business interests like formulaic organization, systems organization, service organization and Technology or Gateway support.

A Business Curves Management system can help an organization achieve success via

- 1. Sustainable Quality of outcome
- 2. Sustainable Quality of structure
- 3. Sustainable Quality of process
- 4. Sustainable maturity in unified enterprise management

What is possible through a Business Curves Management system?

A Business Curves Management system helps an organization implement solutions for all 5 indicators through which the quality of medical care and services can be assessed i.e.

- A. The formulaic organization (business model/ management structure, objectives, facilities, staff/personnel etc)
- B. The systems organization or processes adopted (procedures/SOP, flow of activities, effective utilization of human and material resources, etc)
- C. The service organization or content of services offered (policies, standards, services for improved health, treatment and therapeutic care, quantity & quality of services, approach for patient rights and education, etc)

- D. The knowledge about outcome for services offered (medications and healthcare products for people needing them at the right time with right sufficiency etc)
- E. The Technology or Gateway support for services to create more opportunity and accessibility (supply chain agility, community benefits, customer satisfaction, cost of care appropriateness, etc.)
- 2. Does the organization maintain records that provide evidence that the realization processes and resulting service meets quality level and conformance requirements? Yes/No/Partially
- 3. Are these records that provide this evidence periodically monitored? Yes/No/Partially

- 4. Does the organization understand the importance of a globally aligned policy for quality assurance? Yes/No/Partially
- 5. Does the organization meet emerging needs by carrying out gap analysis for its organizational practices? Yes/No/Partially

Gap Analysis for Management system

- 1. Does the organization establish, document, implement and maintain a quality management system (QMS)? Yes/No/Partially
- 2. Does the organization take steps to continually improve the effectiveness of the QMS? Yes/No/Partially
- 3. Does the organization determine the processes needed for the QMS and their application throughout the organization? Yes/No/Partially
- 4. Does the organization determine the sequence and interaction needed for the determined processes? Yes/No/Partially
- 5. Does the organization determine criteria and methods needed to ensure that both the operation and control of determined processes are effective? Yes/No/Partially

Gap Analysis for Management system

- 6. Does the organization ensure the availability of resources (such as human resources, infrastructure and work environment) and information necessary to support the operation and monitoring of determined processes? Yes/No/Partially
- 7. Does the organization monitor, measure (where applicable), analyze the determined processes? Yes/No/Partially
- 8. Does the organization implement actions necessary to achieve planned results and continual improvement of the determined processes? Yes/No/Partially
- 9. Does the organization manage the determined processes in accordance with the requirements of ISO 9001:2008 standard? Yes/No/Partially
- 10. Has the organization outsourced any process that can affect/ affects the quality of services? Yes/No/Partially

Gap Analysis for Management system

- 11. Which are these outsourced processes?
- 12. Has the organization defined in the quality management system the type and extent of control that is to be applied to such outsourced processes?

 Yes/No/Partially
- 13. Does the organization ensure control over such outsourced processes? Yes/No/Partially

Gap Analysis for Documentation Requirements

- 1. Does the organization have a documented statement of a globally aligned quality policy? Yes/No/Partially
- Does the organization have a documented statement of quality objectives? Yes/No/Partially
- Does the organization have a quality manual? Yes/No/Partially
- 4. Does the organization have documented procedures/processes? Yes/No/Partially
- 5. Has the organization identified documents (and records) determined as important to ensure the effective planning, operation and control of the organization's processes? Yes/No/Partially
- 6. Does the organization maintain such documents (and records)? Yes/No/Partially

Gap Analysis for Documentation Requirements

- 7. Does the quality manual include the scope of the quality management system? Yes/No/Partially
- 8. Does the quality manual mention details of and justification for any exclusion from the quality of service requirement? Yes/No/Partially
- 9. Does the quality manual include a documented procedure in the quality management system for the reference of these exclusions? Yes/No/Partially
- 10. Does the quality manual include a description of the interaction between the processes of the quality management system? Yes/No/Partially
- 12. Are documents required by the QMS controlled/versioned? Yes/No/Partially
- 13. Is there any documented procedure that defines control of the documents? Yes/No/Partially

Gap Analysis for Quality of services

- Is the quality policy appropriate to the purpose of the organization?
 Yes/No/Partially
- Does the quality policy include a commitment to comply with the requirements? Yes/No/Partially
- 3. Does the quality policy include a commitment to continually improve the effectiveness of the quality management system? Yes/No/Partially
- 4. Does the quality policy provide a framework for establishing quality objectives? Yes/No/Partially
- Does the quality policy provide a framework for reviewing quality objectives?Yes/No/Partially
- 6. Is the quality policy communicated all through the organization? Yes/No/Partially

Gap Analysis for Quality of services

- 7. Is the quality policy understood within the organization? Yes/No/Partially
- 8. Is the quality policy reviewed for continuing suitability? Yes/No/Partially

Gap Analysis for Purchasing

- 1. What are the type and extent of controls applied to suppliers of medications, healthcare products, devices, appliances, and infrastructure specific equipment?
- 2. Whether the organization evaluates and selects suppliers based on their ability to supply medications, healthcare products, devices, appliances and infrastructure specific equipment in accordance with the organization's requirements? Yes/No/Partially
- 3. Whether any criteria for selection, evaluation and re-evaluation have been established? Yes/No/Partially
- 4. Are these reviewed periodically to ensure conformity in quality level? Yes/No/Partially
- 5. Are records of the results of evaluation and any necessary actions arising from these evaluations maintained? Yes/No/Partially

Gap Analysis for Purchasing

- 6. Whether the organization documents requirements that describe the medications/healthcare products/devices/appliances/ infrastructure specific equipment to be purchased? Yes/No/Partially
- 7. Whether the organization ensures adequacy of such documentation prior to communication to the supplier? Yes/No/Partially
- 8. Whether the organization establishes and implements inspection or other evaluation activities necessary to ensure that the purchased medications/healthcare products/devices/appliances/ infrastructure specific equipment meets specified purchase requirements? Yes/No/Partially
- 9. Whether the organization states need for such inspection to the supplier before it can sanction approval of medications/healthcare products/devices/appliances/infrastructure specific equipment? Yes/No/Partially

Gap Analysis for Customer Related Processes

- 1. Has the organization determined requirements to provide safe, conformant and patient friendly healthcare assistance? Yes/No/Partially
- 2. Has the organization determined requirements mandated by NABH/NABL/other advisory boards to provide healthcare in any department? Yes/No/Partially
- 3. Has the organization determined which statutory and regulatory requirements need to be met while providing healthcare assistance? Yes/No/Partially
- 4. Has the organization identified any additional requirements that need to be met to provide healthcare assistance? Yes/No/Partially
- 5. Has the organization assessed and justified the need to meet such requirements? Yes/No/Partially
- 6. Does the organization re-determine these requirements from time to time keeping in mind that the dynamics of healthcare is continuously changing? Yes/No/Partially

Gap Analysis for Customer Related Processes

- 7. Does the organization maintain records of such reviews and actions arising from such reviews? Yes/No/Partially
- 8. Is there a documented procedure that guides the organization in satisfying such reviews? Yes/No/Partially
- 9. Is there a report documented to describe how these reviews are satisfied? Yes/No/Partially
- 9. Are customer requirements and ethical marketing practices confirmed by the organization before acceptance to supply, this also includes those specifics where the customer provides no statement of need or prescription? Yes/No/Partially
- 10. What is the arrangement for communicating with customers in relation to enquiries and whether such arrangement is effective? Yes/No/Partially

Gap Analysis for Customer Related Processes

- 11. What is the arrangement for communicating with customers in relation to details about medications / healthcare products supplied and whether such arrangement is ethical and effective? Yes/No/Partially
- 12. What is the arrangement for collecting customer feedback (including accepting of customer complaints) and whether such arrangement is effective? Yes/No/Partially
- 13. What is the arrangement for communicating with customers in relation to customer feedback (including customer complaints) and whether such arrangement is effective? Yes/No/Partially

Gap Analysis for Control of non-conforming services

- 1. Does the organization identify and control non-conforming medications, healthcare products, devices, appliances and infrastructure specific equipment to prevent further issues? Yes/No/Partially
- Is there a documented procedure established that defines controls, related responsibilities and authorities for dealing with such non-conformance? Yes/No/Partially
- 3. How does the organization deal with non-conformance? Does the organization use any service transformation analysis to identify and control actions to be taken for any non-conforming service, marketing strategy, process, medication, healthcare product, device, appliance, infrastructure specific equipment etc? Yes/No/Partially
- 4. Does the organization undertake any re-validation upon correction of non-conforming service, marketing strategy, process, medication, healthcare product, device, appliance, infrastructure specific equipment etc? Yes/No/Partially
- 5. Does the organization maintain records of the nature of non-conformities and any subsequent actions taken, or immediate concessions granted? Yes/No/Partially

Gap Analysis for Control of non-conformities

- Does the organization determine, collect and analyze data for conformity?
 Yes/No/Partially
- Does the analysis of data provide information related to customer satisfaction? Yes/No/Partially
- 3. Does the analysis of data provide information relating to conformity to standards, ethics, regulations and quality levels? Yes/No/Partially
- 4. Does the analysis of data provide information relating to incidences, sudden emergencies and other unforeseen occurrences? Yes/No/Partially
- 5. Does the analysis of data provide information relating to negligence, near-misses and sentinel events? Yes/No/Partially

Gap Analysis for Control of non-conformities

- 6. Does the analysis of data provide information relating to characteristics and trends of processes, medications, healthcare products, devices, appliances, infrastructure specific equipment etc, including opportunities for preventive action? Yes/No/Partially
- 7. Does the analysis of data provide information relating to issues arising from medications, healthcare products, devices, appliances etc provided by pharmaceutical links in the supply chain? Yes/No/Partially
- 8. Does the analysis of data provide information relating to issues arising from medications, healthcare products, devices, appliances or treatment recommended by ancillary practitioners, diagnostic centers, related supply chain units and/or related marketing functions? Yes/No/Partially
- 9. Does the analysis of data provide information relating to suppliers of medications, healthcare products, devices, appliances, infrastructure specific equipment? Yes/No/Partially

- 1. Does the organization continually improve the effectiveness of its Quality management system? Yes/No/Partially
- 2. Does the organization take corrective action? Yes/No/Partially
- 3. Are corrective actions always or nearly always appropriate to the effects of non-conformities encountered? Yes/No/Partially
- 4. Is a documented procedure established for corrective action? Yes/No/Partially
- 5. Is the documented procedure inclusive of defined requirements for reviewing non-conformities and customer complaints? Yes/No/Partially
- 6. Is the documented procedure inclusive of defined requirements for determining causes for non-conformities? Yes/No/Partially

- 7. Is the documented procedure inclusive of defined requirements for evaluating the need for action to ensure non-conformities do not occur? Yes/No/Partially
- 8. Is it inclusive of defined requirements for determining and implementing the corrective action needed? Yes/No/Partially
- 9. Does it include defined requirements for records of results for corrective action taken? Yes/No/Partially
- 10. Is the documented procedure inclusive of defined requirements for reviewing the effectiveness of the corrective action taken? Yes/No/Partially
- 11. Does the organization maintain records of corrective action? Yes/No/Partially
- 12. Does the organization determine preventive action? Yes/No/Partially

- 13. Are the preventive actions taken appropriate or nearly always appropriate to the effects of the potential problems? Yes/No/Partially
- 14. Is a documented procedure established for taking preventive action? Yes/No/Partially
- 15. Is the documented procedure inclusive of defined requirements for determining potential non-conformities and their causes? Yes/No/Partially
- 16. Is the documented procedure inclusive of defined requirements for evaluating the need for action to prevent occurrence of non-conformities? Yes/No/Partially
- 17. Is the documented procedure inclusive of defined requirements for accurately determining and implementing the action needed to prevent occurrence of non-conformities? Yes/No/Partially

- 18. Is the documented procedure inclusive of defined requirements for accurately recording results of preventive action taken? Yes/No/Partially
- 19. Is the documented procedure inclusive of defined requirements for reviewing the effectiveness of preventive action taken? Yes/No/Partially
- 20. Does the organization maintain records of preventive action? Yes/No/Partially
- 21. Does the organization share the results and learning from such preventive action (within the organization from time to time) to foster proactive involvement? Yes/No/Partially

- 1. Does a documented procedure define the controls needed to approve a document/report for adequacy prior to issue? Yes/No/Partially
- 2. Does a documented procedure define the controls needed to review and update as necessary and re-approve documents/reports? Yes/No/Partially
- 3. Does a documented procedure define the controls needed to ensure that changes and current revision status of documents/reports are identified? Yes/No/Partially
- 4. Does a documented procedure define the controls needed to ensure relevant versions of applicable documents/reports are available to people concerned or at points of use? Yes/No/Partially
- 5. Does a documented procedure define the controls needed to ensure that documents/reports remain legible and easily identifiable? Yes/No/Partially

- 6. Does a documented procedure define controls needed to ensure documents/reports of external origin determined by the organization are easily identified, conformant and their distribution controlled? Yes/No/Partially
- 7. Does a documented procedure define the controls needed to prevent the unintended use of obsolete/ erroneous documents/reports and to apply suitable identification to them if they are retained for any purpose? Yes/No/Partially
- 8. Does the organization maintain records to provide evidence of conformity to standards and of the effective operation of the quality management system? Yes/No/Partially
- 9. Are records of the organization legible? Yes/No/Partially
- 10. Are records of the organization readily identifiable and retrievable? Yes/No/Partially

- 11. Does a documented procedure define the controls needed for the identification of records? Yes/No/Partially
- 12. Does a documented procedure define the controls needed for the storage of records? Yes/No/Partially
- 13. Does a documented procedure define the controls needed for the protection of records? Yes/No/Partially
- 14. Does a documented procedure define the controls needed for the retrieval of records? Yes/No/Partially
- 15. Does a documented procedure define the controls needed for the retention of records? Yes/No/Partially

16. Does a documented procedure define the controls needed for the disposition of records? Yes/No/Partially

Gap Analysis for Internal Audits / SERT

An Internal Audit / SERT involves the implementation of gap analysis of your healthcare model (Business Curves management system) where a report is generated to indicate SERT acceptability.

How will the gap analysis be done?

It will be done in multiple steps

Step 1: This involves Gap Analysis for Business Curves or Patterns in services

Step 2: This involves Gap Analysis for Governance, Management and Quality

Step 3: This involves Gap Analysis for SIP Compartmentalization or UEM Cycle sequencing

Step 4: This involves Gap Analysis for Continual Quality Management Approach for sustained success or continual excellence (based on ISO 9004:2009)

Gap Analysis for Internal Audits / SERT

What is SERT acceptability?

It is an indication of complete acceptability that your healthcare model is continually excellent. This understanding is achieved via anytime **gap analysis** to assess how your organization delivers for the following:

- 1. Better availability with demonstration of unique value
- Improved acceptability / intelligence for quality and competence in techniques
- 3. Overall accountability / transformability in services
- 4. Qualified GMP/GCP/GDP or Intelligence or Affordability

SERT acceptability will also improve your ability to manage today's system influencers, and the need to understand and manage cause for change in your business model.

Gap Analysis for Internal Audits / SERT

After anytime gap analysis what is next?

Your pharmaceutical or the auditor will be able to identify the main factors that affect the resultant services offered by your retailers or supply chain endpoints, to thereon look at alternatives/improvements via gaps detected.

Your pharmaceutical or the auditor will be assisted in this effort by a SERT report that will define a "Towards SMART Convergence" framework that could guide your co-associated efforts for growth in competence, practices effectiveness, quality assurance, audit preparedness, and development for future services.

The ASSETs guide Part 1,2 & 3 includes all this and more information. You can place your order for the same by either calling AEOC on the mobile number 9342867666 or by emailing AOEC at ksvenkatram@yahoo.co.in or venkataoec@gmail.com.

Gap Analysis for Management Review

- 1. What are the planned intervals to conduct management reviews? Yes/No/Partially
- 2. Does the top management review the quality management system at planned intervals? Yes/No/Partially
- 3. When were the earlier management reviews conducted? Yes/No/Partially
- 4. Are records of management reviews available? Yes/No/Partially
- 5. Whether input to management reviews includes information on results of audits (internal as well as external audits)? Yes/No/Partially
- 6. Whether input to management reviews includes information from customer feedback? Yes/No/Partially
- 7. Whether input to management reviews includes information on marketing functions/process/procedure performance and quality of service conformity? Yes/No/Partially

Gap Analysis for Management Review

- 8. Whether input to management reviews includes information on status of preventive and corrective actions? Yes/No/Partially
- 9. Whether input to management reviews includes information on follow-up actions from previous management reviews? Yes/No/Partially
- 10. Whether input to management reviews includes information on changes (that could even affect the quality management system)? Yes/No/Partially
- 11. Whether input to management reviews includes information on recommendations for improvement? Yes/No/Partially
- 12. Does the output from the management review include any decisions and actions related to the improvement of the quality management system/processes/ procedures/demand related marketing functions? Yes/No/Partially

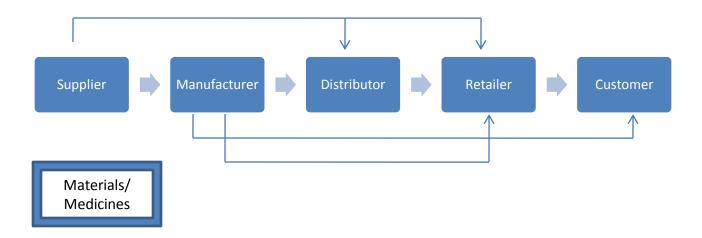
Gap Analysis for Management Review

- 13. Does the output from the management review include any decisions and actions related to improvement of quality of service related to customer requirements? Yes/No/Partially
- 14. Does the output from the management review include any decisions and actions related to resource needs? Yes/No/Partially

Gap Analysis for SIP Compartmentalization or UEM Cycle sequencing (Basic Edition for I-catalog synergy)

This section includes questions that review whether retailers or supply chain endpoints implement standardized quality management practices. Your team can iterate through these questions to understand the current lacunae and thereon bridge the gaps.

• Illustration 1: Supply Chains are made up of stages that involve flow of customer requests, products, information and funds



- Most Pharmaceuticals, Chemists & Druggists or pharmacies supporting or using supply chains rely on marketing functions, strategy, planning, and efficient transportation to maximize the total supply chain profitability.
- Supply chains are a sequence of processes and flows that take place within and between different stages. While deciding upon the flow of information, products or funds in a supply chain, Pharmaceuticals, Chemists & Druggists or pharmacies mostly depend upon processes or process cycles to link one stage in the chain to another.

Process Cycle based Supply Chains

- Most businesses use the following process cycles to interface with and across the 5 different stages of manufacturing, distribution, supply, retail and selling i.e.
- Customer order cycle
- Replenishment cycle
- Manufacturing cycle
- Procurement cycle

Push/Pull Processes based Supply Chains

- Other than this, these businesses also use 2 processes for the flow of products between stages i.e. Push processes, and Pull processes. Push processes operate in an environment where customer demands are not known. Pull processes are reactive processes, they are used in environments where customer demands are known, and help customers react to their requirements.
- A self-assessment framework can help businesses control a supply chain's
 flexibility, costs, quality, marketing functions, delivery metrics and process cycle for
 Good Dispensing practices. The section on Gap analysis for communication with
 supply or retail chains can help a business incorporate this review for
 conformance and agility in both push and pull scenarios.

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- There are different Key Performance Indicators for a supply chain connecting Pharmaceuticals with Chemists and Druggists (some examples follow):
- 1. Short lead times
- 2. Adept inventory control and elimination of waste
- 3. Improved supply, and/or process flow
- 4. Right and ethical marketing functions
- 5. Financial benefits due to smarter decisions for Supply Chain Processes
- 6. Paperwork reduction in decision-making
- 7. Success factor in treating, mitigating or preventing diseases, where the requirement is to connect a supply chain to help it act as a relief bridge and to prevent uncertainty in demand and supply for its supply of medicines/ healthcare accessories / products. The end-to-end requirement is to use a supply chain management solution that ensures that the customers receive a controlled supply of medicines/ healthcare accessories/ healthcare products on time.
- Classifications that help support or use supply chains
- All supply chain processes can be classified into the following 3 macro-processes:
- a. Supplier Relationship Management (SRM)
- b. Internal Supply Chain Management (ISCM)
- c. Customer Relationship Management (CRM)

Supplier Relationship Management Activities typically involve

- 1. Sourcing
- 2. Negotiating
- 3. Buying
- 4. Shop Floor to Shelf Collaboration
- 5. Supply Collaboration

Internal Supply Chain Management Activities typically involve

- 1. Strategic Planning
- 2. Demand Planning
- 3. Supply Planning
- 4. Fulfillment
- 5. Field Service

Customer Relationship Management Activities typically involve

- 1. Marketing
- 2. Easy Pricing
- 3. Selling
- 4. Call Center outsourcing or implementation for a 24/7 arrangement
- 5. Order Management
- UEM cycle sequencing is a methodology for enabling small and continuous improvement in SRM, ISCM and CRM Activities. UEM cycle sequencing will help an organization manage its Quality of Services via a RADIUS of 5 factors such as
- 1. Gap Analysis for Process cycle compatibility
- 2. Gap Analysis for controlled Business Impact
- 3. Gap Analysis for reduced Stock outs
- 4. Gap Analysis for Supply Level Agreement adherence
- 5. Gap Analysis for Incidence Confinement

This guide does not include more details on this. This concept requires a case study to be done at the Chemist & Druggist or pharmacy.

- AOEC's Pharmacy's Lifecycle Review helps design a knowledge base that integrates Gap analysis for the RADIUS of 5 factors
- This knowledge base will package different Gap analysis sections to form a baseline database that can implement a maturity forecaster to help control the SRM, ISCM and CRM activities for SMART Convergence and Quality of Services (QoS).
- The Gap analysis integration will be continually improved via a set of P-D-C-A efforts to help
- a. Plan What should be forecasted, when should it be forecasted, who should be forecasting this, how should it be forecasted and by using what?
- b. Do Enable SRM, ISCM and CRM activities via this plan?
- c. Check Check if SRM, ISCM and CRM activities can support the QoS maturity needed, or carry out "what if" analysis for better results
- d. Act Determine whether the integration improves alignment? Can it work to revise or restructure the SRM, ISCM and CRM processes?

Pharmacy Lifecycle Review for Critical Path Management Feedback

Pharmacy Id:	Customer Id or Name:
The overall efficacy of the organization	n or unit

Explanation: This focuses on how the staff, or on-site consultants worked along with the existing processes, systems, equipment and other facilities to provide medications or healthcare products or referral services.

Your satisfaction ratings:
⊒Excellent
⊒ Good
☐Fair (needs improvement)
☐Poor (unsatisfactory)
□ Not relevant

The appropriateness in delivering services

Explanation: This focuses on whether the medications or products provided were relevant for patient's illness/ problem/needs, or need for any incidence mitigation.

Your observations:

your satisfaction ratings:
□Excellent
□Good
☐ Fair (needs improvement
☐Poor (unsatisfactory)

□ Not relevant

Va.... aatiafaatian matinaa.

The timeliness in delivering services

Explanation: This focuses on whether services were provided keeping in mind the case's urgency or need for care, relief or any incidence mitigation.

Your satisfaction ratings:
□Excellent
□Good
☐ Fair (needs improvement
☐Poor (unsatisfactory)
□Not relevant

The specific availability of services or sustainable procedures

Explanation: This focuses on whether any order placement, or any reordering, or extra assistance was needed, or external consultation was necessary for the medications or products being purchased. Was this satisfactory?

Your satisfaction ratings:
□Excellent
□Good
☐ Fair (needs improvement
☐Poor (unsatisfactory)
■Not relevant

The consistent effectiveness in approach

Explanation: This focuses on whether all concerned with the pharmacy worked effectively as a team, where any systematic evaluation or cross-checking helped ensure good quality for what was sold for care, relief or incidence mitigation.

Your satisfaction ratings:
⊒ Excellent
⊒ Good
☐Fair (needs improvement)
☐Poor (unsatisfactory)
□ Not relevant

The continuity in quality of services

Explanation: This focuses on whether all concerned with the pharmacy adhered to the best methodology policies (for GCP or GDP) during all purchasing of medications or healthcare products.

Your satisfaction ratings:
⊒Excellent
⊒ Good
☐Fair (needs improvement)
☐Poor (unsatisfactory)
Not relevant

The safety adherence in approach

Explanation: This focuses on whether safe practices were adhered to during the demand marketing and sale of medications or products. It questions whether the customer was exposed to any risk. It does also question whether risk management practices like feedback gathering, or disaster management evaluations are in place while delivering services to customers.

Your satisfaction ratings:
⊒ Excellent
⊒ Good
☐Fair (needs improvement)
☐Poor (unsatisfactory)
□Not relevant

The efficiency while depending upon manpower, staff, equipment, procedures Explanation: This focuses on whether all connected with the pharmacy showed a sense of efficiency while dealing with case. It also questions whether all relevant procedures adopted, storage and dispensing equipment used worked satisfactorily.

Your satisfaction ratings:
□Excellent
□Good
☐ Fair (needs improvement
☐Poor (unsatisfactory)
□Not relevant

The respect and care aspect in delivering services

Explanation: This focuses on whether all connected with the pharmacy showed a sense of respect and courteousness while dealing with the case.

Your satisfaction ratings:
□Excellent
□Good
☐ Fair (needs improvement
☐Poor (unsatisfactory)
☐Not relevant

The learning curve reduction aspect in delivering services

Explanation: This focuses on whether all connected with the pharmacy showed a sense of knowing (adequately) as to what needed to be done or were interested in doing things according to a best policy adherence while dealing with the case.

Your satisfaction ratings:
□Excellent
□Good
☐ Fair (needs improvement
☐Poor (unsatisfactory)
□Not relevant

The creativity aspect in the quality management

Explanation: This focuses on whether all connected with the pharmacy showed a sense of better decision-making in demand marketing/interacting/ intervening / providing for information or alternatives while dealing with the sale of medications or healthcare products.

Your satisfaction ratings:
□Excellent
□Good
☐ Fair (needs improvement
☐Poor (unsatisfactory)
□Not relevant

The data reliability while delivering services

Explanation: This focuses on whether all data related to the customer or patient, prescriptions available, information related to illness/problem/need, diagnosis specific details, treatments given, or details used while selling medications or healthcare products for the case was used sufficiently reliably.

Your satisfaction ratings:
□Excellent
□Good
☐ Fair (needs improvement
☐Poor (unsatisfactory)
□Not relevant

Other feedback:

Other comments:

Whether you will recommend this pharmacy to others?

Gap Analysis for Continual Quality Management Approach (Basic Edition)

This section includes questions that review whether retailers or supply chain endpoints operate for continual quality management. Your team can iterate through these questions to understand the current lacunae and thereon bridge the gaps.

What is continual quality management for sustained success about?

A Chemist and Druggist 's environment is ever-changing and not deterministic. The issues affecting the health of people are also not within our control, so the need for healthcare is a complex relationship.

In this scenario, a reputable healthcare organization is one that can deliver services of good quality and continual excellence. To achieve sustained success in its service model, a healthcare organization will need to consistently meet the needs and expectations of its interested parties (like its investors, its stakeholders, its partners, its consultants, its staff, its suppliers, its customers etc), in a balanced way over the long-term.

Planning for and implementing **ISO 9004:2009** is a good way of ensuring a pharmaceutical networks (the pharmaceutical organization, its supply chain/retail chains and Chemist and Druggist links) performs for sustained success or continual excellence. **AOEC's handbook/guide can help an establishment do this.**

To help understand where you are positioned today, there are few questions of common importance that follow on the next few pages.

- 1. Does your organization rely on any long-term planning? Yes/No/Partially
- 2. Does your organization have any methodology to constantly monitor and regularly analyze your organization's environment, delivery model and system influencers? Yes/No/Partially
- 3. Does your organization have a clear idea of all its interested parties, their individual impact on the performance, as well as plan of how to meet their needs and expectations in a balanced way? Yes/No/Partially
- 4. Does your organization continually engage interested parties to keep them informed of the organization's plans, activities and intent for the future? Yes/No/Partially
- 5. Does your organization plan approaches to establish mutually beneficial relationships with consultants, partners, suppliers and other interested parties? Yes/No/Partially

- 6. Does your organization identify associated short-term and long-term risks and deploy overall strategies to mitigate them? Yes/No/Partially
- 7. Does your organization project anticipated future resource needs (including competencies expected of its people)? Yes/No/Partially
- 8. Does your organization plan for and establish processes to achieve the organization's strategies and does it ensure these processes are capable of responding quickly to changing circumstances? Yes/No/Partially
- 9. Does your organization regularly assess conformance of services to quality levels and compliance with plans and procedures? Does your organization take appropriate corrective and preventive actions? Yes/No/Partially
- 10. Does your organization establish and maintain processes for innovation and continual improvement? Yes/No/Partially

- 11. Does your organization ensure its people have sufficient opportunities for learning for their own benefit and also to maintain the quality levels and vitality of the organization? Yes/No/Partially
- 12. Is your organization in a position to make decisions in all cases based upon factual evidence? Yes/No/Partially
- 13. Does your organization have a well-formed approach to assess and understand the current performance, with root cause details of all problems in the past, in order to avoid their recurrence? Yes/No/Partially
- 14. Can new or modified processes be established in a timely manner, with any necessary planning and resources being provided to support them? Is your organization agile? Yes/No/Partially
- 15. Does your organization have a well-formed approach to ensure all communication is meaningful, timely and continual? Yes/No/Partially

- 16. Does your organization ensure resources (infrastructure and non-infrastructure) are used effectively and efficiently, by ensuring processes are in place to provide, allocate, monitor, evaluate, optimize, maintain and protect these resources? Yes/No/Partially
- 17. Does your organization plan for any scarcity setting in the availability of its resources? Does your organization actively pursue ways to improve their utilization? Yes/No/Partially
- 18. Does your organization have a well-formed approach to control financial investment by reducing non-conformity costs, unethical practices, process failures, facility utilization costs and also by eliminating wastage of materials or time? Yes/No/Partially

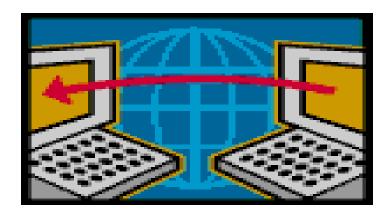
- 19. Does your organization have a well-formed approach to share case studies, information, knowledge and experience within the organization? Yes/No/Partially
- 20. Does your organization perform self-assessments, audits, and other gap analysis periodically? Does your organization show trends of recording and using such results effectively? Yes/No/Partially

You can refer to Part 3 of this handbook to understand how answers to this gap analysis can help a Pharmaceutical and its associated Chemist and Druggist organizations design systematic programs for quality assurance and conformance, and thereon work as forward-thinking healthcare organizations.

Part 3 starts with information about the importance of Quality, SMART Convergence and self-assessment in healthcare. It also justifies the business need for Service Evaluation Review Techniques (SERT) and report generation.

Effectiveness in providing vital and much-in-demand medications & healthcare specific products

The ASSETs Tool will help a pharmaceutical network improve its presence, and contribute for disease mitigation and life saving in a country-wide scenario that could become agile for incidences of diseases, illnesses or emergencies.





Effectiveness / Assurance



The consultant K.S.Venkatram has a B.E. in Computer Engineering, and also holds MCP, MCAD and MCSD certifications. He has 20 years of experience in IT Service Management, manufacturing, healthcare etc