

# ISPE GAMP 5 SOFTWARE CATEGORIES HARDWARE SOFTWARE

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### **What are the gamp 5 categories?**

**What is ispe GAMP?** Good Automated Manufacturing Practice (GAMP®), is a technical sub-committee of the International Society for Pharmaceutical Engineering (ISPE). The goal of this committee is to promote the understanding of the regulation and use of automated systems within the pharmaceutical industry.

**What is the gamp 5 process?** Key Principles of GAMP 5 It encourages organizations to identify and assess potential risks associated with automated systems, allowing them to effectively allocate resources and prioritize validation activities. Lifecycle Approach: The framework promotes a lifecycle approach to system development and maintenance.

**Which GAMP category does infrastructure software fall under?** GAMP category 1: infrastructure Platforms on which computer applications or elements are necessary to operate and manage information technology environments run. Operating systems, firewall, antivirus.

**What GAMP category is excel?** Validation must comply with frameworks like GAMP, which categorizes spreadsheets based on their complexity. Excel spreadsheets are categorized between GAMP 3 and 5 for validation requirements. GAMP 3 requires less rigorous validation than GAMP 5, which involves complex features like macros and sophisticated formulas.

**What is GAMP software?** Good automated manufacturing practice (GAMP) is a set of guidelines for manufacturers and other automation users follow to maintain operational efficiency and reliability.

**What does ISPE stand for?** The International Society for Pharmaceutical Engineering (ISPE) is the world's largest not-for-profit association serving its members by leading scientific, technical and regulatory advancement throughout the entire pharmaceutical lifecycle.

**What are ISPE guidelines?** The ISPE Good Practice Guide: Membrane-Based Water for Injection Systems provides expert guidance on the design, operation, maintenance, and quality aspects of membrane-based WFI systems, including generation, storage, and distribution.

**What is the V model of ISPE?** Pharmaceutical Engineering (ISPE) Development models is the “V” Model, which is a framework or structure for undertaking the design, execution, commissioning and qualification of a design project.

**Is GAMP 5 mandatory?** Why is GAMP 5 important? GAMP is not mandatory, nor is it a legally binding framework, but it remains the industry standard for validating automated systems. Developers in regulated industries typically use GAMP 5 to go to market with greater efficiency and less risk.

**What is GAMP 5 in CSV?** Good Automated Manufacturing Practice (GAMP 5 ®) CSV Good Automated Manufacturing Practice (GAMP 5 ®) sets out principles and procedures that help ensure that pharmaceutical or medical device products have the required quality. GAMP 5 ® details a recognised standard for Computer System Validation (CSV).

**What is the latest ISPE version of the GAMP guideline?** In 2022, ISPE released a new, second edition of the GAMP 5 guide. Read more about this new edition here and/or watch our webinar on demand. GAMP 5, which stands for “Good Automated Manufacturing Processes”, is an approach that has been widely used in life science industries for validating computerized systems.

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procedures that help ensure that pharmaceutical or medical device products have the required quality. GAMP 5 ® details a recognised standard for Computer System Validation (CSV).

**Why is category 2 removed from GAMP 5?** Category 2 from GAMP 5 has been removed. This related to firmware. At the time that GAMP4 was issued firmware was considered to be used for simple instruments. However as technology has advanced it has been recognized that complex software can be embedded (firmware) within systems.

**What are the 4 phases of GAMP?** There are four life cycle phases of a computer system that are employed by GAMP 5: concept, project, operation and retirement.

**What is the difference between GAMP 4 and 5 with examples?** In GAMP 4, user requirements were considered as inputs to the validation process, and they had to be detailed, specific, and testable. In GAMP 5, user requirements are considered as outputs of the validation process, and they can be more general, high-level, and business-oriented.

**Can a damaged LCD TV screen be repaired?** Yes, you can repair your flat-screen television or fix the broken TV screen. TV repair professionals are trained to provide TV repair service for any type of television including LED, OLED, LCD, HDR, and HD.

**Are LCD TVs repairable?** Skilled technicians can diagnose and fix the issue, saving you money. LCD TV repair and services can extend the lifespan of your television set. Fixing minor issues promptly can prevent further damage and ensure your TV continues to function optimally. Repairing and servicing LCD TVs is an eco-friendly choice.

**Is it worth fixing an LCD TV screen?** Another factor to consider is the cost of repair. We recommend asking a TV technician to do a thorough assessment of your unit first. If the repair costs more than half the price of a new TV, then it's probably not worth it. However, if the repair is relatively inexpensive, then it might be worth doing.

**How to fix an LCD TV won't turn on?** Disconnect all external devices connected to the TV. Press and hold the power button on the TV body for about 30 to 45 seconds. After 1 minute, reconnect the device to the wall socket or mains. Then, switch it on with the power button (on the TV, not the remote control device)

**Is it worth fixing a broken LCD screen?** Generally, if the damage is minor, the repair is affordable and easy, and the display is still under warranty or insurance, you should repair it. However, if the damage is major, the repair is expensive and difficult, and the display is out of warranty or insurance, it may be best to replace it.

**How to fix a TV screen that went black?**

**How much is a LCD screen repair TV?**

**How to fix an LCD screen without replacing it?** If you're not ready to invest in a screen repair kit, there are also some DIY hacks you can try to fix your LCD screen. One of the most popular methods is to use toothpaste to fill in small cracks or scratches. Simply apply a small amount of toothpaste to the damaged area and then use a cloth to gently buff it out.

**What causes LCD TV screen damage?** Overheating Extreme temperatures can cause broken LCD screens. One example of this is when you place your TV in direct sunlight. It's also risky to place your TV directly under the aircon, where it can cause the screen to become brittle and develop cracks.

**Are plasma TVs worth fixing?** Plasma TVs are notoriously difficult to repair and are prone to developing multiple issues over time, so you might be better off putting that money towards a new TV that will last you another decade.

**Is it cheaper to buy a new TV or replace the screen?** Since screens are typically the most expensive TV part, your repair person might recommend that you replace the entire TV rather than repair it. "Although TVs repairs are possible, most repairs cost the same or more than a replacement TV," says Andy Kilborn, Expert Review Member and handyperson.

**Do I need to replace LCD or just screen?** The LCD is what lies beneath the glass and is similar to your LCD TV in your living room. Even if the picture looks perfect but

touch is intermitted or non responsive in some parts of the screen, the LCD would need to be replaced.

**What causes an LCD screen to stop working?** The primary cause is usually that the monitor is not receiving a video signal from the signal source (camera, computer, etc). The monitor will automatically enter sleep mode if it cannot detect a video signal.

**What does it mean when your TV won't turn on but the red light is on?** 2 If the red standby light comes on, then your TV has power from the working outlet. This means there is an issue with the original outlet, or the surge protector if you were using one. 3 If the TV still won't turn on and the red standby light is still blinking, this is a sign that something is wrong with your TV.

**Why is my TV turning on but no picture?** You may need to adjust settings like brightness, contrast, or resolution to restore picture visibility. If the menu does not show up on your screen, you may need to do a factory reset. To factory reset your TV when the screen is black, consult your television's user manual for specific instructions.

**Is it worth replacing the screen on a TV?** Often, the cost of repairing a screen is close to the value of the TV itself, making repairs outside of the warranty cost-prohibitive. In some cases, the screen can't be replaced, so you'll need a new TV anyway.

**Can broken LCD be fixed without replacing?** In short, it's impossible to fix your broken screen, and you can't replace the touch system if it's broken. Once you accidentally break your phone screen, you will need to replace the entire screen with an authorized repair center.

**Is LCD screen repairable?** LCD monitors have many complex components, so it's not unusual for them to encounter problems. Most issues short of serious physical damage can be repaired at home. Read the instructions carefully for your own safety, as some repairs may expose you to risk of serious electric shock.

**What to do if LCD screen is broken?** Contact an authorized service provider for an out-of-warranty repair. If your broken screen isn't covered by your warranty (or you

don't have one), the next best option is to have a certified professional repair your screen. Lots of providers even offer same-day service.

**What is the Engine Room Procedures Guide 2nd edition 2024?** The Engine Room Procedures Guide provides authoritative and comprehensive guidance on engine room procedures, to ensure that ships' engine rooms are operated and managed safely while protecting the environment.

**What are the safety procedures for the engine room?** Required engine room PPE, such as anti-slip safety shoes, helmets, puncture-proof gloves, protective eyewear, coveralls, and more. Emergency procedures outlining specific crew member's roles and responsibilities. Safe working loads and capacities for engine room lifts alongside other utilized machinery and equipment.

**What is an engine room checklist?** Inspect engine and look for drips, leaks, belt dust, or fuel (or oil) streaks on engine block. Check raw water strainer and seacock. Sea water pump (is it leaking through the weep hole?) Inspect bilge pump.

**What is the engine room procedure guide second edition?** The Engine Room Procedures Guide provides authoritative and comprehensive guidance on engine room procedures. It ensures that ships' engine rooms are operated and managed safely while protecting the environment.

**Who is responsible for engine room?** The engineering team is responsible for the operation and maintenance of the engine room on a ship. They are also responsible for the inspection, maintenance and repair of deck machinery such as winches and cranes.

**What are the procedures for watchkeeping the engine room?** Conduct Thorough Inspections: Perform complete inspections of the engine room, checking all machinery to identify any potential issues early. Respond to Alarms: Pay attention to alarm systems, distinguishing between faulty and genuine alarms. Report Issues Promptly: Never hide faults or mistakes.

**What is the most common risk in the engine room?** The primary dangers are related to heat and combustible substances. Fires and explosions are among the most common accidents in engine rooms. The volatile and toxic substances in the

engine room can also cause harm without proper ventilation. Workers can inhale these substances.

**What are the three biggest hazards when working with engines?** Working with vehicle engines can present a number of potential hazards, including contact with moving parts, electric shock, burns and carbon monoxide poisoning.

**What are the main machinery in the engine room?** Besides propulsion and auxiliary engines, a typical engine room contains many smaller engines, including generators, air compressors, feed pumps, and fuel pumps. Today, these machines are usually powered by small diesel engines or electric motors, but may also use low-pressure steam.

**What is the engine room slang?** On a boat or a ship, the engine room is the place where the engines are. If you refer to something as the engine room of an organization or institution, you mean it is the most important or influential part of that organization or institution. These firms are regarded as the engine room of the economy.

**Who works in an engine room?** Unlicensed Engine Room Personnel Ratings  
There are many varied roles in the engine room depending on ratings, which can include oiler, mechanical assistant (MA), junior engineer, fireman, deck engine mechanic, engineman, pumpman, electrician, machinist, conveyorman, and refrigerator engineer.

**How to prevent fire in engine room?**

**How do you check an engine room?** While not an exhaustive list, specific areas to check include: all fluid levels, crankcase oil, transmission fluid (some designs require it be running and warm to do this), coolant for all engines (check the recovery bottle every time, and under the pressure cap at least monthly), and hydraulic fluid; belt tension and ...

**What is engine room layout?** Engine Room Layout The propulsion engine with its auxiliary units (to support main machinery) are located in a space, called engine room. To operate and maintain the machinery at their peak performance and efficiency the lay out of engine room to be fully conversant for all marine engineers.

**What is engine room management?** Engine Room Management - is an approach to achieve a ship's safe navigation by appropriately managing the resources of personnel, equipment and information in the machinery space and by effectively utilizing them.

**Who take over control in the engine room?** diesel engine, is run on oil, and the engine-room department is composed of a team of engineer officers and ratings controlled by the chief engineer, who ranks after the master. staff. Every service on board has to come from the engine-room of a seagoing vessel: electric light, heat, running water and refrigeration.

**What is the highest position in seaman?** Captain. The captain or master is the ship's highest responsible officer, acting on behalf of the ship's owner.

**Who is the head of engine room?** A chief engineer, commonly referred to as "Chief" or "ChEng", is the most senior licensed mariner (engine officer) of an engine department on a ship, typically a merchant ship, and holds overall leadership and the responsibility of that department.

**What does stcw mean?** Standards of Training, Certification, and Watchkeeping (STCW)

**What are the four 4 duties of the watchkeeping officer?** The watchkeeping duties of the OOW include maintaining a lookout and general surveillance of the ship, collision avoidance in compliance with the COLREG, recording bridge activities and making periodic checks on the navigational equipment in use.

**What type of fire integrity must be provided for an engine control room?** A-0 Fire Certification: In the A-0 rating, "A" stands for the highest level of fire integrity, and "0" stands for the level of fire insulation. This certification is often required for critical areas like the engine room, control rooms, and other spaces where fire containment is vital.

**What is the most unsafe type of vehicle?** Based on the NHTSA's data, Value Penguin determined that the following are the most dangerous cars in America: Ford F-Series—fatal crashes: 10,845. Chevrolet Silverado—fatal crashes: 7,718. Honda Accord—fatal crashes: 5,079.



**What does ism stand for in the ISM code?** 1.1. 1 "International Safety Management (ISM) Code" means the International Management Code for the Safe Operation of Ships and for Pollution Prevention as adopted by the Assembly, as may be amended by the Organization. 1.1.

**Can you discharge the engine room bilges direct overboard?** If the ship is flooding and the water level in the engine room can not be controlled in any other way, the Captain and Chief Engineer can authorise the direct discharge of the ER Bilge Water overboard by any and all available means, this would not usually be agreed unless the Bilge level was threatening the stability ...

**What is the function of engine control room?** The Engine Control Room (ECR) on board a vessel is the heart of the engine department, where monitoring and operation of numerous systems takes place. It is a vital area for the operation of the vessel.

**How do you check an engine room?** While not an exhaustive list, specific areas to check include: all fluid levels, crankcase oil, transmission fluid (some designs require it be running and warm to do this), coolant for all engines (check the recovery bottle every time, and under the pressure cap at least monthly), and hydraulic fluid; belt tension and ...

**What is engine room management?** Engine Room Management - is an approach to achieve a ship's safe navigation by appropriately managing the resources of personnel, equipment and information in the machinery space and by effectively utilizing them.

**Who is responsible for searching the engine room?** The chief engineer of the ship is the head of the technical department of the ship. It is his duty to ensure that the engine room machinery works properly for a smooth voyage.

**What are the five machineries in the engine room?** To conclude the requirement of the engine room, it is considered to be a space or spaces containing propelling machinery, boilers, oil fuel units, generators, and major electrical machinery, and includes auxiliary machinery spaces, store rooms, workshops, machine shops, the shaft alley, and the steering gear room.

**What is the difference between an engine room and an engine control room?**

The ER is further equipped with auxiliary machinery to support the running of the main engine and a workshop for maintenance and repair work. The operation and monitoring of the equipment of the engine room are performed from the engine control room (ECR) placed in the vicinity of the ER.

**Who takes over the control in engine room?** diesel engine, is run on oil, and the engine-room department is composed of a team of engineer officers and ratings controlled by the chief engineer, who ranks after the master. staff. Every service on board has to come from the engine-room of a seagoing vessel: electric light, heat, running water and refrigeration.

**What is the most common risk in the engine room?** The primary dangers are related to heat and combustible substances. Fires and explosions are among the most common accidents in engine rooms. The volatile and toxic substances in the engine room can also cause harm without proper ventilation. Workers can inhale these substances.

**What are the equipment inside the engine control room?** Besides propulsion and auxiliary engines, a typical engine room contains many smaller engines, including generators, air compressors, feed pumps, and fuel pumps. Today, these machines are usually powered by small diesel engines or electric motors, but may also use low-pressure steam.

**What are the auxiliary machinery in the engine room?** - Engine room auxiliaries – All machinery in the engine room which assist in the working of the propulsion plant: coolers, heaters, pumps, separators, etc.

**What are the duties in engine room?** The engine department operates, maintains and repairs engines, boilers, pumps, generators, and other machinery and systems crucial to a vessel's operation. Personnel working in this department are divided into two categories: licensed and unlicensed personnel.

**What are the duties of the engine room rating?** Engine Room Ratings are responsible for maintaining shipboard machinery through routine oiling, greasing and servicing, stripping, repairing and fitting equipment parts and assisting engineering

officers monitor the smooth and safe running of the main plant (ship's engine) and other essential equipment.

**What is the basic operation of the engine management system?** The engine management system of a modern car is a microprocessor-based computer system that takes inputs such as engine speed, air temperature, throttle opening, and so on to control fuel injection and ignition timing.

**Who is the head of engine room?** A chief engineer, commonly referred to as "Chief" or "ChEng", is the most senior licensed mariner (engine officer) of an engine department on a ship, typically a merchant ship, and holds overall leadership and the responsibility of that department.

**Who is in charge of the engine room?** The Second Engineer is in charge of engine room machinery and personnel and assists the Chief Engineer in the maintenance of all machinery in the engine room and critical machinery on deck. He delegates various jobs to the Engineers and Engine Ratings and monitors their performance.

**What is the highest position in seaman?** Captain. The captain or master is the ship's highest responsible officer, acting on behalf of the ship's owner.

### **Schweser vs. Kaplan Study Packages: A Comprehensive Guide**

Choosing the right study package for the CFA exam can significantly impact your success. Two renowned providers, Schweser and Kaplan, offer extensive packages designed to cater to candidates' diverse needs. Here's a comprehensive guide to help you navigate the key differences between the Schweser and Kaplan study packages:

**1. Content Structure:** Both Schweser and Kaplan provide comprehensive coverage of the CFA exam curriculum. However, their content formats differ. Schweser's study notes are highly structured, with concise summaries, practice questions, and mock exams integrated into each chapter. Kaplan's notes are more narrative-driven, with detailed explanations and an emphasis on conceptual understanding.

**2. Practice Questions:** Practice questions are crucial for CFA exam preparation. Schweser offers a vast number of practice questions in their study notes and QBank.

These questions are highly focused on the exam blueprint and provide immediate feedback. Kaplan's practice questions in their Qbank are more varied and challenging, designed to test candidates' in-depth understanding of the material.

**3. Mock Exams:** Mock exams simulate the actual CFA exam experience and help candidates identify areas for improvement. Schweser provides six mock exams divided into two sections, each with 120 questions. Kaplan offers three mock exams that are longer and more comprehensive, covering all levels of the CFA exam.

**4. Online Access and Support:** Both Schweser and Kaplan offer online access to their study materials. Schweser's online platform provides interactive quizzes, flashcards, and study guides. Kaplan's online resources include videos, virtual classroom sessions, and access to expert instructors.

**5. Cost and Availability:** Schweser's study package is generally more affordable than Kaplan's. Schweser also offers a wider range of study materials, including bundled options for candidates preparing for multiple levels of the CFA exam. Kaplan provides additional support services, such as access to an online forum and personalized advising, at a higher cost.

**Conclusion:** The Schweser and Kaplan study packages each offer unique advantages. Schweser's structured content and extensive practice questions cater to candidates seeking a focused and efficient preparation approach. Kaplan's narrative-driven notes and challenging practice questions are ideal for candidates who prefer a comprehensive and conceptual understanding of the material. Ultimately, the best choice depends on your individual learning style and preferences.

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