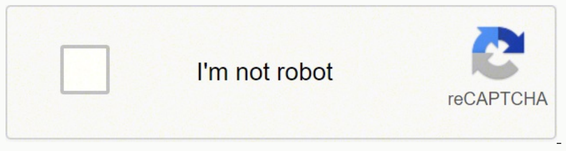

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GAMP® 5 in a nutshell In essence, GAMP represents a structured approach to validating computer systems in digital pharmaceutical products. To create a computer-based system that serves its purpose in a reliable, transparent, and most importantly safe way, companies developing pharmaceutical products need to meet various predefined requirements. International Society for Pharmaceutical Engineering (ISPE) sets the guidelines for manufacturers and the current Version is GAMP 5.GAMP describes a set of principles and procedures that help ensure that pharmaceutical Software (Like QMS Software, LMS software, DMS software etc.) has required quality.Computer system validation (CSV) following GAMP guidelines require users and suppliers to work together so that responsibilities regarding the validation process are understood.For users: GAMP provides a documented assurance that a system is appropriate for the intended use before it goes “live.”Suppliers can use GAMP to test for avoidable defects in the supplied system to ensure quality products are produced.Facilitates the interpretation of regulatory requirements.Establishes a common language and terminology.Promotes a system life cycle approach based on good practice.Clarifies roles and responsibilities.Focus attention on those computerized systems with the most impact on patient safety, product quality, and data integrityAvoid duplication of activitiesProduct and Process UnderstandingLifecycle approach within QMSScalable Lifecycle ActivitiesScience Based Quality Risk ManagementLeveraging Supplier InvolvementNote: Category 2 is discontinuedConfiguration and customization of software are terms that are poorly defined in the validation world and frequently used interchangeably, especially in a vendor’s marketing literature.It is important to understand the difference between these two terms as they mean entirely different things and consequently can have a dramatic impact on the amount of validation work that you could undertake.Configuration: The modification of the function of a software product to meet the business process or user requirements using tools supplied by the supplier. GAMP® 5 also struggles to establish clear procedural controls. For the first time, they are delivering a pharma software solution. These best practices are respected and used by regulated companies and their suppliers all over the world. Related reading: Making the Case for ALM in Pharma Project Management Who does it apply to? Then, rather than a “one size fits all approach”, GAMP® 5 standards recommend different lifecycles depending on the category of software the product falls into: This refers to the operating system where the application software resides. (Examples: commercial off the shelf software, lab instruments, Programmable Logic controllers) Here the guideline describes software applications which are configured to meet user-specific business needs, which is the broadest and most complicated category of the four. (Examples: operating systems, databases, programming languages) This category includes software which can meet the requirements of the business process without modification, or is ‘used as installed’, as well as configurable software that is used but only with its default settings. Although it provides guidelines and information on validating automated systems, it does not propose a concrete procedure for checking that those processes are in fact in place. Change management and control are also somewhat lacking in this guideline, which means that new modifications along the way can put system validation at risk. This has a chain reaction effect and influences how much validation work companies put into it. Testing leads to (ideally) Internal Acceptance, Factory Acceptance, and Site Acceptance. The five main principles of GAMP® 5’s risk-based approach to compliance are as follows: To have a clear understanding of product and process To manage the system lifecycle using a quality management system To make these lifecycle activities scalable To verify that the approach to risk management is science-based To leverage supplier involvement throughout the system If pharmaceutical companies take these guidelines on board carefully and apply them, their products will be up to standards and they can avoid running into any complications in testing and auditing. Not to mention that it aligns with both US and EU regulations which govern computer system validation, 21 CFR Part 11 and Annex 11 respectively, as well as various other international standards. By adhering to this guideline, you can significantly reduce risk when developing your product, confidently expand to new markets, and guarantee that your products are safe and fit for use. First it outlines commonly used terminologies so that everyone can align on the production approach it suggests depending on the category of product. GAMP® 5 is the latest standard of the guideline; it was released in February 2008 by the International Society for Pharmaceutical Engineering, also known as ISPE. It is important to note that rather than being a regulation, GAMP® 5 is a set of principles and procedures created to help validate automated computer systems for manufactured pharmaceutical products. For manufacturers, GAMP® 5 guides them to ensure their products meet necessary standards according to a risk-based approach to compliance. Intland’s Pharma GAMP® 5 Template was developed in collaboration with pharmaceutical automation experts and is designed to help pharma companies, suppliers, and system integrators achieve compliance smoothly and easily. It begins with a User Requirements Specification, which leads to a Functional Requirement and a Design Specification. In other words, this guideline helps manufacturers meet regulations they must comply with to go to market. The challenges Computer software validation in regulated industries can be tricky, and GAMP® 5 validation is no exception. Using a risk-based approach will also encourage you to plan and execute testing logically, focusing on areas of high risk and avoiding duplicate activities. A detailed overview of Good Automated Manufacturing Practice guidelines (GAMP® 5). In other words, companies should not rely solely on checking off a ‘GAMP® 5 checklist’ as it were, but should rather establish a more thorough validation process which this standard forms a crucial part of. Using a quality management system with a predefined template is the first step to expediting the validation process and making going to market a thorough and rewarding process. Read on to learn more about who it applies to, its contents, requirements, and systems validation according to GAMP® 5! Computer-based systems validation in regulated industries is no walk in the park. GAMP — or the Good Automated Manufacturing Practice — is the definitive industry guideline for creating compliant computer systems. (Examples: LIMS, SCADA, DCS, etc.) The last category includes software that is created to meet a bespoke business need. These tools can include the input of user-defined text strings for drop-down menus, turning software functions on or off, graphical dragging and dropping of information elements, and creation of specific reports using the standard functionality of the package.Customization: The writing of software modules, scripts, procedures, or applications to meet business requirements. That’s where GAMP comes in. In practice, this means that these recommendations apply both to the users of automated pharmaceutical products, as well as the manufacturers who create and market them. For users, the guideline outlines the principles that they should be aware of which assure computerized pharmaceutical products are appropriate for their intended purpose. Created in 1991 by pharmaceutical professionals, it was specifically designed to address industry needs and meet the evolving expectations of the FDA and regulatory bodies in Europe for computer system compliance and validation. The latter two elements form the foundation of a traceability matrix which creates a basis for formal testing. The software categories are broad and open to interpretation, and there is often ambiguity about where a certain software application falls. GAMP 5 Categories, V Model and 21 CFR Part 11, EU Annex 11Good Automated Manufacturing Practice, Founded in 1991. It then establishes a system lifecycle approach which covers good practices for the whole production process. Helpful resource: Experts Talk: Using Pharmaceutical ALM for GAMP® 5 Compliance Let’s talk software categories Software categories are key to supporting the approach according to GAMP® 5 validation. When the customer team comes for an audit what software development methodologies they need to demonstrate to win the auditor.Whenever there is an audit of the customer need to explain the detailed procedure followed to develop software right from the beginning of User requirement gathering to the maintenance and support.Even if the company does not know the standard guidelines, we can map the existing followed procedure with the guidelines and standards to comply with client requirements.The company which comes to audit have a set of guidelines or criteria which the supplier should comply to pass the audit.The pharma companies investigate whether the software follows GAMP, or Part 11 or EU annexure 11.To win the auditor the company must have followed an SDLC Methodology with Proper Reviews and Tracking.A software company doesn’t want to follow the V model, still wanted to deliver pharma software (Quality Management Software, Document Management System, ANDA and DMF tracker etc.). It aims to clarify the requirements you must meet, establish a common language as well as clear roles and responsibilities for all involved, and promote processes based on industry best practices. GAMP® 5 aims to provide a comprehensive explanation of how pharmaceutical companies should validate their computer systems. This is possibly the riskiest category, since it is often developed in-house from scratch and then customized, meaning a higher level of risk in the code. A closer look at the contents of GAMP® 5 As a whole, the guideline provides an interpretation of regulatory requirements in the field of pharma manufacturing, specifically, about computerized pharmaceutical production systems. Will this be acceptable to Pharma Company?Acceptable if Software Company follows standard SDLC models and follows the Standards for developing and managing the code.For further queries, and suggestions reach out to info@amplelogic.com or contact us The guide also outlines a formal process of documentation, testing, and procedure that validate the necessary specifications for the product. Advantages of GAMP® 5 computer system validation At first, it may seem like just another standard to adhere to (understandably) – but GAMP® 5 is here to make your life easier in the long run. This can be achieved using an external programming language (such as C++ or .NET or PL*SQL for database procedures), macro instructions, or an internal scripting language specific for a commercial application.Depending on the user requirements the same implementation can be Category 4 or 5What is SDLC Model? What model GAMP 5 Suggests?The software development life cycle (SDLC) is a framework defining tasks performed at each step in the software development process.SDLC is a structure followed by a development team within the software organization.It consists of a detailed plan describing how to develop, maintain and replace specific software.The life cycle defines a methodology to deliver the quality of software and the overall development process.21 CFR (Code of Federal Regulations) Part 11 has defined by the US FDA regulations that set forth the criteria applies to electronic records and electronic signatures that persons create, modify, maintain, archive, retrieve, or transmit under any records or signature requirement set forth in the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or any FDA regulationAnnex 11 is part of the European GMP Guidelines and defines the terms of reference for computerized systems software used by organizations in the pharmaceutical industry.Any relation between GAMP 5 or v Model with 21 CFR Part 11?Both are the set of guidelines which are used to validate a computer-based software used in pharma manufacturing companies.The guidelines are predefined, and software should comply with the guidelines.GAMP talks about “the How” and the 21 CFR talks “the What” during the Validation of computer-based software for Pharma companies.GAMP is a methodology and 21 CFR are a regulation21 CFR Part 11 is US FDA and Annex 11 is EU guidelines.A Company is delivering software to the banking sector they never heard of part 11 but when the Pharma customer wants them to map Part 11 requirements will the solution comply with them?Even if a company is delivering software to the banking sector, the solution will generally comply with part 11 requirements.In banking software’s there may not be the reference of Part 11, but the requirements of Part 11 will be met by the banking software’sA software company is following SDLC models from the past 8 years. To kick things off, systems are first evaluated and categorized by predefined labels depending on what the manufacturers intend to use it for and how complex the system is.

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