GAMP 5 and the Supplier

Leveraging supplier advantage out of compliance

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GAMP 5 and the supplier

Overview

- This document is designed to assist suppliers who wish to sell computer based equipment into the highly regulated pharmaceutical environment. It describes the details of validation for those who are new to the subject and describes the development of a suitable documentation set that we refer to as the pre-validation documentation set.

- This pre-validation documentation set should be supplied to the pharmaceutical company along with or shortly after the equipment, this way the company can begin the validation immediately. Part of the pre-validation set can also be offered at product release, as the product release documentation set

- Remember that the validation process must occur before the end customer can product drug; therefore the pre-validation documentation set is as important to the end customer as the equipment itself.

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Overview

- A salesman is often reluctant to bring up the subject of validation!
- So in many cases I have observed this issue does not arise until the equipment is actually due for delivery and then the arguments can begin over increasing costs and slipping schedules
- This can be avoided if the subject is broached at an initial sales project meeting with the customer or OEM representative. They may not know the details of the requirements but they will contact the relevant person within the end company and that will begin the process

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Overview

- The supplier has an important role in providing equipment that can be validated. If the customer cannot validate the equipment it is of no use to them. More than this, the equipment should be easy to validate and have the documentation to support this operation

- Different pharmaceutical companies have different ways of validating equipment, so this sounds like the supplier has a difficult or impossible job in supplying documentation.

- This is just not the case. Once the rules are understood then the supplier can be of help to all customers and everyone will be satisfied

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Overview

- Also – do not be afraid of telling the end customer or OEM the validation costs. It would cost the pharmaceutical company far more to have a validation consultant, who is not familiar with the equipment, perform this work. By leveraging know-how the pharmaceutical company helps itself
- So it is more cost effective for the supplier to make the pre-validation pack than anyone else and this can be used this as a sales tool
- Remember that the support can be just the documentation set, or providing assistance with the testing
- I emphasise assistance because the supplier is not responsible for the testing, the end customer is and it is he who will report in any regulatory audit, not the equipment supplier

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Overview

- GAMP guidance aims to achieve computerised systems that are fit for intended use and meet current regulatory requirements, by building upon existing industry good practice in an efficient and effective manner

- It is not a prescriptive method or a standard, but rather provides pragmatic guidance, approaches and tools for the practitioner

- When applied with expertise and good judgment, this guide offers a robust, cost effective approach

– Introduction to GAMP 5 guide

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Overview

GAMP 5 is an accepted source of guidance for regulators and practitioners worldwide:

- ICH Guidance Q8, Q9 and the forthcoming Q10
- FDA Good management practices
- PIC/S guidance on good practices for computerised systems
- ASTM E55 committee on drug development and manufacture

Therefore manufacturing companies worldwide have accepted GAMP methodology and used it in their policies

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Key Concepts

- Product and process understanding
- Life cycle approach within a QMS
- Scalable life cycle activities
- Science based quality risk management
- Leveraging supplier involvement

– GAMP 5 guide

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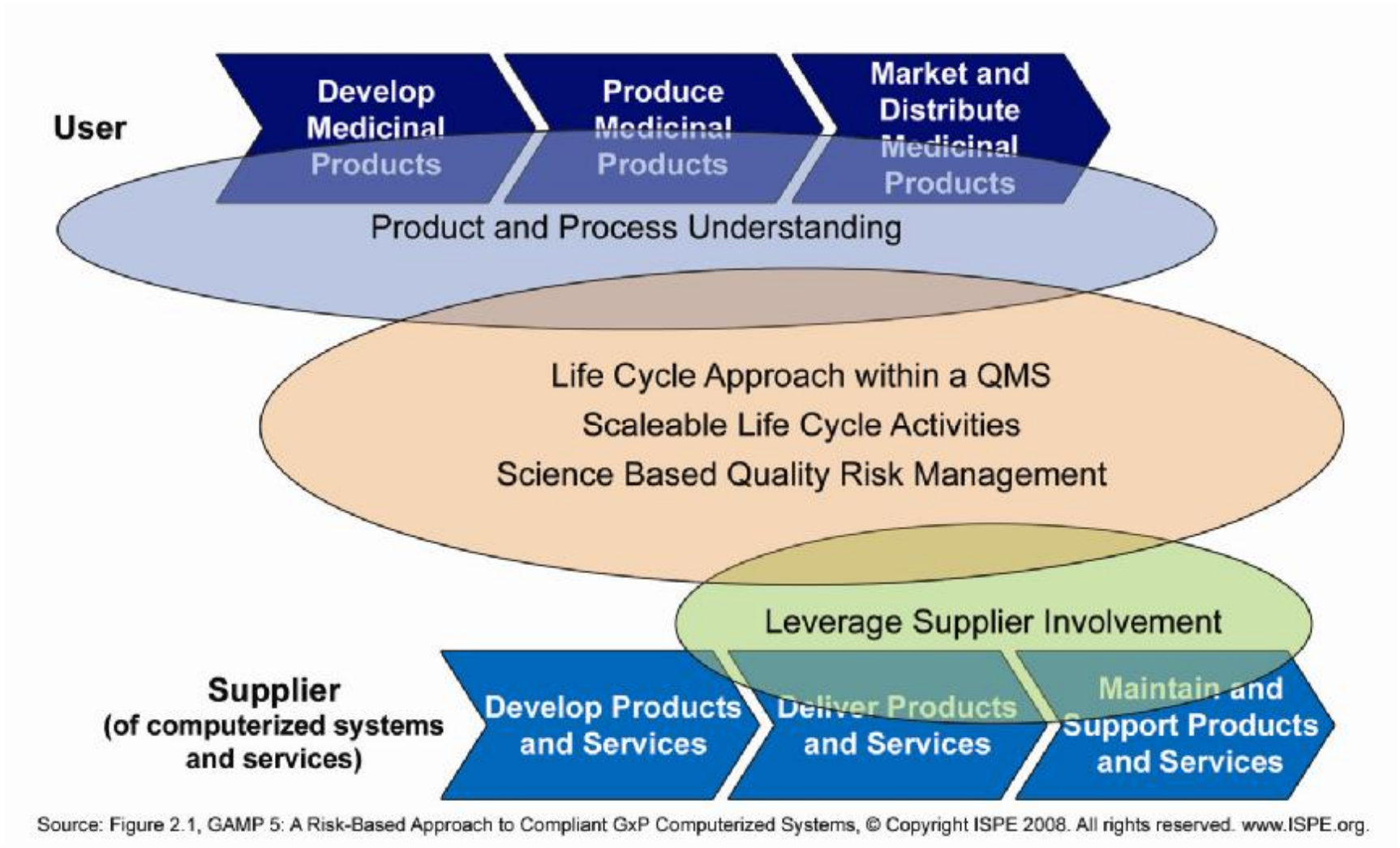

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Key Concepts

- Regulated Pharmaceutical companies should seek to maximise supplier involvement throughout the system life cycle in order to leverage knowledge, experience and documentation, subject to a satisfactory supplier assessment

- The supplier may assist with requirement gathering (URS), risk assessment, the creation of functional and other specifications (FS), system configuration (IQ), testing (OQ), support and maintenance

– GAMP 5 guide

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Key Concepts

- Justification for the use of supplier documentation should be provided by the satisfactory outcome of supplier assessments, which may include supplier audits

- Documentation should be assessed for suitability, accuracy and completeness. There should be flexibility regarding acceptable format, structure and documentation practices

– GAMP 5 guide

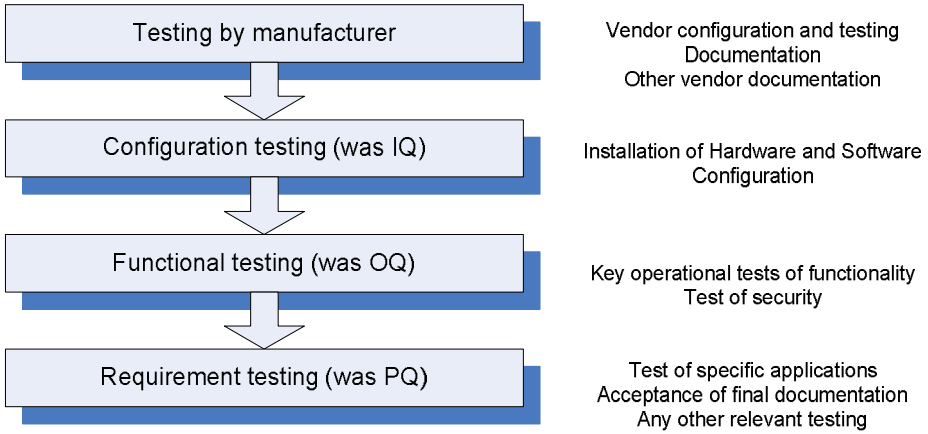
Packaging Lines – Control and Validation

- The more that standard software is used and the less customisation made for such software the less testing is required by individual users. GAMP has developed software categories based on the level of customisation. In total there are four categories defined in GAMP 5. We are usually concerned with category 4

Category	Description
3	Standard software package. No customization. Examples: MS Word (without VBA scripts). Computer controlled spectrophotometers. Temperature and Humidity controllers. Older barcode readers.
4	Standard software package. Customization of configuration. Examples: LIMS, Excel spreadsheet application where formulae and/or input data are linked to specific cells. Networked data systems. PC Based Machine Control systems. Machine vision systems.
5	Custom software package. Either all software or a part or the complete package has been developed for a specific user and application. Examples: Add-ons to GAMP Categories 3 and 4, Excel® with VBA scripts. Dedicated and unique Machine control system using Industrial PC hardware. Vision systems having PLC functionality.

Packaging Lines – Control and Validation

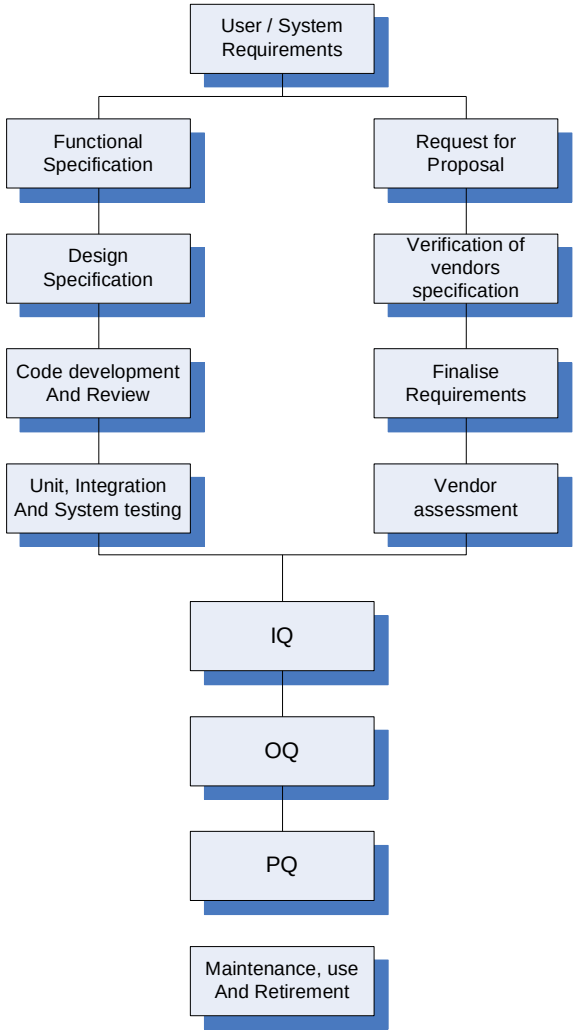
- A GAMP 5 level 4 category system, where the system is a standard Hardware and Software product that is in serial production and only configuration is needed to make it operational
- Phases like design specification or code development and code testing are not necessary provided that adequate design and testing documentation exists for the system



Packaging Lines – Control and Validation

- The 4 Step model is not suitable when systems need to be programmed for specific applications or when additional software is required that is not included in the standard product and is developed by the user's firm or by a 3rd party

- This means that the system immediately moves into a GAMP 5 level 5 category system. In this case a life cycle model that combines system development and system integration is preferred



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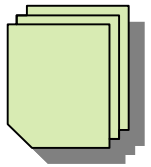
So what can a company supply as a package to the end customer or OEM? to support GAMP 5 level 4, configurable computer systems?

- Dedicated FS and IOQ documentation set. The type of system supplied decides how generic or dedicated this documentation set must be



- Please note that the FS this is the application FS

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- QMS system overview
- Specifications for the design - equipment design FS or minimum installation documentation
- Design review details. Sometimes called a Design Qualification (DQ)
- Software configuration
- Testing of the system – or reference that documentation can be viewed

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- User documentation
- Training details
- CE marking documentation
- System support - details of the your system of software release documentation - defining fixes, changes and new features. Any system for customer notification of problems
- Reference to results of an audit, including source code review, made by an independent and qualified auditor on your company and its major sub-suppliers

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Recommended documentation set:

- Computer system validation - GAMP 5 level 4 definitions – © PPtech
- Supplier system validation – © PPtech
- Company Audits – © PPTech
- GAMP 5 Guide – Available from ISPE

Thank you for your attention.

Find us and your documentation at:

www.pptech.eu