Disclaimer

- This presentation is made at the request of ASQ.

- The presenter is a full-time employee and stockholder of Allergan, Inc.

- The information provided and opinions expressed during this presentation are those of the presenter and are not the position of and may not be attributed to Allergan, Inc.
Agenda

- Overview
- Life Cycle Approach
- Life Cycle Phases
- Concept
- Project
- Software Category and Life Cycle Approach
GAMP Document Structure

GAMP 5 Guide
Principles and Framework

Appendices
Management Development Operation
Special Interest General

Good Practice Guides
Laboratory Global Information Systems Process Controls
Infrastructure Calibration Management Testing
Electronic Data Archiving Electronic Records and Signatures

Other Information
Papers and Articles Templates and Examples Training Materials
Drivers for GAMP 5

Focus on Patient Safety, Product Quality, and Data Integrity

Life Cycle Approach within QMS

Effective Governance to Achieve and Maintain GxP Compliance

Science Based Quality Management of Risks

Quality by Design (QbD)

Scaleable Approach to GxP Compliance

Continuous Improvement within QMS

Effective Supplier Relationships

Critical Quality Attributes (CQA)

Use of Existing Documentation and Knowledge

Improving GxP Compliance Efficiency

Configurable Systems and Development Models
Purpose

- Computerized systems are fit for intended use
- Compliant with applicable regulations
  - Good Manufacturing Practice (GMP)
  - Good Clinical Practice (GCP)
  - Good Laboratory Practice (GLP)
  - Good Distribution Practice (GDP)
  - Medical Device Regulations (excluding medical device software)
- Provide framework which aims to safeguard patient safety, product quality, and data integrity, while also delivering business benefit
- Framework aims to safeguard patient safety, product quality, and data integrity, while also delivering business benefit
Main Body Structure

- Life cycle approach within a Quality Management System
- Life cycle phases:
  - Concept
  - Project
    - Planning
    - Specification, Configuration, and Coding
    - Verification
    - Reporting and Release
  - Operation
  - Retirement
- Science based quality risk management
- Regulated company activities:
  - Governance for achieving compliance
  - System specific activities
- Supplier activities
- Efficiency improvements
Key Concepts

User

Develop Medicinal Products

Produce Medicinal Products

Market and Distribute Medicinal Products

Product and Process Understanding

Life Cycle Approach within a QMS
Scaleable Life Cycle Activities
Science Based Quality Risk Management

Leverage Supplier Involvement

Supplier
(of computerized systems and services)

Develop Products and Services
Deliver Products and Services
Maintain and Support Products and Services
Computerized System

Computerised System

Operating Environment
(including other networked, or standalone computerised systems, other systems, media, people, equipment and procedures)

Software

Hardware

Operating Procedures and People

Equipment

Controlled Function or Process

Computer System (Controlling System)
Typical Computerized Systems

- Clinical Trials Data Management
- Manufacturing Resource Planning
- Laboratory Information Management
- Automated Manufacturing Equipment
- Automated Laboratory Equipment
- Process Control and Process Analysis
- Manufacturing Execution
- Building Management
- Warehousing and Distribution
- Blood Processing Management
- Adverse Event Reporting (vigilance)
- Document Management
- Track and Trace
Life Cycle Approach

Good Engineering Practice

- Requirements
- Specification and Design
- Verification
- Acceptance and Release

Operation and Continuous Improvement

Risk Management

Design Review

Change Management

Life Cycle Phases

PHASE
- Concept
- Project
- Operation
- Retirement

Potential Migration
- Requirements
- GxP Assessment
- Changes
- Retirement

Potential Retention, Migration, Destruction
Concept Phase

- Strategic Planning
- Need Identification
- Business Justification
- Compliance Justification
- Migration Need
- Technical Feasibility
- Management Commitment
- User Requirement Initiation
- Project Initiation
Project Phase - Stages

- Planning
- Specification, Configuration, Coding
- Verification
- Reporting and Release

Supporting Processes
- Risk Management
- Change & Configuration Management
- Design Reviews
- Document Control
- Traceability
Operation Phase - Stages

- Planning
- Specification
- Configuration and/or Coding
- Verification
- Reporting

Project Stages:
- Potential Retention
- Migration
- Destruction
- Retirement

Supporting Processes:
- Risk Management
- Design Review
- Change and Configuration Management
- Traceability
- Document Management

Concept
- Supplier Involvement

Project

Operation

Retirement
Planning Stage

- A clear and complete understanding of User Requirements is needed
- Planning should cover all required activities, responsibilities, procedures, and timelines
- Activities should be scaled according to:
  - system impact on patient safety, product quality, and data integrity (risk assessment)
  - system complexity and novelty (architecture and categorization of system components)
  - outcome of supplier assessment (supplier capability)
- The approach should be based on product and process understanding, and relevant regulatory requirements
The role of specifications is to enable systems to be developed, verified, and maintained based on the user’s requirements and risk profile.

Any required configuration should be performed in accordance with a controlled and repeatable process.

Any required software coding should be performed in accordance with defined standards.

Configuration management is an intrinsic and vital aspect of controlled configuration and coding.
Verification Stage

- Verification confirms that specifications have been met
- Verification activities occur throughout the project stages
  - Design Reviews
  - Testing
- An appropriate test strategy should be developed based on the risk, complexity, and novelty.
- Supplier documentation should be assessed and used if suitable.
- The test strategy should be reviewed and approved by appropriate SMEs
- Tests should cover hardware, software, configuration, and acceptance
Reporting and Release Stage

- At the conclusion of the project, a computerized system validation report should be produced summarizing the activities performed, any deviations from the plan, any outstanding and corrective actions, and providing a statement of fitness for intended use of the system.
- The system should be accepted for use in the operating environment and released into that environment in accordance with a controlled and documented process.
- Acceptance and release of the system for use in GxP regulated activities should require the approval of the process owner, system owner, and quality unit representatives.
- Well managed system handover from the project team to the process owner, system owner, and operational users is a pre-requisite for effectively maintaining compliance of the system during operation.
Supporting Processes

- Risk Management
- Change and Configuration Management
- Design Review
- Traceability
- Document Management
Software Categories

- Category 1 – Infrastructure Software
  - Established or commercially available layered software
  - Infrastructure software tools

- Category 3 – Non-Configured Products
  - Commercial-Off-The-Shelf (COTS) system that cannot be configured to conform to business processes or are configurable but only the default configuration is used.

- Category 4 – Configured Products
  - Products provide standard interfaces and functions that enable configuration of user specific business processes.

- Category 5 – Custom Applications
  - These systems or subsystems are developed to meet the specific needs of the regulated company
## Typical Life Cycle Approach – Category 1

<table>
<thead>
<tr>
<th>Description</th>
<th>Typical Examples</th>
<th>Typical Approach</th>
</tr>
</thead>
<tbody>
<tr>
<td>Layered Software</td>
<td>• Operating Systems</td>
<td>Record version number, verify correct installation by following approved</td>
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<tr>
<td></td>
<td>• Database Engines</td>
<td>installation procedures</td>
</tr>
<tr>
<td></td>
<td>• Middleware</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Programming Languages</td>
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<tr>
<td></td>
<td>• Statistical Packages</td>
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<tr>
<td></td>
<td>• Spreadsheet Application</td>
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</tr>
<tr>
<td></td>
<td>• Network Monitoring Tools</td>
<td></td>
</tr>
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<td></td>
<td>• Scheduling Tools</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Version Control Tools</td>
<td></td>
</tr>
<tr>
<td>Software used to manage the operating environment</td>
<td>• Version Control Tools</td>
<td></td>
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</tbody>
</table>
### Typical Life Cycle Approach – Category 3

<table>
<thead>
<tr>
<th>Description</th>
<th>Typical Examples</th>
<th>Typical Approach</th>
</tr>
</thead>
<tbody>
<tr>
<td>Run-time parameters may be entered and stored, but the software cannot be</td>
<td>• Firmware-base Apps</td>
<td>• Abbreviated life cycle approach.</td>
</tr>
<tr>
<td>configured to suit the business process.</td>
<td>• COTS Software</td>
<td>• URS.</td>
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<td></td>
<td>• Instruments</td>
<td>• Risk-based approach to supplier assessment.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Record version number, verify correct installation.</td>
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<tr>
<td></td>
<td></td>
<td>• Risk-based tests against requirements as dictated by use.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Procedures in place for maintaining compliance and fitness for intended use.</td>
</tr>
</tbody>
</table>

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Typical Life Cycle Approach – Category 3
## Typical Life Cycle Approach – Category 4

<table>
<thead>
<tr>
<th>Description</th>
<th>Typical Examples</th>
<th>Typical Approach</th>
</tr>
</thead>
<tbody>
<tr>
<td>Software, often very complex, that can be configured by the user to meet the specific needs of the user’s business process. Software code is not altered.</td>
<td>• LIMS • Data acquisition systems • SCADA • ERP • MRPII • Clinical Trial monitoring • DCS • ADR Reporting • EDMS • BMS • CRM • Spreadsheets • Simple HMIs</td>
<td>• Life cycle approach. • Risk-based approach to supplier assessment. • Demonstrate supplier has adequate QMS • Some life cycle documentation retained only by supplier (e.g., Design Spec) • Record version number, verify correct installation. • Risk-based testing to demonstrate application works as designed in a test environment • Risk-based testing to demonstrate application works as designed within the business process • Procedures in place for maintaining compliance and fitness for intended use • Procedures in place for managing data</td>
</tr>
</tbody>
</table>
Typical Life Cycle Approach – Category 4
## Typical Life Cycle Approach – Category 5

<table>
<thead>
<tr>
<th>Description</th>
<th>Typical Examples</th>
<th>Typical Approach</th>
</tr>
</thead>
<tbody>
<tr>
<td>Software custom designed and coded to suit the business process.</td>
<td>Varies, but includes:</td>
<td>Same as for configurable, plus:</td>
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<tr>
<td></td>
<td>• Internally and externally developed IT applications</td>
<td>• More rigorous supplier assessment, with possible supplier audit</td>
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<tr>
<td></td>
<td>• Internally and externally developed process control applications</td>
<td>• Possession of full life cycle documentation (FS, DS, structural testing, etc.)</td>
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<tr>
<td></td>
<td>• Custom ladder logic</td>
<td>• Design and source code review</td>
</tr>
<tr>
<td></td>
<td>• Custom firmware</td>
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<tr>
<td></td>
<td>• Spreadsheets (macro)</td>
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</table>
Typical Life Cycle Approach – Category 5
Questions?

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