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GAMP 5
A Risk-Based Approach to Compliant GxP Computerized Systems

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10 September 2013

ASQ – Orange Section Meeting – Part 1

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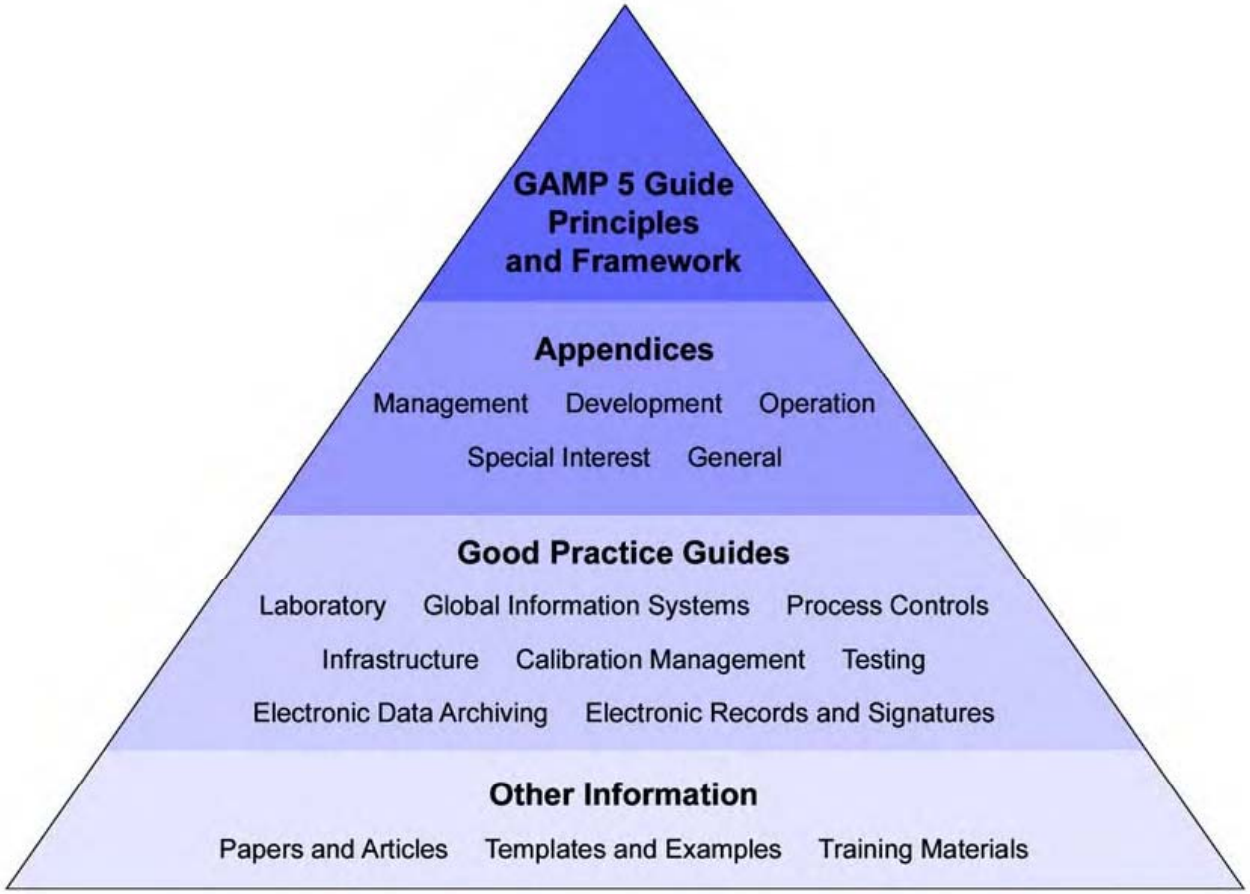
Agenda

- Overview
- Life Cycle Approach
- Life Cycle Phases
- Concept
- Project
- Software Category and Life Cycle Approach

GAMP Document Structure



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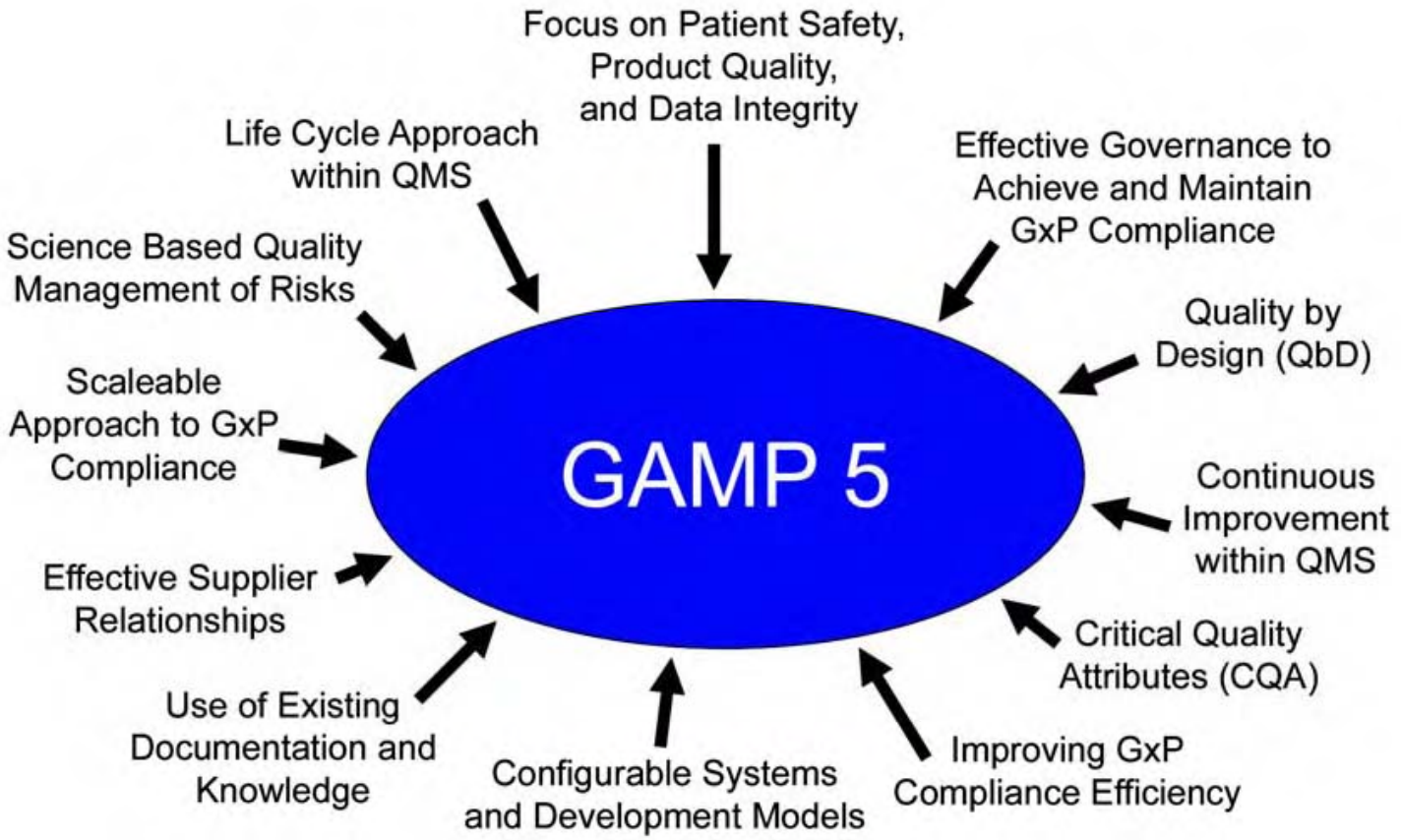
Drivers for GAMP 5



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

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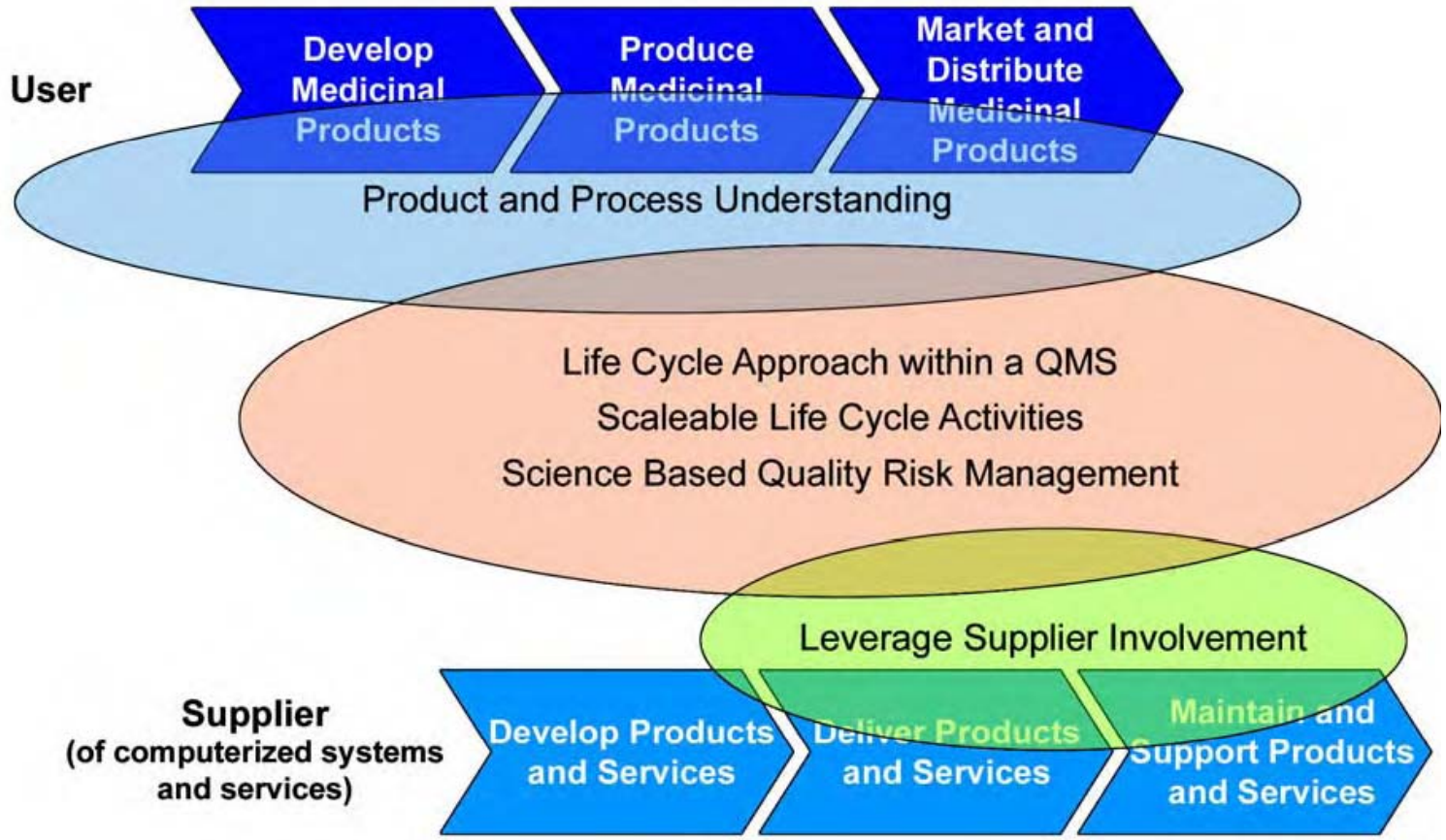
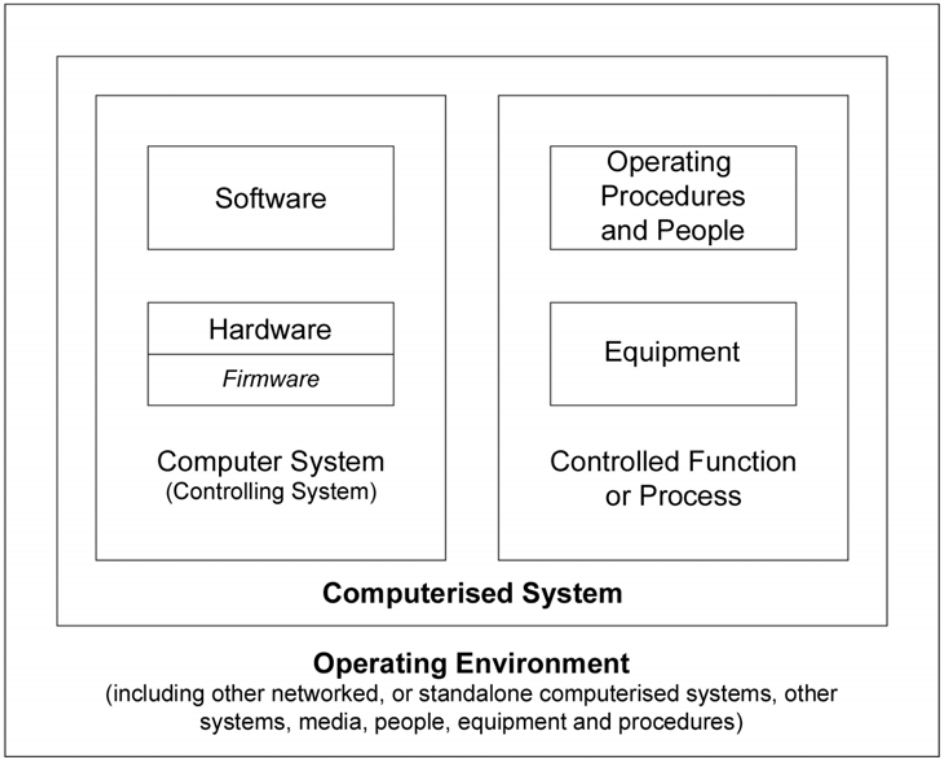
Key Concepts



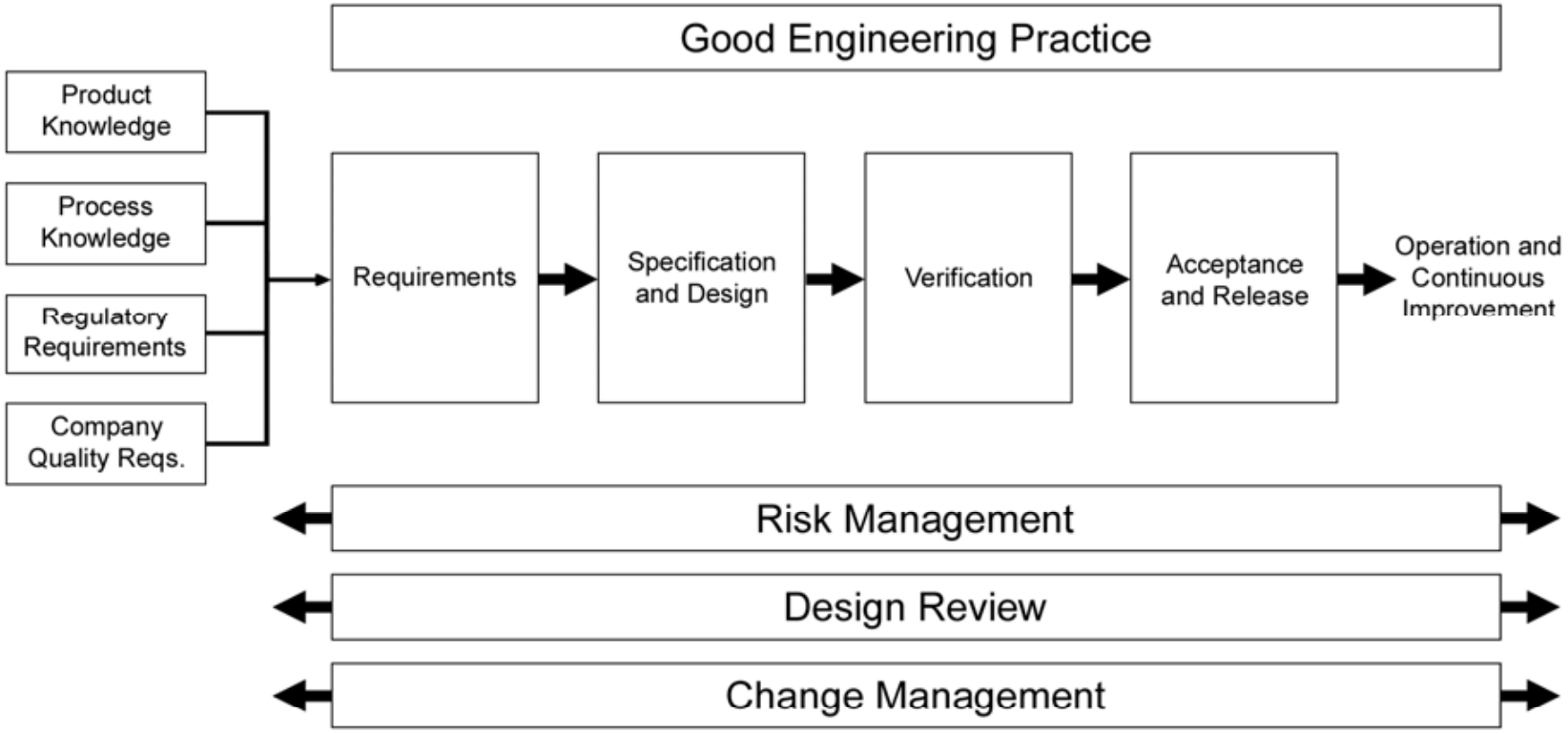
Computerized System



Typical Computerized Systems

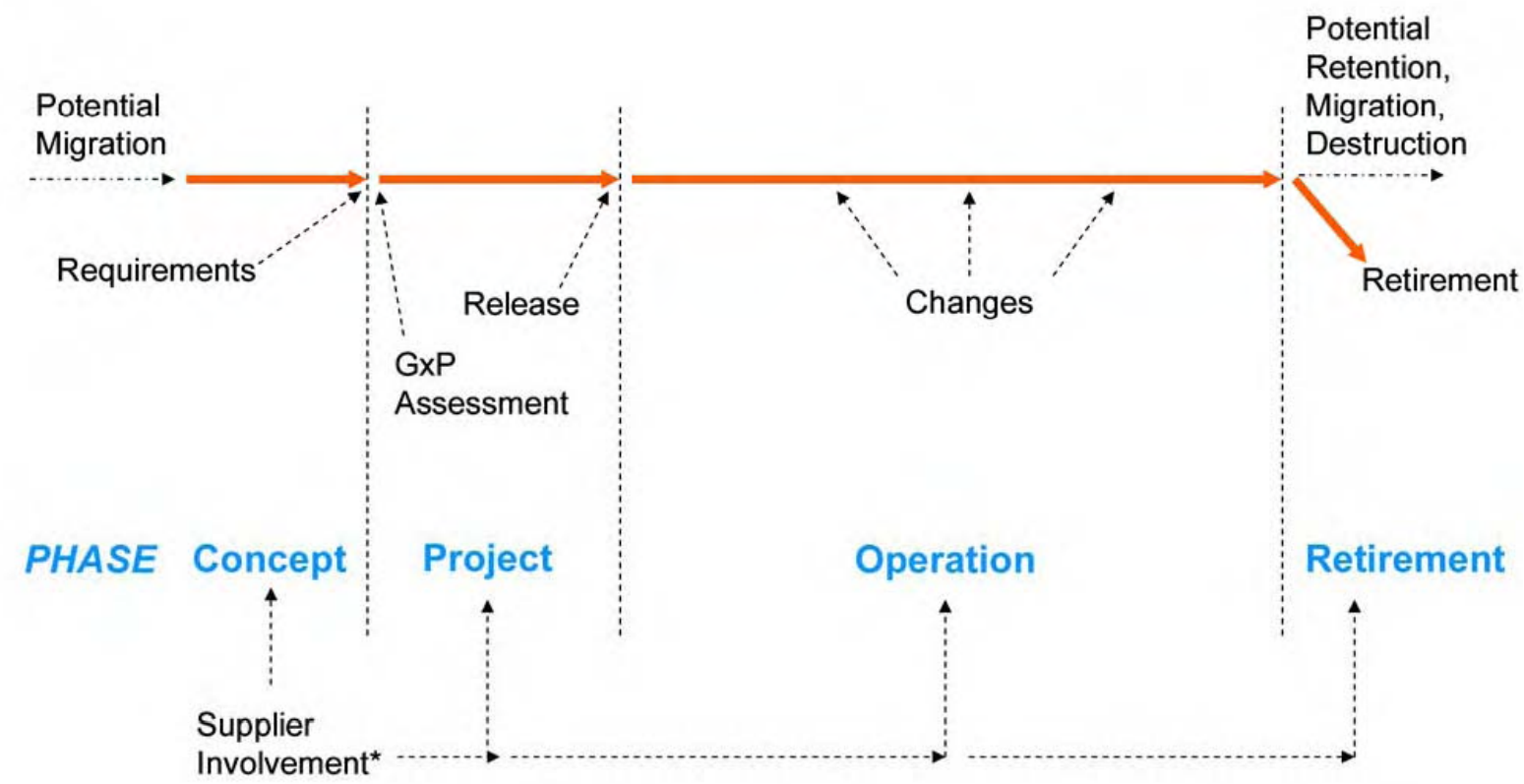
- Clinical Trials Data Management
- Manufacturing Resource Planning
- Laboratory Information Management
- Automated Manufacturing Equipment
- Automated Laboratory Equipment
- Process Control and Process Analysis
- Manufacturing Execution
- Building Management
- Warehousing and Distribution
- Blood Processing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

Life Cycle Approach



ASTM E2500-07 Standard Guide for Specification, Design, and Verification of Pharmaceutical and Biopharmaceutical Manufacturing Systems and Equipment,

Life Cycle Phases

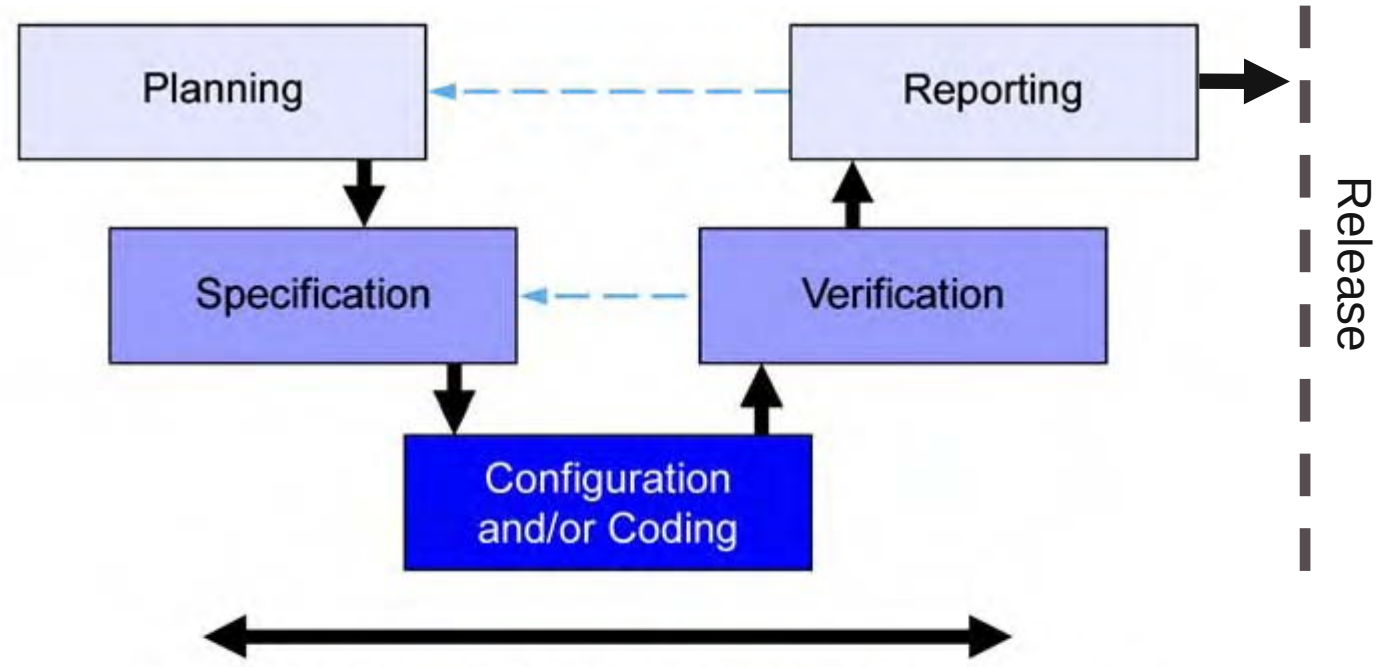


Concept Phase

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

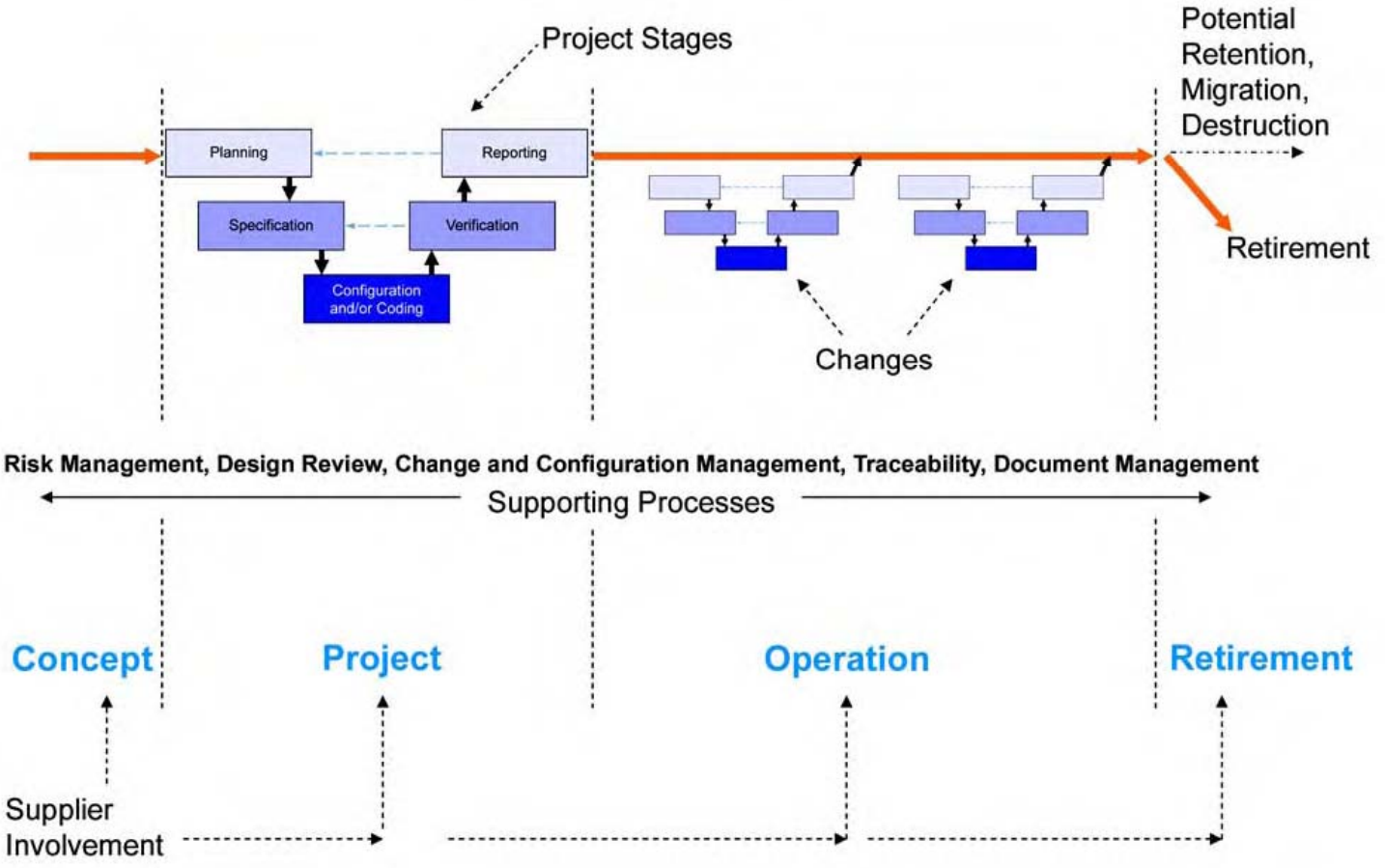
Project Phase - Stages

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



Risk Management – Change & Configuration Management – Design Reviews – Document Control – Traceability

Operation Phase - Stages



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

Specification, Configuration, and Coding Stage

- 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

Description	Typical Examples	Typical Approach
Layered Software Software used to manage the operating environment	• Operating Systems • Database Engines • Middleware • Programming Languages • Statistical Packages • Spreadsheet Application • Network Monitoring Tools • Scheduling Tools • Version Control Tools	Record version number, verify correct installation by following approved installation procedures

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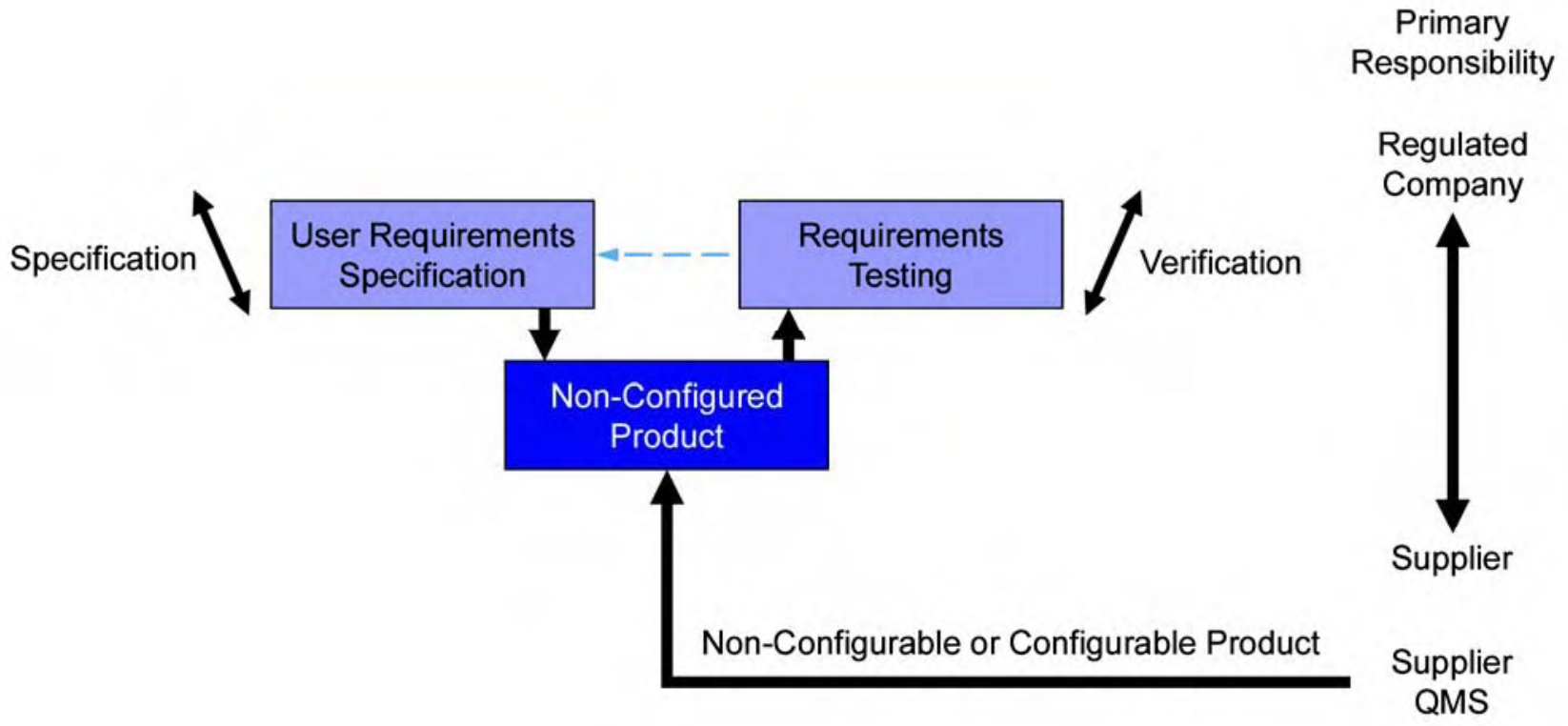
Typical Life Cycle Approach – Category 3

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

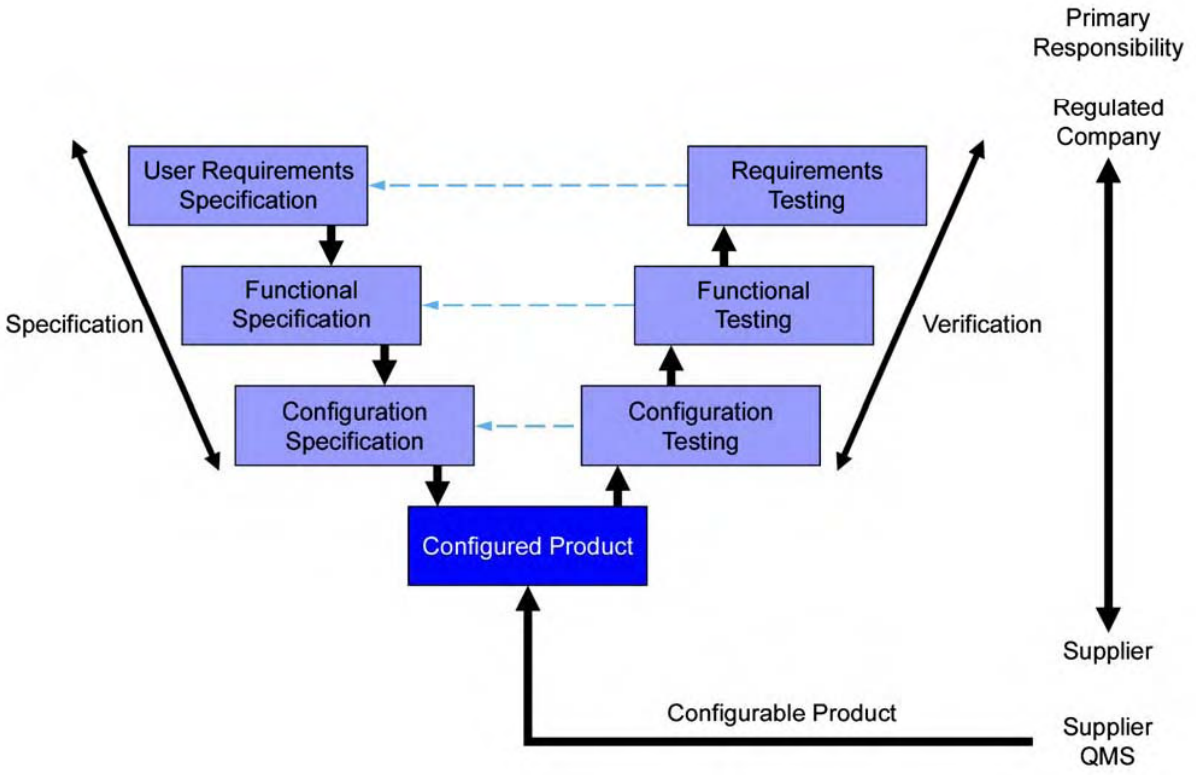
Typical Life Cycle Approach – Category 3



Typical Life Cycle Approach – Category 4

Description	Typical Examples	Typical Approach
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.	• LIMS • Data acquisition systems • SCADA • ERP • MRPII • Clinical Trial monitoring • DCS • ADR Reporting • EDMS • BMS • CRM • Spreadsheets • Simple HMIs	• 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

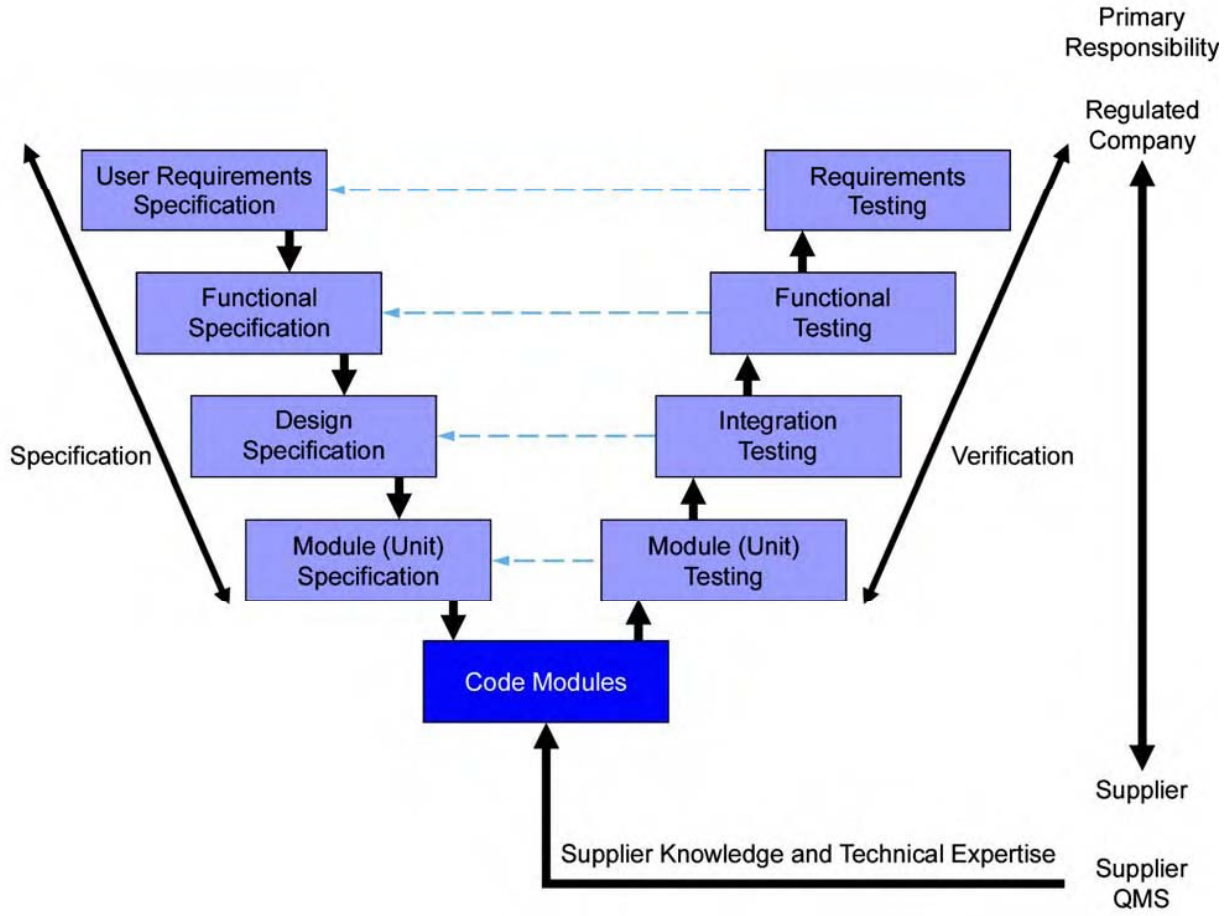
Typical Life Cycle Approach – Category 4



Typical Life Cycle Approach – Category 5

Description	Typical Examples	Typical Approach
Software custom designed and coded to suit the business process.	Varies, but includes: • Internally and externally developed IT applications • Internally and externally developed process control applications • Custom ladder logic • Custom firmware • Spreadsheets (macro)	Same as for configurable, plus: • More rigorous supplier assessment, with possible supplier audit • Possession of full life cycle documentation (FS, DS, structural testing, etc.) • Design and source code review

Typical Life Cycle Approach – Category 5



Questions?

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