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DIGITAL TRANSFORMS PHYSICAL

GAMP® 5 Template

for Pharmaceutical Project Validation & Quality Risk Management

codebeamer™

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Pharmaceutical project delivery happens in a complex and heavily regulated environment. For process maturity and compliance, pharma developers, system integrators, and suppliers are applying Good Automated Manufacturing Practice guidelines to manage computerized and software-based systems in their collaborative projects.

This GAMP 5 Template enables the documented management of computerized production systems using PTC®'s Codebeamer technology. It supports pharma project delivery, systems validation, and quality management all in one. The template helps apply a risk-based approach to GxP computerized systems management. Traceability, accessibility, and advanced document management across stakeholders helps simplify and accelerate audits. Use the template out of the box, or map your processes and tailor the template to your organization's individual needs. Define custom workflows for all work items and documents, and use preconfigured or custom reporting options.

Use this template to cut costs and project times, identify and manage hazards and defects, and to enable effective change management in GxP-compliant pharmaceutical project delivery. Reduce waste, implement systemic risk management, and achieve GAMP® 5 compliance with optimal effort.

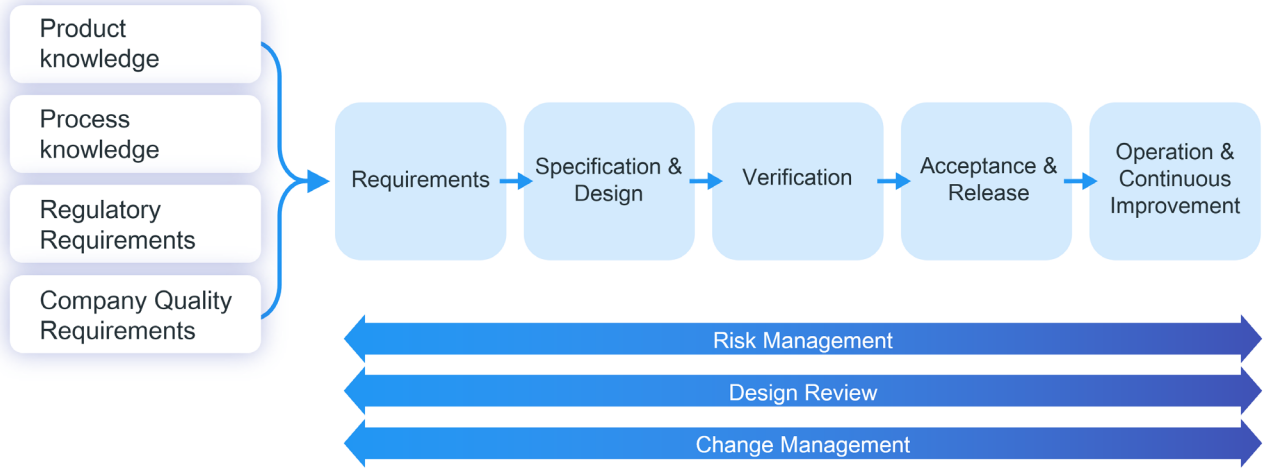
Cut Costs & Project Times

Manage Hazards & Defects

Effective Change Management

The Specification, Design, and Verification Process

Good engineering practice



This GAMP 5 template is intended for use by:

- **Pharmaceutical end users (pharma production companies)**
- **Systems Integrators providing services for pharma producers**
- **Suppliers of automated systems (including hardware & software for the pharma industry)**

Scope of this GAMP 5 Template for Pharma Validation & Quality Management:

Use Case 1 — Pharma Validation Process Management

Use Case 2 — Quality Risk Assessment

Use Case 3 — Quality Audit and CAPA Management

Use Case 4 — FDA 21CFR11 Requirements and Compliance Check

Use Case 1

Pharma Validation Process Management

Maintain full control over every stage of the validation lifecycle using this GAMP 5 Template. Link regulatory requirements to specifications and to test cases, guaranteeing traceability across the validation chain.

The template provides adequate management control, change management, and a consistent approach across systems from validation planning all the way through to reporting. From user requirements through system design specifications and test cases for validation, the template comes preconfigured with purpose-built trackers. These data containers, as well as their underlying workflows, have been designed to suit the use cases of pharmaceutical companies. Use trackers for planning & specification, project control, compliance/QMS, and risk management out of the box, or adapt them to your needs as you see fit.

Use Case 2

Quality Risk Assessment

Use a science-based risk management approach, focus on product and process understanding, and apply Quality by Design concepts with the help of this GAMP 5 Template.

Dedicated Quality Risk Management artifacts and workflows help the implementation of a systematic process for the assessment, control, communication, and review of hazards. Link risk assessment artifacts to risk control work items in order verify the effectiveness of your mitigation actions, and use this template to document all your risk-related processes. Rely on automatically created risk matrix diagrams, or build custom dashboards to report on your quality risk management activities.

Use Case 3

Quality Audit and CAPA Management

Connect all your work items to corresponding GAMP standard requirements, and build airtight audit checklists to validate your pharma systems.

Use this template to establish a trail of interlinked artifacts along project delivery (including user requirements, functional, system, and software design specifications, as well as the test cases that verify them). Manage non-conformities and Corrective and Preventive Actions (CAPA) in a traceable manner. Access informative example checklists, and create your own custom audit checklists based on relevant regulatory requirements. Define and execute project verification plans, and simplify compliance audits using this GAMP 5 Template.

Use Case 4

FDA Title 21 CFR Part 11 Requirements and Compliance Check

Codebeamer is a fully equipped electronic Quality Management System that helps pharma users adhere to the FDA's requirements on electronic quality records and digital signatures. Use this template to implement a digital, paperless eQMS that complies with Part 11 of Title 21 of FDA's Code of Federal Regulations Part 11 (21CFR11).

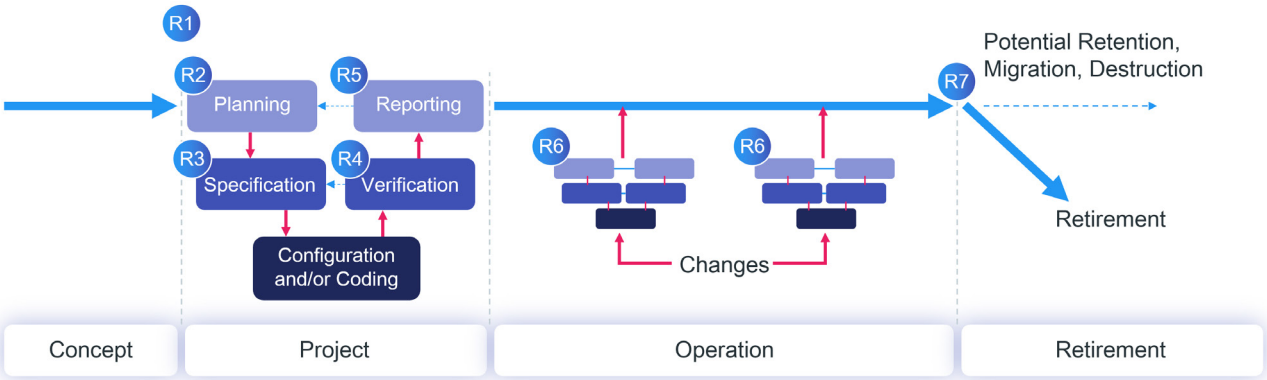
Item-based reviews may be used on all artifacts within this template, letting users approve each artifact with digital signatures that are equivalent to handwritten signatures. All 21CFR11 requirements and the test cases that verify them are available within this template. Map your intended use case, pick the appropriate requirements, and verify the correct functioning of your system as per Title 21 CFR Part 11. Validate Codebeamer's functionality around record generation, audit trails, and digital signatures to achieve regulatory compliance with optimal effort.

Why use Codebeamer's GAMP 5 Template?

codebeamer™

Initial Risk Assessment

Typical Use of Risk-Based Decision Making



- R1 Initial risk assessment
- R2 Risk-based decisions during planning
- R3 Functional risk assessments
- R4 Risk-based decisions during test planning
- R5 Risk-based decisions during planning of operational activities
- R6 Functional risk assessments in change control
- R7 Risk-based decisions when planning system retirement

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