

Project Quality Plans

Gillian Sandilands
Director of Quality

Fulcrum Regulatory Services, Ltd.
A Division of Fulcrum Pharma Developments

.fulcrum>

Project Quality Plans

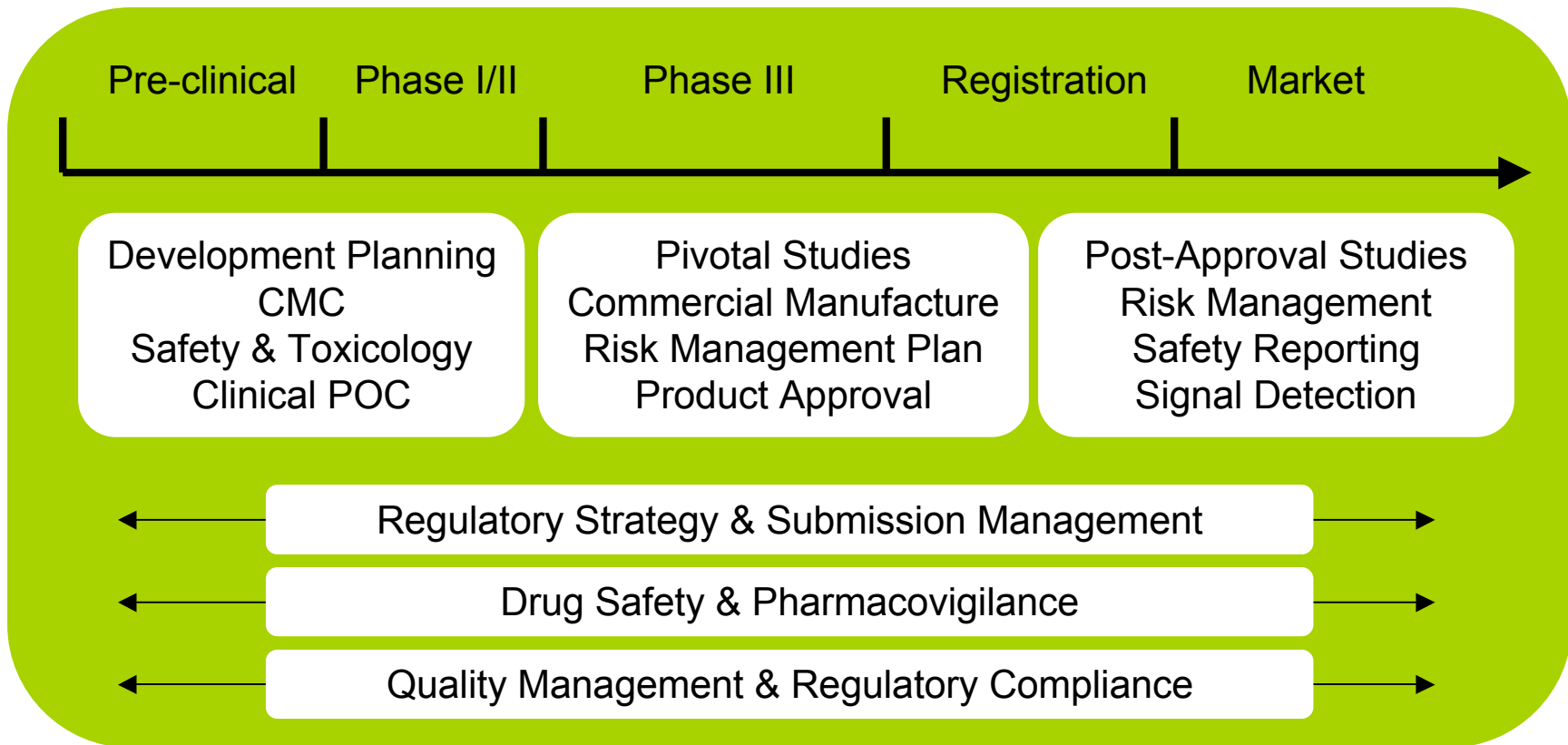
- > Product development is complex and involves a process that requires a high degree of coordination and management
- > Despite the intensity and quality of upfront planning, product development never follows an exact path
- > The implementation of a quality management approach significantly decreases the risk of project failure
- > The Project Quality Plan is a tool that minimises Project Risk

What is a Project Quality Plan (PQP)?

- > A PQP is an approach to quality that incorporates a set of quality-related project activities. It is generated at the start of a project and helps deliver Project Quality
- > A PQP is an integral and critical part of a product development programme and if fully executed should meet or exceed client or regulatory authority expectations on Quality
- > A PQP has to be appropriate to the phase of development and designed to ensure regulatory compliance
- > A PQP is essential to every part of the drug development process

Project Quality Plans

Quality Management is relevant to every part of the Product Development Process



What is the Purpose of a PQP?

The Purpose of a PQP is to define the tasks and activities that ensure delivery of the project elements required to meet client and regulatory agency expectations for Quality

Who defines the PQP?

The PQP is defined by the project team with appropriate representation from technical functions, regulatory and QA

Who delivers the PQP?

The PQP is delivered by Quality Assurance (QA) but must be fully integrated into the Product Development Plan

What should be included in a PQP?

- > A description of the responsibilities of all stakeholders including technical functions (non-clinical, CMC, clinical), regulatory and QA
- > A description of the Quality Management System (QMS) to be followed by the organisation responsible for delivering the project
- > A list and timetable of all quality-related activities including internal and external audits, quality review meetings

Key Elements for Delivery of a PQP

> Document Control

Defines which documents generated during the execution of the project will be subject to document control and how they will be managed and distributed

> Change Control

Defines how change will be managed during the course of the project and how review and approval of project changes will be agreed between stakeholders

> Quality Audits

Defines external audits required to support the execution of the project and internal audits to assess progress and adequacy of corrective actions to problems encountered during project delivery

Key Elements for Delivery of a PQP

> Review of the PQP

Within the plan there should be a specified time period for periodic review of the plan and its effectiveness and scope. Any amendments to the plan should be considered when implementing project changes

> Training and Expertise

The minimum qualifications, training and experience of staff required to undertake project activities should be documented. Documented evidence should be provided that these requirements are met by project members or that specific training needs have been identified and met

Key Elements for Delivery of a PQP

- > Evaluation of applicable regulations and standards

It is important to clearly define the project scope to ensure that the applicable GXP regulations can be referenced and their requirements in relation to the project established

- > Phase Appropriate Quality System Activities

There are different GXP requirements at each phase of the drug development process and the understanding of these and the appropriate application of these requirements are key to successful regulatory compliance

- > Project Team Members Responsibilities

It is important to establish the role and responsibilities of the Quality Manager for the project and the interaction with the project leader and other team members

When to design and review the PQP as part of your Project Planning Process

- > During definition and finalisation of Project Scope
- > Project Kick Off Meetings (to engage the Team)
- > Regular Project Team Meetings
- > Key Milestone Review Meetings
- > Project Steering Meetings
- > Post Project Review Meetings

Responsibilities of Quality Assurance

- > Implementation of the PQP
- > Conduction and reporting of audits
- > Generation and monitoring of corrective action plans
- > Organisation of project quality reviews
- > Evaluation of project performance
- > Determination of compliance with regulations

Delivery of Regulatory Compliance

- > Through all clinical stages of Drug Development the data in support of the Clinical Trial is included in the regulatory submission. Regulatory approval has been granted to conduct the trial on the basis of that data set
- > During the drug development process, changes will be required for example to the manufacturing process or to clinical trial protocol. These changes may necessitate amendments to product development history files and Investigator Brochures
- > The QA function steers the project through these activities, assessing the impact of changes and ensuring that any updates to regulatory filings are communicated and made

Project Quality Plans Summary

- > Quality must be built into a project from Day 1
- > PQP is a tool for ensuring Project Quality and minimising Project Risk
- > PQP is constructed by the Project Team
- > PQP is implemented by Quality Assurance
- > PQP must be structured to deliver the quality standards of the organisation
- > PQP should be used to address potential quality issues and identify actions to resolve
- > PQP should ensure that project deliverables and customer expectations are met