SEQOVA
WHERE INNOVATION BEGINS

Implementing a QMS (Quality Management System) for Clinical, Manufacturing and Distribution Activities

This case study illustrates SEQOVA's expertise in implementing a QMS to support the start-up of your operational activities.

Scenario

The Client decided to open a new manufacturing plant in response to the growing demand for sterile injectable products. Designed for large-scale fill-and-finish operations, this plant requires a high level of precision and regulatory compliance. Recognizing the critical importance of quality in the pharmaceutical industry, the client's management team aimed to establish a quality management system (QMS) from the outset to ensure the plant operates according to the strictest standards.

The plant is still under construction, with equipment being installed and teams being formed and trained. The main challenge is to ensure that all processes meet regulatory requirements and high-quality standards from day one of production. This is crucial to prevent non-compliance risks that could result in financial losses, delays in market entry, and most importantly, risks to patient safety.

SEQOVA has provided a comprehensive support to ensure the success of this critical project, working collaboratively with the client's teams from strategy through operations.

The strategies deployed for the project:

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Assessment & Process Mapping	Team Establishment	Roadmap and Project Phasing
QMS Implementation: Strategy to Ops	Documentation Review	Tracking of Deliverables

Planning & Execution

Following the defined strategies, SEQOVA collaborated closely with the team. An organizational analysis was conducted to establish the governing processes and risk mitigation plan, incorporating appropriate Key Performance Indicators (KPIs) and service level expectations. This ensured a structured and measurable approach to the implementation of the QMS.

ASSESSMENT AND PROCESS MAPING

- From raw material to product distribution
- Collection and analysis of the existing documentation
- Assessment of client resources with required skill set and experience
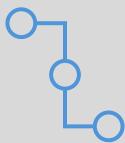- Project planning integration

TEAM ESTABLISHMENT
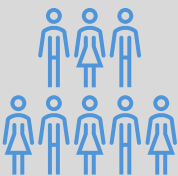
- Number of resources analyzed
- Skill set and experience defined
- Effective team structure analyzed
- Onboarding process structured
- Recruitment initiated

PROJECT PHASING AND ROAD MAP DEFINITION (PHASE 1)

**Project divided in 3 phases**

Phase 1: Road Map definition

- Centralized and aligned roadmap establishment with project phasing integrated in the global planning and documents to be delivered
- Documentation and Training systems defined (paper vs software.
- Governance, communication, project steering defined
- Documentation review process defined

QMS IMPLEMENTATION (PHASE 2 and PHASE 3)

Phase 2
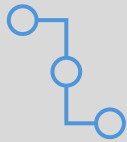
- Implementation of defined and prioritized processes (SOPS, WI, forms, records, archiving, etc)
- Development of all agreed deliverables in a collaborative way
- Weekly and monthly follow-up of defined KPIs
- Effective communication channel defined for the smooth communication with the internal and external teams

Phase 3

- Development of staff skills
- Ad-hoc support (expertise and governance)

DOCUMENTATION REVIEW

- Close internal review of the documentation produced by SEQOVA teams prior sharing with the Client's team
- Review of the documentation by the Client's QA team
- Tracking of all modifications to be implemented

TRACKING OF DELIVERABLES

- Conducted weekly internal review of project to ensure on-time delivery of the allocated tasks
- Conducted weekly meetings with stakeholders to identify the issues at the early stages to address it timely
- Conducted monthly steering committees to address all project perimeters (Deliverables, Planning, Quality, Finance)

Risk Mitigation Plan

A well-crafted risk mitigation plan is essential for ensuring smooth operations and successfully managing scope changes. By setting clear expectations for all stakeholders, this plan addresses potential challenges and provides effective strategies to manage them. SEQOVA's team, with its expertise and experience, played a crucial role in implementing this plan, facilitating decision-making, and preventing any deviations during the project.

Challenges

- The client's team was still being formed and was not always available as needed.

- Building strong working relationships with stakeholders to gain their trust and confidence

- Addressing misalignment between on-field operations and stakeholder expectations

- Fostering collaboration across diverse teams

- Maintaining high levels of team motivation throughout the project

Mitigation

- Organized regular meetings with the training department to integrate SOPs and conduct knowledge-sharing sessions

- Established regular meetings to discuss project progress and proactively identify risks

- Organized workshops involving stakeholders and operations personnel to align on decisions, mitigate risks, and implement appropriate actions

- Engaged the client's teams in the collaborative development of documents

- Maintained an action log to record and share improvements

- Scheduled lessons learned sessions to reflect on project outcomes and improvements

Outcome

Thanks to the collaborative efforts of various stakeholders, a successful outcome was achieved. Although some difficulties were encountered, including resistance, limited availability and involvement, turnover, scope changes, and planning delays, these challenges were pragmatically managed. The overall project timeline was maintained, and a secondary subproject was initiated to accommodate operational changes.

Objectives Met

Major milestone objectives were achieved, reinforcing confidence in the project's success. For any missed milestones, review and revision sessions were scheduled to ensure appropriate corrective actions were taken.

Resource & Operations Cost Optimized

During the writing phase, operational teams were established to optimize costs. A few senior consultants were involved in Phase 1 for project management and to provide expertise as needed.

Standardization

Standardizing documentation and processes helped achieve planning milestones, reduce errors, optimize resources, and improve operational efficiency.

Global Documentation Management

Rigorous document management has enabled the client to improve the archiving and accessibility of records from production to distribution, ensuring they are readily available for audits.

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