INTEGRATED MANAGEMENT SYSTEM IN PHARMACEUTICAL INDUSTRY– THE NEW APPROACH IN CAPITAL PROJECT MANAGEMENT

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Agenda

- Introduction
- Capital Project Management and PDCA model
- Project Management phases
- Integrated process
- Conclusion

Introduction

- Similarity among the standards:
  - GMP
  - ISO 9001
  - ISO 14001
  - OHSAS 18001
  - ISO 31000
  - BS 25999
  - ISO 10006

Introduction

- Certified management systems

  give a signal of liability and concern for stakeholder relation
- Multidimensional quality at the organization level, understanding of the ” expectation and needs” of all interested parties are preferable
- Integrated Management System

  enable the organization to achieve the ultimate goal of avoiding the risk of negative impact on the organisation objectives

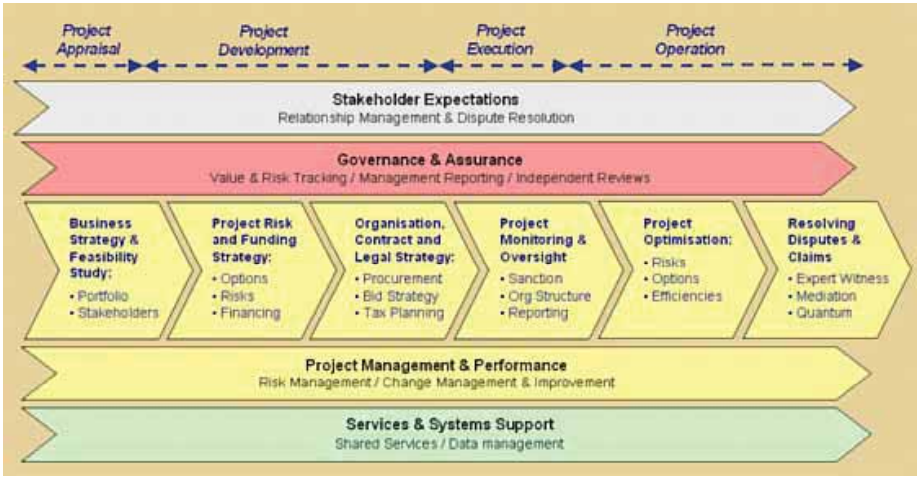
Introduction

WHEN and HOW
to start the management system integration?

The best solution:
during the Capital project phase

Capital project management

- ALVOGEN PHARMA SERBIA – Packaging plant



Capital project management

- Guidance on quality management in projects – ISO 10006:2003, based on eight quality management principles
- Two aspects to the quality management in a project:

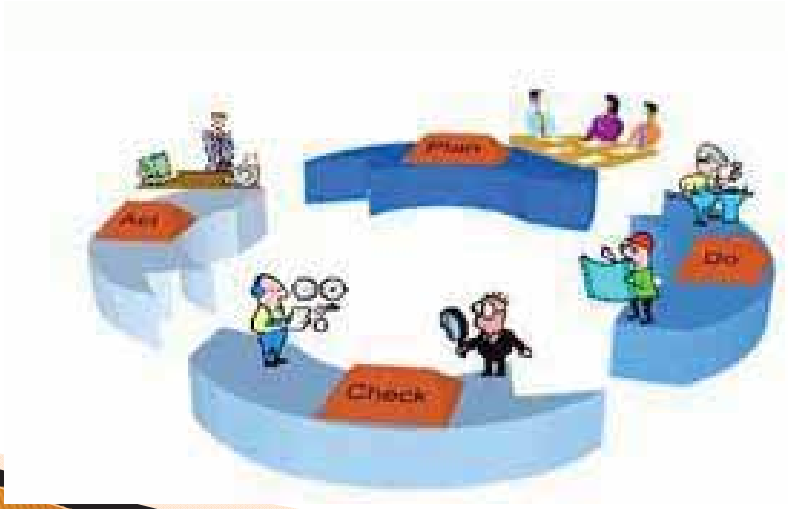
a) Process approach the integration of management systems (GMP, ISO 9001, ISO 14001, OHSAS 18001, ISO 10006) has been implemented, through PDCA model

b) Project product

Alvogen Pharma Serbia -Packaging plant has to achieve the expectation and needs of all interested parties (stakeholders, regulatory authorities, contractors, municipality, suppliers, customers and employees)

Capital project management

The integration of management systems (GMP, ISO 9001, ISO 14001, OHSAS 18001, ISO 10006) has been implemented, through PDCA model

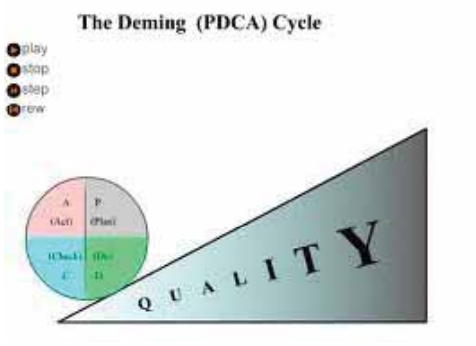


Management Systems elements through PDCA cycle

Standard	*ISO 9001:2008*	*ISO 14001:2009*	*OHSAS 18001:2007*	*„Concept paper"- GMP*	*ISO 10006:2003*
Plan (P)	Quality policy Quality objectives planning	Enviroment policy Enviroment objectives planing	Occupational Health & Safety policy OHS objectives planning	Quality, sefety, efficiency of pharmaceutical Quality objectives planning	Quality plan for the project Time –relation processes Resource planning
Do (D)	Product realisation	Operation and implementaion of EMS programs	Operation and implementaion of OHS programs	Product realisation	Project product realisation
Check (C)	Analysis and continual improvement	Audits and CAPA	Audits and CAPA	Analysis and continual improvement/ CAPA	Measurement, analysis and improvement
Act (A)	Management review	Management review	Management review	Management review	Management reviews and progress evaluation

Project Management phases and integrated process

- Management responsibility PLAN
- Resource management DO
- Measurement, analysis and improvement CHECK
- Operational packaging plant ACT



Management responsibility

- It was a direction – setting process, which includes planning the establishment and implementation of QMS, EMS and OHSAS principles. The management team made a decision about documentation structure, QEHS policy and Risk management policy. Validation Master Plan was approved. Risk assessment formal documents have been raised to facilitate project outcomes.

Resource management

- Management team has identified, estimated, scheduled and allocated all relevant resource- contractors, suppliers in project organization and provided human resources during the packaging process start up
- In this phase, GMP/ ISO/ OHSAS /regulatory/ legal requirements have been evaluated
- Integrated elements have been managed- Standardized Management System SOPs were prepared to assure the broad outlines of what the Packaging facility will do.
- Change management has been assessed through Change Control System

Documantation management

- Q & EHS Manuel
- Programs (12)
- SOPs (42)

Measurement, analysis and improvement

Measurement, analysis and improvement

- The organization learned from the project - Knowledge Management is in place
- Collection and validation of data for continual improvement have been established
- Common internal audit has been performed, lead by corporate Operation head

Conclusion

- The presented results of the possible model of IMS have been based on the process approach implemented in PDCA cycle
- The process approach has been reflected in PDCA model, using the key management enablers - Risk management and Knowledge Management
- The benefits of the IMS, through project management are: a) cost reduction b) resource optimisation and c) efficacy improvement.

THANK YOU