Establishing Quality Management Systems

Dr. Petra Dörr
Head of Management Services and Networking
Swissmedic, Swiss Agency for Therapeutic Products
petra.doerr@swissmedic.ch

14th ICDRA
Workshop H
2 December 2010, Singapore
Swissmedic Quality Management System

Outline of presentation

• Quality Management at Swissmedic
• Key Elements of the Quality Management System
• Critical Success Factors / Lessons learnt
• Summary and Outlook
Quality Management at Swissmedic: Accredited units

Swissmedic Inspectorate
- Accredited since 2006
- According to ISO/IEC 17020:1998 (general criteria for the operation of various types of bodies performing inspection)

Official Medicines Control Laboratory
- Accredited since 1996 (pharmaceuticals) and 2000 (biologics)
- According to ISO/IEC 17025:2005 (general requirements for the competence of testing and calibration laboratories)
Quality Management at Swissmedic: Change process

*Strategic goals (i.a.):
- Optimisation of processes
- Modernisation of infrastructure
Quality Management at Swissmedic: Change process

Analysis of processes and organisation (2006)

• Outcome:
  • Need to improve transparency, consistency and efficiency
  • New structure at management board level
  • High-level process map

Reorganisation (2007)

• Process-oriented structure
• QM functions integrated
• Detailed process map
• High-level process description
High-level Process Map

Management processes

Corporate Governance, QM, Business Continuity Management

Support Processes

Communication, IT, Lab testing, Facility management

Market Surveillance
Marketing Authorisation
Licensing
Enforcement/Penal Action

Signal
Decision
Application
Action

Measure
Quality Management Functions

Executive Director: Management representative

Head of Sector: Process owner

Support/Head of Division: Responsible for process
Quality Management at Swissmedic: Change process

Project QMS

- Establish Swissmedic-wide QMS as a supporting management tool and provide necessary structures for the implementation of the QM policy.
- ISO 9001:2008 as guiding principle
- Certification not a primary goal ("certifiable")
Quality Management at Swissmedic: Change process

Project QMS

• Problem statement:
  • Lack of basic principles and standards for process management
  • Lack of a process-centred culture
  • Lack of „network-oriented thinking“
  • Static, structure-oriented thinking rather than dynamic view of a network-oriented flow of processes
Quality Management at Swissmedic: Change process

Project QMS

• Key elements/figures
  • Duration: Aug 2008 – Jan 2009
  • Phased approach: Processes split in three groups according to priorities
  • Number of days (employees): 2245 (= 11 years)
  • Cost: 33’000 CHF/$
Key Elements of the Quality Management System

1. QM Policy

- Stakeholder
- Mission / legal mandate & Regulatory environment
- QM policy
Key Elements of the Quality Management System

2. QM Organisation

- Management representative: Executive Director
- Central unit Quality Management
- Defined process owner and responsible for processes
- Accredited units with separate QM functions
QM Organisation

Executive Director
(Mgmt representative)

Head of Management Services and Networking

Quality Management
• Quality manager
• Secretary
• Lead-Auditor

• QM-responsible Inspectorate
• QM-responsible OMCL

Head of process sector 1
Process owner

Process team 1 consists at least with:
process responsible and BPE or Employee

Head of process sector 2
Process owner

Process team 2 consists at least with:
process responsible and BPE or Employee

Head of process sector n
Process owner

Process team n consists at least with:
process responsible and BPE or Employee

Head of accredited sectors
Inspectorate and OMCL

Head of Inspection
Inspectorate (accredited)

Technical manager
OMCL (accredited)
Key Elements of the Quality Management System

3. Continual Improvement

- Internal audits
- Feedback process (negative and positive)
- Training / introduction of new employees
- Process engineering
  - Description of process as is
  - Process improvement (increased efficiency)
  - Process optimisation
Key Elements of the Quality Management System

4. Transparency
- Internal
  - All valid QM documents are available on the intranet
- External
  - Selected documents are published on the internet
Key Elements of the Quality Management System

5. Process Management
   • Guideline Process Management
     • Unified format
   • Process description “Processes”
     • New processes
     • Changes to existing processes
     • Withdrawal of processes
   • Checklist Processes
     • Formal requirements
     • Comprehensiveness/ completeness
Key Elements of the Quality Management System

6. Performance Measurement

- Performance indicators
  - Degree of transparency (%)
  - Quality of specifications (from internal audits)
  - Quality of execution (from internal audits)
  - Number of complaints (customer satisfaction)
Critical Success Factors / Lessons Learnt (1)

Bottom up vs. Top down…
  • Specialist input and top management commitment – both are equally important

Resource planning
  • Amount of resources needed for work on processes and other specifications was widely underestimated

Dedicated and committed project manager…
  • Driving force
  • Internal resource
Critical Success Factors / Lessons Learnt (2)

No external consultants running the project
• Only methodological support for project manager

Communication (int./ext.)
• Information for staff members available on the intranet
• Information on website can be improved (traceability)

Less may be more…?
• ~ 165 processes; ~ 1800 documents\(^1\) (as of today)

\(^1\) including different language versions (e.g. standard letters in ger/f/it/e)
Critical Success Factors / Lessons Learnt (3)

Training is key

- Training of new employees
  - Introduction day (key elements)
  - Process training (relevant processes for function; defined in job description)
- Training following introduction of new processes/process changes

Positive and negative feedback instead of “complaints”

- Database “feedbacks” contains both positive feedback (including proposals for improvement) and negative feedback
Summary and Outlook

• Successful implementation
• High level of acceptance
• Entering into a phase of consolidation
• Implementation of new IT-architecture
  • Business process engineering necessary for “computerisation”
  • Cooperation IT/QM/specialist divisions
  • QMS specifications/documents as pilot for electronic document management in 2011
Thank you for your attention!