Good Review Practices and QMS Implementation: an FDA Perspective

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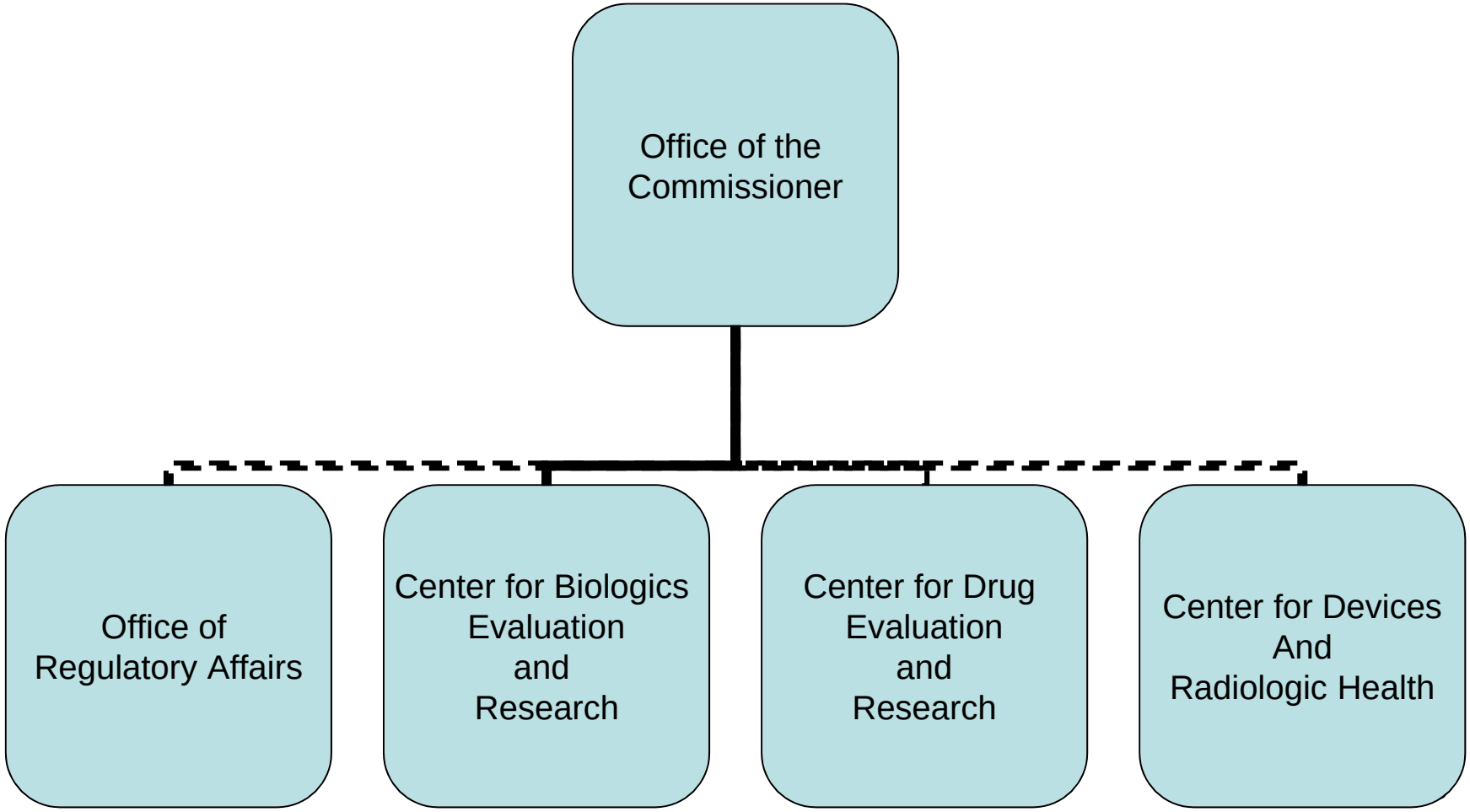
Presentation Outline

- Organizational overview
- Harmonization Efforts
- Success Factors
- QMS as a solution
- FDA Approach to QMS
- Product and Services
- Training
- Future goals
- References

FDA Organizational Chart



Harmonization Efforts

- External
  - International Conference on Harmonization
  - International Standards (e.g., ISO)
- Internal
  - FDA Standards Committee
  - Common Technical Document
  - Good Review Practices and Tools
  - Certification (e.g., ISO 17025)
  - Implementing ISO 9001:2008
  - Malcolm Baldridge National Quality Award Criteria
  - FDA Staff Manual Guide 2020

Common Goal = Global Quality

Asia
Africa
Europe
North America
South America
Antarctica
Australia

Critical Factors for Success

- **Management support**
- Clear, consensus standards and guidelines
- Transparency and consistency in decision making
- Processes capable of handling regulatory variation (internal and external)
- Understanding how products/services are used
- Understanding of diverse customer base
- Common understanding of risks and risks management
- Feedback loop/continual improvement
- Optimize performance practices, processes, and results
- Facilitate communication across the organizations
- Share best practices to enhance work products
- Implement effective processes

The journey begins at home.

A Solution: Quality Management System

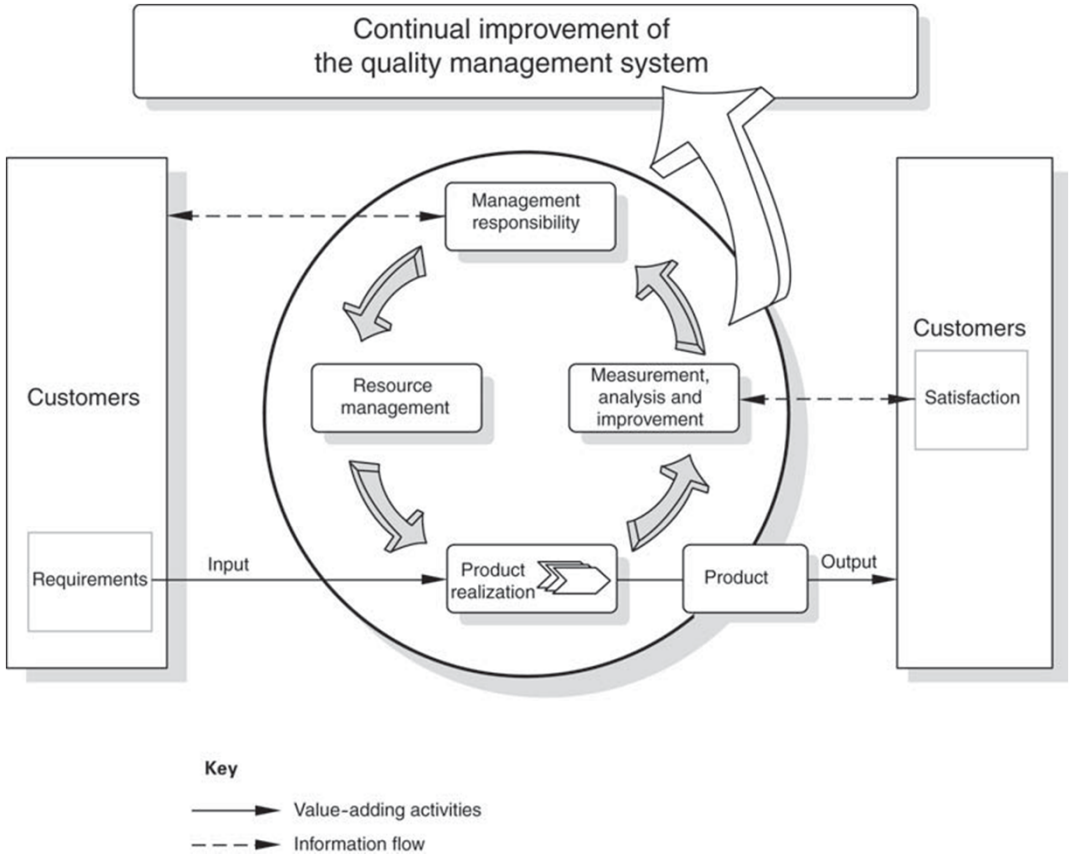


Figure 1 — Model of a process-based quality management system
Source: ANSI/ISO/ASQ(E) Q9001:2008 Quality management system - Requirements

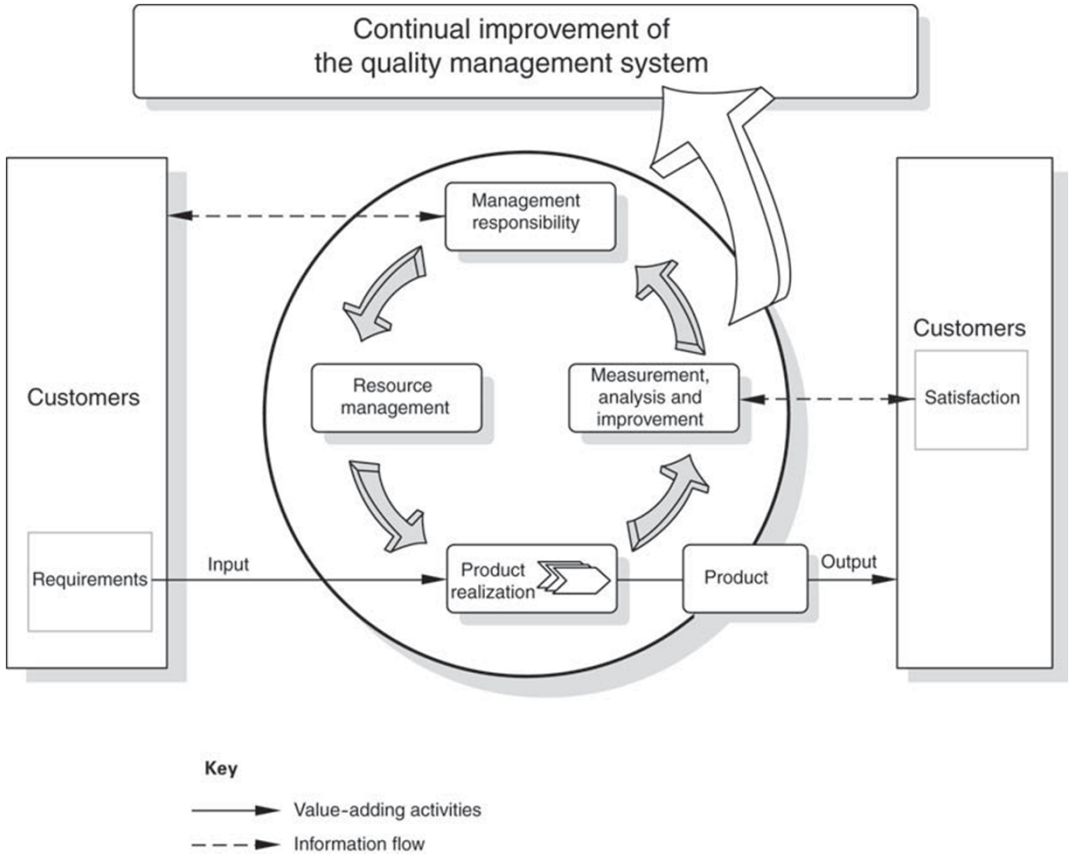
Basic Approach

- FDA Quality Resource and Guidance Team
  - Say what you do (Plan)
  - Do what you say (Do)
  - Prove it (Check)
  - Improve it (Act)
- Began document internal processes (i.e., procedures and process maps)
- Good Review Practices and tools not enough
- Needed a clearer standard
- Moved to ISO 9001:2008 framework
- Timeliness, Predictability, Transparency, and Good Quality

FDA Products & Services

- Internal customer elicitations
- Products and services identified
  - Medical Product Reviews
  - Regulatory actions
  - Communications/Interactions
  - Discipline Consults
  - Guidance/Policy
  - Inspections
  - Internal Resource Materials (e.g., policies, procedures, templates, training, etc.)
  - Meetings and conferences
  - Project management services

A Solution: Quality Management System



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Medical Product Review – Secondary Review Controls

- Distinction of primary reviewer comments and sponsor data
- Resolution of issues with recommendations
- Rationale
- Organized
- Material reviewed
- Conclusion
- Deficiencies linked to regulations (e.g., potency, purity, etc.), as applicable
- Material reviewed

Develop into checklist!

Acceptance Criteria for Medical Product Reviews

- Usable by multiple customers
- Clarity
- Accuracy
- Organization
- Analytical thinking
- Science-based
- Regulatory-based
- Collaborative

Develop into a checklist.

FDA Training

- Training on QMS procedures
- On the Job
- Mentoring
- Core competencies
- Case studies
- Lessons learned
- ASQ Training
  - Certified Manager of Quality/Organizational Excellence
  - Certified Quality Auditor
  - ISO 9001:2008 Implementing and Auditing

Future goals

- Identify opportunities for improvement based on external assessment
- Identify useful quality metrics
- Identify best practices within other FDA quality programs and international regulatory programs
- Assure personnel have ready access to needed tools (e.g., procedures, guidance documents, statistical, templates, etc.).
- Customer elicitations
- Integrate QMS across business processes
- Institute QMS Management Review

References

- ISO 9001:2008
- FDA Staff Manual Guide 2020

  http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/ucm052570.htm

- FDA Good Review Practices

  http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/ucm118777.htm