Auditing Within the Culture of the Medical Device Industry & ISO 13485:2016 Overview

ASQ Quality Conference 2017 for Region 5
October 25, 2017

Introduction / Purpose

- Discuss the influences of regulatory schemes on the audit practice.
- Help you prepare for these types of audits
- ISO 13485:2016 Overview

Introduction - Bill McLain

- Keystone Regulatory Services, LLC
- Past Chair - ASQ Biomedical Division
- RABQSA Certified Principal Auditor
- Over 25 Years in Medical Device Industry
- Ten years as a contract auditor for KEMA/DEKRA
- Regulatory Strategy and Submissions
- QMS Development and Maintenance
- Auditing - Privately and With NB’s

For Each Scheme

- Discuss the focus/purpose of each scheme.
- Potential influences on auditing
- How to prepare for that type of audit

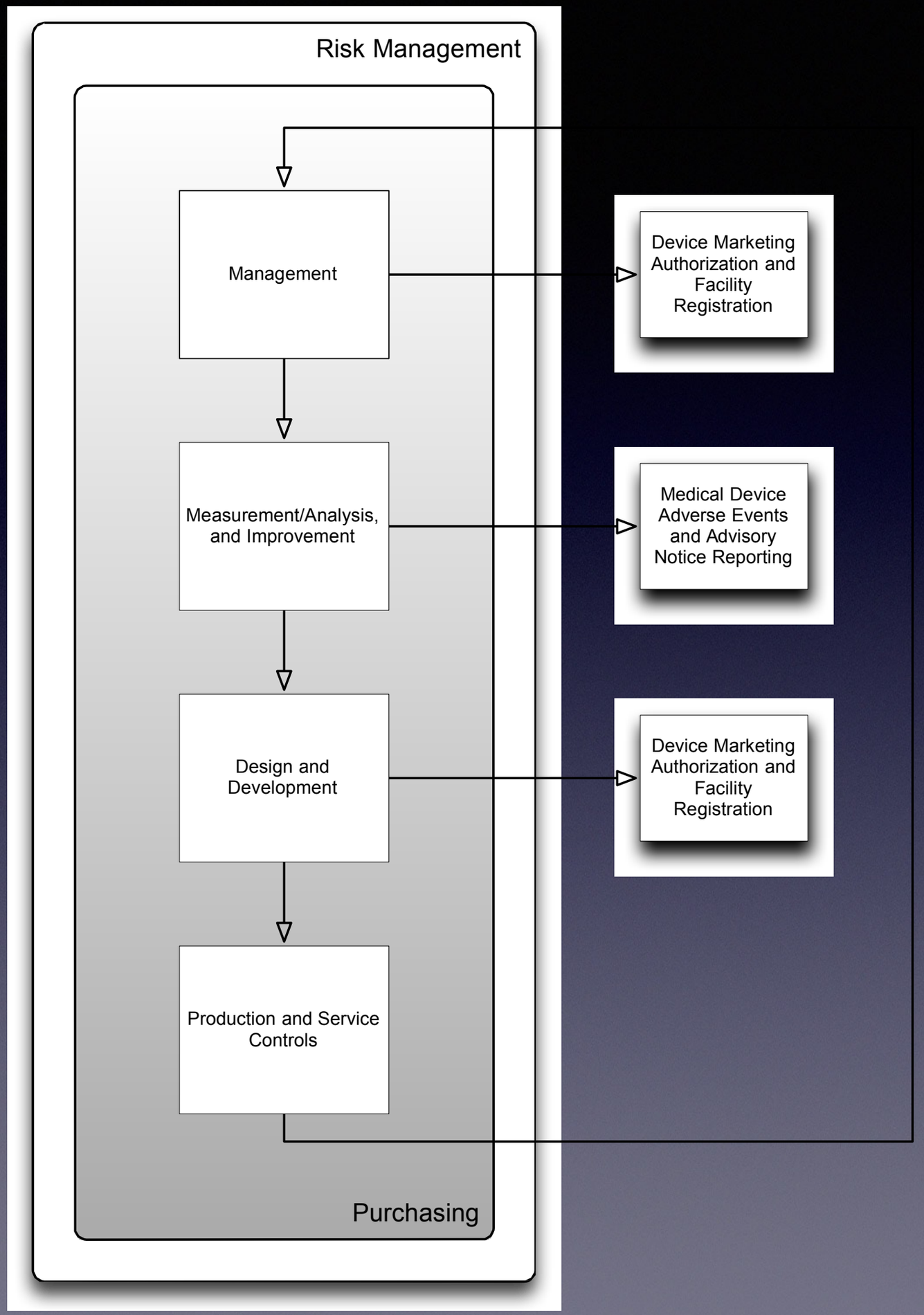
MDSAP - Medical Device Single Audit Program

MDSAP - Focus/Purpose

- The Medical Device Single Audit Program allows an MDSAP recognized Auditing Organization to conduct a **single regulatory audit** of a medical device manufacturer that satisfies the relevant requirements of the regulatory authorities participating in the program.

MDSAP - Influences

- The audit is based on executing “audit tasks”
- Tasks grouped
- Order inflexible
- Tasks time based


Risk Management
Management
Measurement/Analysis, and Improvement
Design and Development
Production and Service Controls
Purchasing
Device Marketing Authorization and Facility Registration
Medical Device Adverse Events and Advisory Notice Reporting
Device Marketing Authorization and Facility Registration

MDSAP - Influences

- Not the process approach
- Repeat findings come at greater cost
    - Finding scheme based on GHTF/SG3/ N19:2012
    - Grading Matrix followed by Escalation

MDSAP - Influences

- Greater emphasis on regulatory topics
- Registration and listing
- Changes to marketing authorizations

MDSAP - Impact/Preparation

- Move back to checklist audit
- Topics only minimally reviewed now subject of focus
- Use the companion document to identify weaknesses in your system.

Medical Device Single Audit Program (MDSAP)

MDSAP Documents

MDSAP Audit Procedures and Forms

Back to Available Documents

MDSAP AU P0002

- MDSAP AU P0002.003 Audit Model (PDF - 984KB)
  (ISO 13485:2003)
- MDSAP AU P0002.004 Audit Model (PDF - 680KB)
  (ISO 13485 :2016)
- MDSAP AU G0002.1.003 revised 2017-04-17 (PDF - 1.1MB)
  (ISO 13485 :2003)
- MDSAP AU G0002.1.004 revised 2017-04-17 (PDF - 1.1MB)
  (ISO 13485 :2016)

FDA

FDA - Focus/Purpose

- Regulations based on demonstrating devices are neither misbranded nor adulterated

- Compliance with GMPs addresses “adulteration”

FDA - Influences

- Inspection vs. Audit
- Regulatory compliance
- Legal implications
- Nonconformities are directly linked to violations of Federal Law

FDA - Impact/Preparation

- Recognize the seriousness
- Remember FDA violations can **potentially** lead to charges.
- Those in the industry take the FDA regulations seriously.

MDD - Medical Device Directive

MDD - Focus/Purpose

- QMS demonstrates fulfillment of the Essential Requirements related to manufacturing

MDD - Influences

- Risk
- Human factors
- Evidence of clinical safety and performance

MDD - Impact/Preparation

- Risk, risk, risk! (Design/process/usability/use risk)
- The three legged stool
- Technical documentation current
- Pay attention to EU MEDDEVs

ISO 13485:2016 - Overview

ISO 13485:2016 - Overview

- **Major Changes** - New or enhanced requirements requiring resources to implement.

- **Minor Changes** - Clarification enhancements

ISO 13485:2016 - Overview

- It's been out well over a year. Published March 1, 2016
- 2018 is your upgrade year.
- CMDCAS certs expire 12/31/17
- Non CMDCAS certs expire 2/28/18
- Annex A: Comparison of content between ISO13485:2003 and ISO 13485:2016.

2016 Revisions - The Big Picture

- Heightened emphasis on Risk Management throughout the whole standard.
- More complete integration of regulatory requirements into QMS.
- More explicit requirements for documentation
- Heightened validation requirements.
- Departure from ISO 9001 and the High Level Structure.

ISO 13485:2016 - Overview

- **Major Changes** - New or enhanced requirements requiring resources to implement.

- **Minor Changes** - Clarification enhancements

ISO 13485:2016 - Major Changes

- 4.1.2 - Apply risk based approach to control processes needed for the QMS
- 4.1.5 - **Outsourced** processes require written quality agreements.
- 4.1.6 - Validation of software used in QMS.
- 7.2.1 and 7.2.2 - Identifying user training needed for specified performance and safe use

ISO 13485:2016 - Major Changes

- 7.5.6 - The organization shall validate any processes for production and service provision where the resulting output cannot be **or is not** verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered.

ISO 13485:2016 - Major Changes

- 7.6 - Software validation procedure for software used for monitoring and measurement of requirements.

ISO 13485:2016 - Minor Changes

Clause 4 - QMS

- QMS process change assessed for impact on ams and devices
- Medical Device File - Mirrors FDA DMR requirements.
- Confidential health information protected
- Changes to records identifiable

Clause 5 - Management Responsibility

- Management Representative responsibility changes - regulatory requirements and QMS requirements
- Management Review procedure
- Reporting to regulatory authorities discussed at Management Review.
- Management Review output contains response to new regulatory requirements.

Clause 6.2 - Human Resources

- Procedure required.

- Effectiveness of training actions proportionate to risk of subject.

Clause 6.3/6.4 - Infrastructure and Work Environment

- Document requirements for infrastructure.
- Maintenance requirements now include work environment.
- Document requirement for control of microorganisms or particulate (Sterile devices only)

Clause 7.1 - Planning of Product Realization

- Document one **or more** processes for Risk Management
- Planning of product realization now includes handling, storage, distribution and traceability activities.

Clause 7.2 - Customer Related Processes

- Need to ensure regulatory requirements are identified and met.
- Communicate with regulatory authorities as required.

Clause 7.3 - Design

- Plan identifies methods to ensure traceability of inputs to outputs.
- Plan identifies resources needed and competencies.
- Verification and validation protocols with methods, acceptance criteria, statistical rationales.
- Verification and validation assessed for devices with connections.
- Validation on representative product, else rationale.
- Design transfer process identified.

Clause 7.4 - Purchasing

- Purchasing information includes product spec and requirements for acceptance.

- Written agreement (as applicable) not to change product or process.

- Method for determining when changes have been made and assessing impact.

Clause 7.5 - Production and Service Provision

- Production controls include qualification of infrastructure.
- Servicing records assessed for complaints and improvement.
- Validation procedure.
- SW Validation proportionate to risk.
- Validation of sterilization and **sterile barrier systems**
- UDI
- Enhanced requirements for protection during transport.

Clause 7.5 - Production and Service Provision

- Production controls include qualification of infrastructure.
- Servicing records assessed for complaints and improvement.
- Validation procedure.
- SW Validation proportionate to risk.
- Validation of sterilization and **sterile barrier systems**
- UDI
- Enhanced requirements for protection during transport.

Clause 7.6 - Measuring Instruments

- Instruments calibrated or verified **or both**
- Adjustments **recorded.**

Clause 8.2.1 - Feedback

- Feedback feeds into Risk Management.
- Post Market Surveillance part of Feedback.

Clause 8.2.2 - Complaint Handling

- Procedure required.
- Enhanced to match FDA requirements.
- Investigation else rationale.

Clause 8.2.3 - Reporting to Regulatory Authorities

- If applicable, procedure.

- Clarification of existing requirements.

Clause 8.2.6 - Monitoring/ Measurement of Product

- Identify equipment used, as appropriate.

Clause 8.3 - Nonconforming Product

- Evaluation of nonconformity includes the need for investigation and notification to external parties.
- Accepted by concession only if justification provided, approval is obtained, and applicable regulatory requirements are met.
- Advisory notice now part of 8.3
- Retain records of rework

Clause 8.4 - Analysis of Data

- Procedure includes determination of appropriate methods, including statistical techniques and extend of their use.

- Service reports now included.

Clause 8.5 - CAPA

- CA made without undue delay.
- Planning of actions documented. (CAPA)
- Verifying actions have no negative impact (CAPA)

Questions and Discussion

Bill McLain

President and Principal Consultant
Keystone Regulatory Services, LLC

www.keystoneregulatory.com
bill.mclain@keystoneregulatory.com
717-656-9656
@keyreg