ASQ SECTION 304 NORTH JERSEY'S VIRTUAL SPRING QUALITY CONFERENCE

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Proposed Changes to 21 CFR 820 Quality System Regulation

Now What?

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Quality Systems Compliance LLC

Est 2012

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ISO 9001:2015 Certified
ISO 13485:2016 Certified

- ✓ ISO 9001
- ✓ ISO 13485
- ✓ ISO 14001
- ✓ ISO 15378
- ✓ IATF 16949
- ✓ ISO/IEC 17025
- ✓ ISO 22442
- ✓ ISO 45001
- ✓ 21 CFR 4
- ✓ 21 CFR Part 210/211
- ✓ 21 CFR Part 820
- ✓ 21 CFR Part 1271
- ✓ EFfCI Cosmetics
- ✓ IFS PACsecure
- ✓ AATB Tissue Banking

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Agenda and Overview

- ✓ Welcome and Introductions
- ✓ Evolution of the Regulation and Standard
- ✓ Summary of the Proposed Changes
- ✓ The Effects of the Proposed Changes
- ✓ Conclusion
- ✓ Questions

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Regulations vs Standards

REGULATIONS

- ✓ A rule or order issued by an executive authority or regulatory agency of government and is used to implement the law
- ✓ 21 CFR 820 Quality System Regulation
- ✓ Medical devices placed on the market fall under 21 CFR 820
- ✓ Regulations can be supported by standards
- ✓ Regulations are compulsory

STANDARDS

- ✓ A universally agreed upon practice that is accepted as the minimum expectation within a given area.
- ✓ Standards are developed by: Industry, Regulators, Academics, Trade Associations, etc.
- ✓ ISO 13485 defines Quality Management System requirements for Medical Devices
- ✓ Standards can be used to support regulations
- ✓ Standards are voluntary

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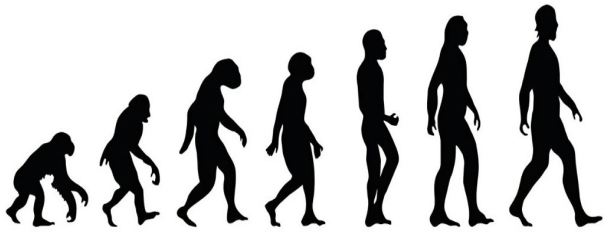
Evolution of the Regulation and Standard



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ISO 13485 Clause Structure

1. Scope
2. Normative References
3. Terms and Definitions
4. Quality Management System
5. Management Responsibility
6. Resource Management
7. Product Realization
8. Measurement, Analysis, and Improvement

ISO 13485

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Current 21 CFR 820 Structure

Subpart A--General Provisions
Subpart B--Quality System Requirements
Subpart C--Design Controls
Subpart D--Document Controls
Subpart E--Purchasing Controls
Subpart F--Identification and Traceability
Subpart G--Production and Process Controls
Subpart H--Acceptance Activities
Subpart I--Nonconforming Product
Subpart J--Corrective and Preventive Action
Subpart K--Labeling and Packaging Control
Subpart L--Handling, Storage, Distribution, and Installation
Subpart M--Records
Subpart N--Servicing
Subpart O--Statistical Techniques

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Current part 820	ISO 13485 Requirements	Proposed Rule
Subpart A--General Provisions	Clause 1. Scope Clause 4. Quality Management System	Requirements substantively similar
Subpart B--QS Requirements	Clause 4. Quality Management System Clause 5. Management Responsibility Clause 6. Resource Management Clause 8. Measurement, Analysis, and Improvement	Requirements substantively similar
Subpart C--Design Controls	Clause 7. Product Realization	Requirements substantively similar
Subpart D--Document Controls	Clause 4. Quality Management System	Differences addressed in 820.35
Subpart E--Purchasing Controls	Clause 7. Product Realization	Requirements substantively similar
Subpart F--Identification and Traceability	Clause 7. Product Realization	Requirements substantively similar
Subpart G—Production and Process Controls	Clause 4. Quality Management System Clause 6. Resource Management Clause 7. Product Realization	Requirements substantively similar
Subpart H--Acceptance Activities	Clause 7. Product Realization Clause 8. Measurement, Analysis, and Improvement	Requirements substantively similar
Subpart I--Nonconforming Product	Clause 8. Measurement, Analysis, and Improvement	Requirements substantively similar
Subpart J—Corrective and Preventive Action	Clause 8. Measurement, Analysis, and Improvement	Requirements substantively similar
Subpart K--Labeling and Packaging Control	Clause 7. Product Realization	Differences addressed in 820.45
Subpart L--Handling, Storage, Distribution, and Installation	Clause 7. Product Realization	Requirements substantively similar
Subpart M--Records	Clause 4. Quality Management System	Differences addressed in 820.35
Subpart N--Servicing	Clause 7. Product Realization	Differences addressed in 820.35
Subpart O--Statistical Techniques	Clause 7. Product Realization Clause 8. Measurement, Analysis, and Improvement	Requirements substantively similar

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Potential Effects on the ISO 13485:2016 QMS

4. Quality Management System
   - Quality Manual
   - Control of Records SOP
   - External Inspections SOP
7. Product Realization
   - Communications SOP
   - Design and Development SOP
   - Control of Production and Service Provision SOP
   - Labeling and Packaging SOP
   - Servicing SOP
   - Identification and Traceability SOP
8. Measurement, Analysis, and Improvement
   - Complaint Handling SOP
   - Reporting to Regulatory Authorities SOP
   - Nonconforming Product SOP

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Certification and Inspections

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Next Steps

- ANSI/AAMI/ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes
- ANSI/AAMI/ISO 13485:2016 - Medical Devices - A Practical Guide
- AAMI TIR102:2019 U.S. FDA 21 CFR mapping to the applicable regulatory requirement references in ISO 13485:2016, Quality management systems
- 21 CFR Part 820 Quality System Regulation (QSR)
- 21 CFR Part 820 Quality Management System Regulation (QMSR)

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