ISO 13485:2016 INTRODUCTION
&
7 KEY CHANGES

Asia-Pacific Economic Cooperation

Regulatory Harmonization Steering Committee
Life Sciences Innovation Forum

APEC Harmonization Center

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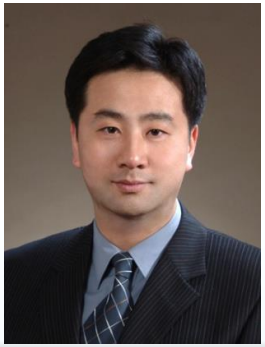
Ver. 1.0

PRESENTER

Profile



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Experience

- **7 Years experience in Medical Device Manufacturer**
- **15 Years experience in EU NB Auditor (MDD & IVD)**
- **NIDS Trainer** (KGMP Auditor course)
- **SGS Korea Medical Device Trainer**
  (ISO 13485:2016, MDR/IVDR ISO 13485 IA, Design control CAPA, Clean room Validation and Usability, MDR TF & IVDR TF, MDR/IVDR QMS and PMS Training etc)

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- Structure & Term
- 7 Key change in ISO 13485:2016
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INTRODUCTION

- ISO / DIS 13485
  - Feb 2015
- ISO / FDIS 13485
  - Oct 2015
- ISO 13485:2016
  - 1 Mar 2016

STRUCTURE & TERM

- ISO 13485:2016 – A structure suitable for the quality management system of medical devices
  - Manufacturer
  - Service Provider (outsourced process)
- Organize Economic Operator in the medical device industry to meet regulatory requirements
- Structure suitable for the life cycle of medical device products

ISO 13485:2016

1. Scope
2. Normative
3. Term and Definition
4. QMS
5. Management
6. Resource control
7. Product Realization
8. Measurement, Analysis and Improvement

NEW TERMS

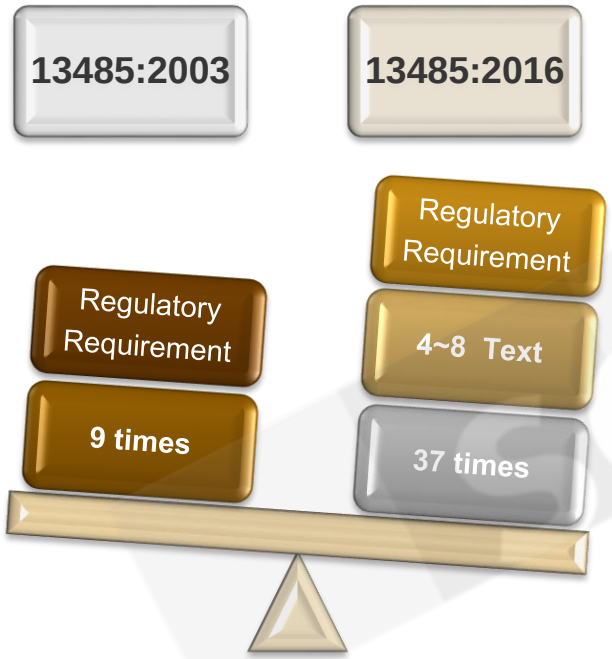
- New Terms and definition of ISO 13485:2016

ISO 13485 Clause	Terms
3.2	Authorised Representative
3.3	Clinical Evaluation
3.5	Distributor
3.7	Importer
3.9	Life-Cycle
3.10	Manufacturer
3.12	Medical Device Family
3.13	Performance Evaluation
3.14	Post-Market Surveillance
3.16	Purchased Product
3.17	Risk
3.18	Risk Management
3.19	Sterile Barrier System

ISO 13485 KEY CHANGE

- Focus on internationalized ‘Regulatory Requirements'
- Application of ‘Risk Management’ across quality systems
- Clear demand for ‘Design Verification and Validation activities'
- Improve the ‘Supplier Control' process
- Improved ‘Feedback Processes’
- Clear requirements for QMS ‘Validation’ incl. S/W
- ‘Identify and Traceability' Hardened Requirements

1. REGULATORY REQUIREMENTS



- Highlight organizations that fit regulatory requirements for customer safety and performance
- Requires an impact assessment on regulatory requirements in the manufacturer's activities
- Communicate with regulators about regulatory requirements that apply
- Assess the impact of 'applied regulatory requirements' on product design changes

2. RISK MANAGEMENT

- Document one or more processes for risk management across product realization activities
- Results of design changes are reviewed through risk management
- Risk management assessment of the data in the feedback process is documented

3. DESIGN CONTROL

- Planning and review of design and development is documented throughout the design process
- Outputs for design and development should be traceable to relevant design inputs
- Resources in the design and development process should be documented, including the competence of participants.
- Design validation, design validation, and design transfer
- Addition of Design Transfer and DHF

4. SUPPLIER CONTROL

- ‘Contract' between the organization and its supplier is provided, including notification of major changes
- Risk based supplier evaluation, monitoring and inspection.
- Purchasing product changes require the review of product realization and medical devices

5. FEEDBACK PROCESS

- Documentation of how feedback is collected
- Data supporting feedback includes production and post-production activities
- Feedback is applied as risk management, product realization and design input
- Requirements for handling segmented and specialized complaints

6. VALIDATION

- Acceptance criteria, statistical techniques and sample sizes used for validation must be documented
- If applicable, product compatibility with other medical devices should be completed during validation
- Software must be validated to match the level of potential risk to the product.
- Results, conclusions and further actions of validation must be documented.

7. ID & TRACEABILITY

- Identifying product status throughout the product realization process
- UDI(Unique Device Identification) system documentation.
- Specific requirements, including records of traceability of implanted devices

FDA 21 CFR PART 820 COMPATIBILITY

- Apply additional FDA requirements such as design transfer, DMR, and DHF
- Clarification of provisions applicable to the reporting procedures (MDR)
- Adding procedures for reporting changes from suppliers

MDSAP COMPATIBILITY

- MDSAP compatible and NC Matrix (NC 1~ 5)

- Indirect QMS (4.1 ~ 6.3)
  - First Issue : 1
  - Same Clause re-issue : 2
  - No Process & Procedure : + 1
- Direct QMS Clause (6.4 ~ 8.5)
  - First Issue : 3
  - Same Clause re-issue : 4
  - No Process & Procedure : + 1
- Release Nonconforming products outside QMS management : +1

SUMMRY

- The scope of ISO 13485:2016 has been extended to include all economic operator in the medical device industry.
  (eg. Manufacture, Importer & Distributor)

- ISO 13485:2016 requires an organization to apply a risk-based approach to quality management systems and product realization systems.

- ISO 13485:2016 highlights organizations suitable for all applicable regulatory requirements.

Q&A