Content Overview E-Learning Library

Learning Units

In vitro Diagnostic Medical Devices

- Introduction
- IVD Qualification, Regulatory Framework, Definitions, Areas of Application
- Implementing Rules for Classification
- Overview of Tasks – Categories for Approval under IVDR
- How to Know When Conformity has been Achieved
- Qualifying Devices as IVD – Comparing Intended Purpose and IVD Definition
- Product Types – Understanding the Relationships between Products
- Implementing the Strategy – Creating Product-Specific Files
- IVD Conformity Assessment
- Qualifying your own Device as an IVD
- The Seven Rules of IVD Classification
- Milestone Planning
- Gap Analysis of Technical Documentation
- Qualification and Differentiation of Combination Products
- Classification of Combination Products
- Developing a Project Plan
- Verifying Conformity – How to Find and Avoid Typical Errors

An Introduction to the Legal System under MDR

- Introduction
- General Requirements
- Classification
- Conformity Assessment Procedures
- Unique Device Identification
- Clinical Evaluation & PMCF
- Post-Market Surveillance
- Roles
- Quality Management System

Regulatory Basics: Is your product a medical device?

- Introduction & Basics for Successful FDA Clearance
- The Various FDA Clearance Procedures
- Introduction - Qualification
- Intended Use and Intended Purpose
- Classification
- General Safety and Performance Requirements

FDA Clearance

- Introduction & Basics for Successful FDA
- Clearance
- The Various FDA Clearance Procedures
- 510(k) Procedures
- Your Path to FDA Clearance
- Predicate Device Strategy
- 510(k) Variants, RTAs and AI Requests, and
- Special Cases Involving Software
- Product Changes, Labeling, Sterilization,
- Shelf Life, and Biocompatibility
- De Novo, Breakthrough, and STeP, QSR
- & QMSR and Software Guidelines
- Medical Device Reporting, Corrections &
- Removals, eMDR, and Testing
- End of Course

MDR for Auditors

- Welcome
- Scope
- Chapter 2
- Annex I, Part 1
- Annex I Software
- Annex II
- Classification
- Conformity Assessment
- Quality Management System
- Post-Market Surveillance
- Economic Operators
- PLM-OEM

Unique Device Identification (UDI)

- Introduction
- Basics
- Device Categories
- Basic UDI
- Regulatory Requirements
- Allocation and Assignment of UDIs
- GS1
- HIBCC
- UDI Application
- UDI Carriers
- Affixing
- Implants
- Systems and Procedure Packs
- IVDR
- Configurable Devices
- UDI for Software
- New UDI
- EUDAMED
- Differences FDA
- Transition Periods

Person Responsible for Regulatory Compliance (PRRC)

- Introduction
- Regulations
- Obligation to PRRC
- Qualification
- Responsibilities (Overview)
- Product Release
- Technical Documentation
- Post-Market Surveillance
- Vigilance, Reporting Obligations (Part 1)
- Vigilance, Reporting Obligations (Part 2)
- Investigational Devices
- Find a PRRC

Technical Documentation

- Welcome & Introduction
- Regulatory Basics
- Overview of QM Requirements
- The Initial Structure
- MDR Annex I
- Relevant SOPs
- Structure for International Approvals
- Annex II
- SOPs of the Johner Institute
- Product-Specific Structure
- MDR Annex III
- Medical Device File
- Sorting Documents
- Standards
- TD Review
- Checklists
- Meta Requirements
- Updates

Risk Management according to ISO 14971

- An Introduction to Risk Management
- Definition of Terms
- Risk Acceptance Matrix: Introduction
- Risk Acceptance Matrix: Severity Axis
- Risk Acceptance Matrix: Probability Axis
- Risk Acceptance Matrix: Acceptance Criteria
- Risk Analysis: Introduction
- Risk Analysis: General
- Risk Analysis: PHA
- Risk analysis: FMEA
- Risk analysis: FTA
- Risk analysis: Special Case Software
- Risk analysis: Probabilities
- Risk Control
- Risk Management: Post-Production Phase
- Documentation and ISO 14971: Documentation
- The Standard for Risk Management: ISO 14971
- Risk Analysis: Software Specifics

Intended Purpose for a Product that is not your own

- Your Mission
- Preparation
- Fundamental Principles
- Review the Intended Purposes (Part 1)
- Working with Templates
- IEC 62366-1 and Intended Use
- Review the Intended Purposes (Part 2)
- Intended Purpose for Third-Party Devices
- Requirements of ISO 14971
- Intended Purpose for Own Devices
- Conflict Prevention and Resolution

The Software Development according to IEC 62304

- Software-Lifecycle: Introduction
- Software-Lifecycle: V-Model
- Software requirements: Introductions
- Software Requirements: User Interface
- Software Requirements: Data Interface
- Software Requirements: Other Interfaces
- Software Requirements: Documentation, Verification
- Software Architecture: Introduction
- Software Architecture: Regulations
- Software Architecture: Safety Classification
- Software Architecture: Documentation & Verification
- Software-Tests: Unit-Tests
- Software-Tests: Integration Test
- Software-Tests: System Test
- Software file: Release

Usability according to IEC 62366-1

- Basics: Introduction
- Basics: Terms and Concepts
- Basics: Regulations
- Basics: The Process
- IEC 62366-1: Part 1 – Introduction
- IEC 62366-1: Part 2 – “Use Specification”
- IEC 62366-1: Part 3 – Risk Management
- IEC 62366-1: Part 4 – UI Specification
- IEC 62366-1: Part 5 – UI Evaluation
- IEC 62366-1: Part 6 – UOUP
- IEC 62366-1: Part 7 – Documentation
- Methods 1: Overview
- Methods 2: Prototyping
- Methods 3: Formative Procedure
- Methods 4: Usability Test

Clinical Evaluation according to MEDDEV 2.7/1 rev. 4

- Objectives of the Series
- Basics
- Regulations: EU MDR
- Regulations: EU MDR MDD
- Regulations: EU – Further Requirements
- Regulations: MEDDEV
- Regulations: Waiver
- General Concepts: Omitting
- General Concepts: Procedure
- General Concepts: Equivalence 1
- General Concepts: Equivalence 2
- Planning: Regulatory Requirements
- Planning: Documentation
- Planning: Evaluation Criteria
- Literature: Sources
- Literature: Search
- Literature: Process
- Literature: Individual Evaluation
- Literature: Conclusions
- Concepts: Medical Writing
- Concepts: Interfaces 1
- Concepts: Interfaces 2

Biocompatibility

- Biocompatibility ISO 10993-1 – Material Certificates Are Not Enough!
- Cytotoxicity Test according to EN ISO 10993-5: Avoid Pitfalls in Laboratory Selection
- No Animal Testing to Prove Biocompatibility
- EN ISO 18562: Biocompatibility of Respiratory Tracts in Medical Applications
- ISO 17664-1 – Information on the Reprocessing of Medical Devices

Quality Management according to ISO 13485

Introduction to QMS and ISO 13485

- Objectives
- Fundamentals
- The Path to QMS
- Standards and Regulations

ISO 13485 – QM Manual

- QMM 1: Quality Policy
- QMM 2: Quality Objectives

ISO 13485 – QM System: Roles and Responsibilities

- Roles and Responsibilities 1: Fundamentals
- Roles and Responsibilities 2: Regulations
- Roles and Responsibilities 3: QMR

ISO 13485 – QM System: Processes and Procedures

- Processes and Procedures
- Create a List of SOPs
- Contents of Standard Operating Procedures
- Contents of Standard Operating Procedures II
- Write Standard Operating Procedures
- Review Standard Operating Procedures

ISO 13485 – QM System: Document Control

- Basics
- Regulations
- Define Measures
- Write Standard Operating Procedures

ISO 13485 – QM System: Development

- Introduction
- ISO 13485
- ISO 9001:2015
- IEC62366:2015
- IEC60601-1
- IEC62304
- SOP Development Options
- SOP Development Structure

ISO 13485 – QM System: Development

- Introduction
- ISO 13485
- ISO 9001:2015
- IEC62366:2015
- IEC60601-1
- IEC62304
- SOP Development Options
- SOP Development Structure

ISO 13485 – QM System: Risk Management

- Write SOP Risk Management
- Synchronize SOP Risk Management with Development

ISO 13485 – QM System: Management Review

- Regulations
- SOP Management Review

ISO 13485 – QM System: Internal Audits

- Introduction
- Regulations
- Writing SOPs for Internal Audits

ISO 13485 – QM System: Purchasing

- Introduction
- Regulations
- Writing SOPs for Purchasing

ISO 13485 – QM System: Response – Measures

- Introduction
- Regulations
- Vigilance
- CAPA

ISO 13485 – QM System: Training

- Training 1: Introduction
- Training 2: Regulations
- Training 3: Standard Operating Procedures Training

ISO 13485 – QM System: Production

- Production 1: Preliminary Remarks
- Production 2: Black Box
- Production 3: Production Process
- Production 4: Production Risks
- Production 5: Risk Control Measures
- Production 6: Identification
- Production 7: Traceability
- Production 8: Standard Operating Procedures
- Production 9: Production Audit

ISO 13485 – QM System: Process Validation

- Process Validation 1: Fundamentals
- Process Validation 2: IQ, PQ, OQ
- Process Validation 3: Regulations

ISO 13485 – QM System: Storage and Transport

- Storage and Transport 1: Introduction
- Storage and Transport 2: Measures
- Storage and Transport 3: Risk Management
- Storage and Transport 4: Regulations

ISO 13485 – QM System: Sales

- Sales 1: Introduction
- Sales 2: Risks
- Sales 3: Measures & SOPs
- Sales 4: Regulatory Requirements

ISO 13485 – QM System: Infrastructure

- Infrastructure: Part 1 Introduction
- Infrastructure: Part 2 Requirements
- Infrastructure: Part 3 Maintenance Activities & Documentation

ISO 13485 – QM System: Measuring Equipment

- Measuring Equipment 1: Introduction
- Measuring Equipment 2: Regulatory Requirements 13485 (Overview)
- Measuring equipment 3: Regulatory Requirements 13485 (7.6 - Part 2 - Measuring Equipment)
- Measuring Equipment 4: Regulatory Requirements 13485 (7.6. - Part 3 - Software)
- Measuring Equipment 5: Regulatory Requirements 13485 (Standard Operating Procedure)

IT Security for Medical Devices

- Overview
- Definitions
- Protection Goals
- The Context
- Regulations: The Regulations
- Regulations: EU Laws
- Regulations: Harmonized Standards
- Regulations: FDA
- Vulnerability Analysis: An Overview
- Vulnerability Analysis: Objects
- Vulnerability Analysis: Threats
- Vulnerability Analysis Methods: An Introduction
- Vulnerability Analysis Methods: Checklists
- Vulnerability Analysis Methods: Additional Checklists
- Vulnerability Analysis Methods: Your Own Data
- Vulnerability Analysis Methods: Input-Output Analysis
- Penetration Testing: Introduction
- Penetration Testing: Procedure
- Penetration Testing: Brute Force
- Penetration Testing: Reverse Engineering

Computerized System Validation

- Computerized System Validation – An Introduction
- Definition of Terms 1
- Definition of Terms 2
- Regulations: Europe
- Regulations: USA
- Regulations: Rest of the World
- The CSV Process: Overview
- The CSV Process: Intended Purpose and Validation Obligation
- The CSV Process: Criticality
- The CSV Process: The Validation Plan
- The CSV Process: Test Specifications
- The CSV Process: Test Execution and Documentation

Artificial Intelligence

- Fundamentals of AI: Objectives
- Fundamentals of AI: Introduction
- Fundamentals of AI: Definitions
- Methods: Overview
- Methods: Linear Regression
- Methods: Logistic Regression
- Methods: Support Vector Machines
- Methods: Clustering
- Methods: Bayesian Classifiers
- Methods: Decision Trees
- Methods: Random Forests
- Methods: Neural Networks – Introduction
- Methods: Neural Networks – Image Recognition
- Methods: Neural Networks – Fit Parameters
- Regulations: EU – MDR
- Regulations: EU – MDR Annex I
- Regulations: EU – MDR Annex II + III
- Regulations: Harmonized Standards
- Evaluation of Algorithms: Challenges
- Evaluation of Algorithms: Framework
- Evaluation of Algorithms: Quality Measures 1
- Evaluation of Algorithms: Quality Measures 2
- Explainable AI: Introduction
- Explainable AI: Stakeholders
- Explainable AI: Interpretability
- Explainable AI: Taxonomy

LLM Power for Medical Device Ecosystem

- Sprint 1: Introduction, Basics, and Definitions
- Sprint 2: Context Engineering
- Sprint 3: Institutionalization
- Sprint 4: Regulatory Requirements
- Sprint 5: Outlook and Becoming an AI-first Company

Additionally Included in the Auditgarant

AI Act for Medical Device and IVD Manufacturers

- Sprint 1: Introduction, Awareness and Motivation
- Sprint 2: Regulatory Basics
- Sprint 3: Gap Analysis
- Sprint 4: Implementation Planning
- Sprint 5: Roles and Competences
- Sprint 6: Implementation
- Sprint 7: Review, Retrospective and Completion