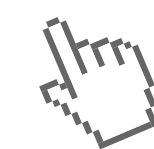


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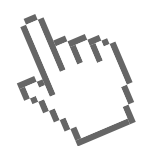


Tip: Clicking on a chapter heading will take you directly to that chapter!

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Courses



Regulatory Basics: Is your product a medical device?

- Introduction - Qualification
- Intended Use and Intended Purpose
- Classification
- General Safety and Performance Requirements

An introduction to the legal system according to MDR

- Welcome
- Introduction
- Essential requirements
- Classification
- Conformity assessment

- Unique Device Identification
- Clinical Evaluation & PMCF
- Post Market Surveillance
- Roles
- Quality Management



In vitro diagnostic medical devices

- Introduction
- Sprint 1.1: IVD qualification Regulatory framework, definitions, areas of application
- Sprint 1.2: Implementation rules for classification
- Sprint 1.3: Overview of tasks for approval under IVDR
- Sprint 1.4: How we know when conformity is achieved
- Sprint 2.1: Qualifying products as IVDs - comparison of intended purpose and IVD definition
- Sprint 2.2: The product types
- Sprint 2.3: Implementing the strategy - creating product-specific files
- Sprint 2.4: IVD conformity assessment
- Sprint 3.1: Qualify your own product
- Sprint 3.2: The seven rules of IVD classification
- Sprint 3.3: Milestone planning
- Sprint 3.4: GAP analysis of the technical documentation
- Sprint 4.1: Qualification and differentiation of combination products
- Sprint 4.2: Classification of combination products
- Sprint 4.3: Develop project plan
- Sprint 4.4: Assessing conformity and how to avoid typical errors



AI Act for medical device and IVD manufacturers

- Sprint 1: Introduction, Awareness and Motivation
- Sprint 2: Regulatory Basics
- Sprint 3: Gap analysis
- Sprint 4: Planning the implementation
- Sprint 5: Roles and Competencies
- Sprint 6: Implementation
- Sprint 7: Conclusion

FDA approval - create your submission file

- Sprint 1: Introduction & Basics for Successful FDA Approval
- Sprint 2: The various FDA approval procedures
- Sprint 3: 510(k) submission file
- Sprint 4: Your path to FDA approval
- Sprint 5: Predicate Device Strategy
- Sprint 6: 510k Variants
- Sprint 7: Product Changes, Labeling, Sterilization, Shelf Life and Biocompatibility
- Sprint 8: Select approval procedure
- Sprint 9: Medical Device Reporting, Corrections & Removals, eMDR and Testing
- Sprint 10: End of the course

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



Structured data for LLMs

- Welcome
- Modeling
- Exercise: Modeling
- Solutions hints: Modeling
- YAML - A Gentle Introduction
- Exercise: YAML
- Solution Hints: YAML
- JSON - The Structured Alternative
- Exercise: JSON
- Solutions hints: JSON
- JSON Schema - The Structure of the Structure
- Exercise: JSON Schema
- Solutions hints: JSON Schema
- JSON Schema „Advanced“
- Exercise: Practical Application
- Solutions hints: Practical Application
- Outlook



The intended purpose

- Your mission
- Preparation
- Fundamental principles
- Regulatory requirements
- Review the intended purpose (part 1)
- Working with templates
- Intended use
- IEC 62366-1 and context of use
- Review the intended purpose (part 2)
- Intended purpose for a product that is not your own
- Requirements of ISO 14971
- Intended purpose of your own product
- Conflict prevention and resolution

Technical documentation

- Sprint 1.1: Welcome & Introduction
- Sprint 1.2: Regulatory Basics
- Sprint 1.3: Overview of QM requirements
- Sprint 2.1: The first structure
- Sprint 2.2: MDR Annex I
- Sprint 2.3: Relevant SOPs
- Sprint 3.1: Structure for international approvals
- Sprint 3.2: Annex II
- Sprint 3.3: SOP of the Johner Institute
- Sprint 4.1: Product-specific structure
- Sprint 4.2: MDR Annex III
- Sprint 4.3: Medical device file
- Sprint 5.1: Sorting the documents
- Sprint 5.2: Standards
- Sprint 5.3: TD Review
- Sprint 6.1: Checklists
- Sprint 6.2: Meta requirements
- Sprint 6.3: Update



Quality Management (ISO 13485)

- Introduction to QMS and ISO 13485
- QM Manual
- QM system: roles and responsibilities
- QM-System: Processes and procedures
- QM-System: Document Control
- QM-System: Development
- QM-System: Risk Management
- QM system: Management Review
- QM system: Internal Audits
- QM system: Purchasing
- QM system: Feedback-Measures
- QM system: Training
- QM system: Installation & Maintenance
- QM system: Production
- QM-System: Process Validation
- QM-System: Storage and Transport
- QM-System: Sales
- QM system: Infrastructure
- QM system: Measuring equipment

The person responsible for regulatory compliance (PRRC)

- Introduction
- Regulations
- Obligation to have a PRRC
- Qualification
- Responsibilities (overview)
- Product release
- Technical Documentation
- Post Market Surveillance
- Vigilance, Reporting 1
- Vigilance, Reporting 2
- Investigational devices
- Finding PRRC



Risk management according to ISO 14971

- An introduction to risk management
- Definitions
- Risk assessment matrix: Introduction
- Risk acceptance matrix: Severity Axis
- Risk assessment matrix: Probability Axis
- Risk assessment matrix: Acceptance Criteria
- Risk Analysis: General
- Risk Analysis: PHA
- Risk Analysis: FMEA
- Risk Analysis: FTA
- Risk Analysis: Software Specifics
- Risk Analysis: Probabilities
- Risk Control
- Risk management: Post Production
- Documentation and ISO 14971: Documentation
- The standard for risk management: ISO 14971
- ISO 14971:2019 Scope/Definitions
- ISO 14971:2019 Risk Management Process
- ISO 14971:2019 Post Market



The Unique Device Identification (UDI)

- Introduction
- Basics
- Product categories
- Basic UDI-DI
- Regulatory requirements
- Allocation and assignment of UDI
- GS1
- HIBCC
- UDI carrier
- Application
- Implants
- Systems and procedure packs
- IVDR
- Configurable products
- UDI and Software
- New UDI
- EUDAMED
- FDA differences
- Transition periods



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 engineering according to IEC 62366-1

- Basics: Introduction
- Basics: Definition of terms
- Basics: Regulations
- Basics: Process
- IEC 62366-1: Part 1
- IEC 62366-1: Part 2 - Subclause 5.1
- 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 procedures
- Methods 4: Usability tests
- Human Factors: Chapter 6
- Human Factors: Chapter 7
- Human Factors: Chapter 8



Clinical evaluation according to MEDDEV 2.7/1 Rev 4

- Goals of the series
- Basics
- Regulations: EU-MDR
- Regulation: EU-MDR-MDD
- Regulations: More EU
- Regulations: MEDDEV
- Omitting
- General Concepts: Claims
- General Concepts: Process
- General Concepts: Equivalence 1
- General Concepts: Equivalence 2
- Planning: Regulations
- 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



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
- Roles
- PLM-OEM

Computer System Validation

- Computer System Validation - An introduction
- Definitions 1
- Definitions 2
- Regulations: EU
- Regulations: USA
- Regulations: Rest of the world
- The CSV process: Overview
- The CSV process: Intended purpose and validation requirement
- The CSV process: Criticality
- The CSV process: The validation plan
- The CSV process: Test specifications
- The CSV process: The execution and documentation of tests

Biocompatibility

- ISO 10993-1 and Biocompatibility - Material Certificates Are Not Enough!
- Cytotoxicity Testing According to EN ISO 10993-5: Avoiding Pitfalls When Choosing a Laboratory
- No animal testing to prove biocompatibility
- EN ISO 18562: Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications
- ISO 17664-1 – Information on Processing of Medical Devices



IT security for medical devices

- Overview
- Definitions
- Safety objectives
- Context
- Regulations: An overview
- Regulations: IT security and EU laws
- Regulations: Harmonized standards
- Regulations: FDA
- Analysis of vulnerabilities: Overview
- Analysis of vulnerabilities: Objects
- Analysis of vulnerabilities: Threats
- Vulnerability Analysis Methods: Checklists
- Vulnerability Analysis Methods: More checklists
- Vulnerability Analysis Methods: Your own data
- Vulnerability Analysis Methods: Input-output analysis
- Penetration testing: Procedure
- Penetration testing: Brute Force
- Penetration testing: Reverse Engineering



Artificial intelligence

- Basics of AI: Goals
- Basics of AI: Introduction
- Basics of AI: Definitions
- Methods: Overview
- Methods: Linear regression
- Methods: Logistic regression
- Methods: Support Vector Machines
- Methods: Clustering
- Methods: Bayes
- Methods: Decision trees
- Methods: Random Forrests
- 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: Measures of quality 1
- Evaluation of algorithms: Measures of quality 2
- Explainable AI: Introduction
- Explainable AI: Stakeholders
- Explainable AI: Interpretability
- Explainable AI: Taxonomie

Templates



Note:

Templates are provided in German and/or English, where available



1. Types of templates

Type	Description	Purpose/Benefit
SOP	Standard Operating Procedure	Describes mandatory processes and procedures within the company (Who does what, when, and how?). Forms the basis for the quality management system.
FOR	Form	Operational checklists and forms used to directly generate documentation (e.g., evaluations, inspections).
TPL	Template	Structured documentation templates that are filled out on a product- or project-specific basis (e.g., plans, reports).
LIS	List / Index	Overviews, indexes, and directories for management, tracking, and monitoring (often Excel-based).



2. Templates for Quality Management in accordance with ISO 13485

Quality Management & Organization

Domain	Number of templates	Brief description
QM-Manual (QM)	4	Core documents of the QM system: QM Manual, Quality Policy and Quality Objectives, Communication
Management Review & Audit (MR / IA / UA)	10	Management review and internal or unannounced audits: Process descriptions and templates for plans and reports
Corrective and preventive actions (CA)	3	CAPA Process, including form and overview
Document & Record Control (DC)	9	Document control, templates for SOP, LIS and TPL
Human Resources & Training (HR)	6	Recruitment, Training & Evidence of Effectiveness

Infrastructure, Development & Operations

Domain	Number of templates	Brief description
Infrastructure (IS)	15	SOPs for IT systems, CSV, measuring equipment, and the work environment, including lists and templates for validation plans and reports, as well as test reports
Development and Product Management	18	SOPs covering the entire product lifecycle: including risk management, product development, software development, clinical evaluation/performance evaluation, risk management, IT security, AI development, clinical follow-up, biocompatibility
Production & Service Delivery (PR / SU / LG / PSA / LA)	16	Production, Process Validation, Product Labeling, Warehouse, Support
Change Management (CC)	3	Changes to the Product and Quality Management System



Supplier Management & Procurement

Domain	Number of templates	Brief description
Supplier Management & Procurement (SA / PS)	10	Management of Sales, Purchasing, and Suppliers: Selection, Monitoring, and Evaluation of Suppliers, Non-Disclosure Agreements, and Quality Assurance

PMS & Regulatory

Domain	Number of templates	Brief description
Post-Market Surveillance, Feedback (CH, PM)	10	SOPs and templates for MDR/IVDR-compliant complaint handling and post-market surveillance (plan and report)
Authorities and Regulatory Affairs (TF, RU, VI)	9	Market authorization and regulatory oversight in accordance with the MDR and IVDR, as well as product approval and incident assessment for the U.S. market



3. Templates for Technical Documentation

Technical Documentation

Domain	Number of templates	Brief description
Technical File (TF)	11	Support for classification and compliance with the MDR and IVDR: MDR/IVDR checklists based on Annexes I–III, classification forms, IVDD–IVDR gap analysis, and a template for the declaration of conformity



Note: These documents serve as guidelines and framework documents. They do not replace the complete technical documentation.



Product Review, Risk & Safety

Domain	Number of templates	Brief description
Design Input (DI)	5	Documentation of MDR/IVDR-compliant intended use and stakeholder requirements
Risk Management File (RM)	6	Risk management according to ISO 14971
Usability File / Human factors (HF)	5	Suitability for use according to IEC 62366-1
Clinical Evaluation (CE)	6	Clinical evaluation and literature review according to MDR
Post-Market-Clinical-Follow-Up (CF)	2	PMCF plan & report in accordance with MDR
Development (PD)	15	PMCF Plan & Report in accordance with MDR: Structured Product Development (MDR & IVDR): Development plans and product requirements, product design specifications, checklists for design reviews, forms for design freeze, design transfer, and development approval, as well as a traceability list for product development
IVD-Performance Evaluation (PE)	17	Performance evaluation according to the IVDR
Labeling (LA)	4	MDR/IVDR-compliant labeling and instructions for use (IFU), as well as a checklist for reviewing the IFU
Biocompatibility (BC)	2	Templates for assessing biological safety in accordance with ISO 10993



Software, AI & IT-Security

Domain	Number of templates	Brief description
Software File (SW)	21	Templates for documenting the software lifecycle in accordance with IEC 62304
Artificial Intelligence (AI)	7	Documentation of AI models, training data and processes, labeling
IT-Security (IT)	12	Cybersecurity & Security-PMS
IT-Security Risk-Management (ITRM)	5	Specific risk management for IT security: security-related features, security risk and vulnerability management, security risk management plan and report (MDR/IVDR-compliant)