CERTIFICATE

We hereby certify

MDU
Medical Device University

Annett Arndt

the successful graduation of the following courses of the
E-Learning-Offer MDU of the Johner Institute:

Course: Risk management according to ISO 14971 (19 videos with a total length of 110 minutes.)

The following knowledge was taught in this course:

- Regulatory requirements for risk management according to ISO 14971:2019 and Medical Device Regulation 2017/745 (MDR)
- Important definitions of terms in risk management (harm, hazard, risk, probability, hazardous situation, severity)
- What a risk acceptance matrix is, and how product-specific acceptance criteria and severity and probability axes can be derived
- Methods for risk analysis: FMEA, FTA and PHA
- Best practice tips for finding probailites for the occurence of harm
- Risk control options: inherent safety, protective measures or information
- Post-production phase and how it relates to post-market surveillance (PMS) of the MDR
- What documents need to be prepared for an ISO 14971-compliant risk management file

As an effectiveness test for the contents learned, 14 out of a total of 14 self-tests were successfully answered, which corresponds to a **rate of 100%**.

Course: Technical documentation (1 tasks)

The following knowledge was taught in this course:

- **Regulatory Requirements:**
- The regulatory requirements for technical documentation (TD) according to MDR/IVDR, especially Annexes I, II, and III.
- Understanding of the demands of Annexes I, II, and III, their interrelation, and how evidence of conformity to the requirements of the annexes can be provided.
- Connection between the demands of Annexes I, II, and III and standards, guidelines, and common specifications.
- Additional specific requirements and/or content demanded by standards such as ISO 14971, IEC 62304, and IEC 62366-1.
- Retention periods and language requirements for technical documentation.

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- **Structure of Technical Documentation (TD):**

- Options for structuring product-specific technical documentation.
- Aspects to ensure that the TD is presented in a "clear, organized, easily searchable, and unambiguous form."
- Formal aspects that must be fulfilled for compliant technical documentation.
- Distinction between a filing structure and a submission structure.
- Market-specific requirements for a submission structure.
- Possible tools for managing technical documentation.
- **Integration of TD into a Quality Management System (QMS):**

- Interaction between technical documentation and a quality management system (and resulting records).
- Best practices for a procedure manual for the creation, compilation, and approval of technical documentation.
- Relevant roles and activities needed to compliantly represent the creation, compilation, approval, and updating of TD in a quality management system.
- Specifics when collaborating with suppliers.
- Typical errors in TD creation and aspects that auditors and reviewers should pay particular attention to.

Constance, the 4th September 2024

Prof. Dr. Christian Johner

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