Johner Institute

e-Learning platform guides you to FDA approval and CE-mark

The e-Learning platform instructs manufacturers of active medical devices to develop, document and register products as quickly, easily, and safely as possible without having to read 100+ regulatory documents.

Online Training Courses

The e-Learning platform offers comprehensive online courses that help navigate the medical device approval process in the US (FDA) and Europe (CE-mark) consisting of:

1. 60+ instructional **videos**
2. **Templates** and example documents to accelerate compiling submisson files even more
3. **Transcripts**
4. **Self-assessments** and **certificates**

The Content

The training videos and templates cover:

- **Regulatory affairs**: Legal frameworks, FDA approval processes, CE-marking
- **Risk management & ISO 14971**: Risk analysis, mitigation and acceptance. Documenation
- **Human factors engineering & IEC 62366**: Usability specification, formative and summative evaluation. Documentation
- **Software life cycle & IEC 62304**: Requirements, architecture, unit, integration and system testing, safety classes, SOUP
- and much more

The Target Group

The e-Learning platform is specifically made for these manufacturers of active medical devices and engineering service providers:

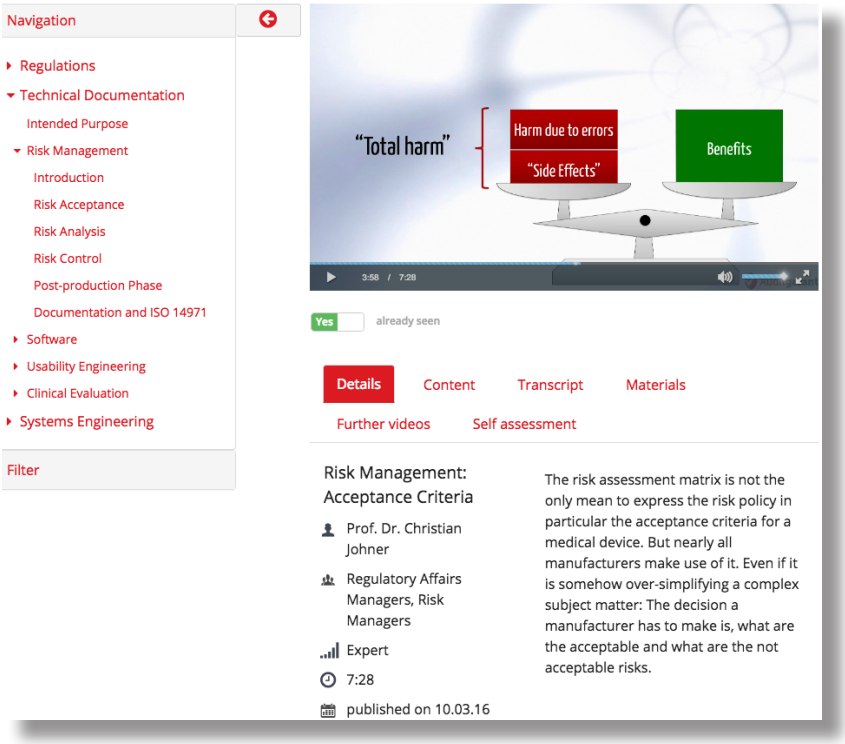
1. **Small and medium size companies** including **start-ups** that are new to medical device regulation and that want to ensure legal compliance while still quickly bringing the device to market
2. Medical device **enterprises** that want to consistently and efficiently train employees.

The Johner Institute

When it comes to regulatory affairs, medical device software, risk management and human factors engineering, the Johner Institute is **the** consultancy and training provider for medical device manufacturers, engineering service providers, and most of the German notified bodies.

With no exception, all of Johner Institute's customers (several hundred) passed audits, inspections and submissions successfully.

Screenshot (example: Defining risk acceptance criteria)



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