Knowledge Foundation
@ Reutlingen University

Regulatory Thinking Basics

Certificate Programme: Regulatory Thinking (Course 1)

"Regulatory thinking means knowing and mastering regulatory requirements and strategically combining them with business aspects in a way that competitive advantages are created. "

- Ingo Hämmerle, Medical Innovations Incubator (creator of the programme & course lecturer)

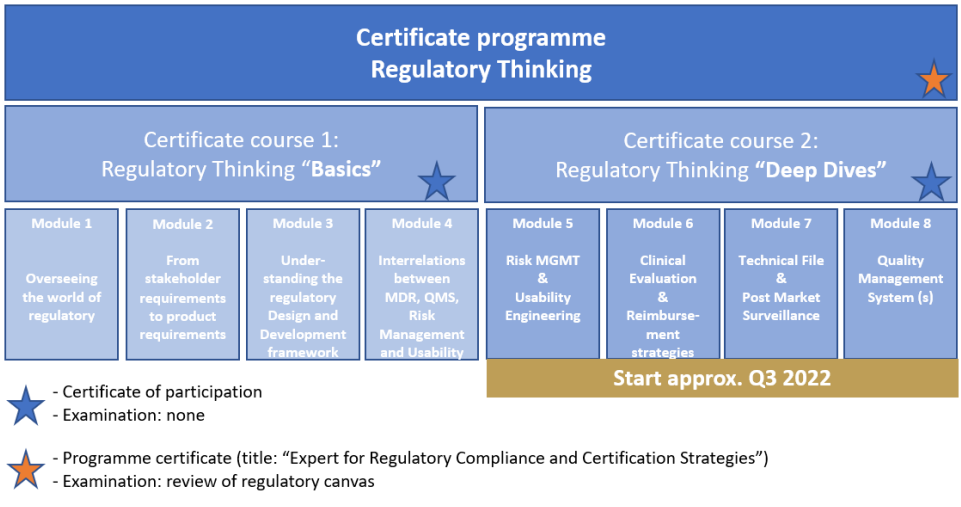
"Regulatory Thinking covers the development process of a new medical device from the idea through laboratory, in vitro and in vivo testing and the approval process with a view to market application. With this course, you define the right path for your company's success from the very beginning. "

- Prof. Dr. Rumen Krastev, Dean of the Faculty of Applied Chemistry at Reutlingen University

Content

This certificate programme is not only about imparting knowledge, but above all about the practical further development of one's own project. The course is therefore designed for practitioners! The limited number of participants enables the lecturers to give direct and intensive feedback to the participants. Thus, in the sense of "Regulatory Thinking", one's own regulatory roadmap and at the same time one's own business model will be further developed efficiently. Building up know-how and productive work go hand in hand in this course.

The programme consists of two certificate courses to be completed: Regulatory Thinking Basics and Regulatory Deep Dives with the respective associated modules. Successful completion of both certificate courses and the successfully passed project work together result in the successfully completed certificate programme Regulatory Thinking and lead to the certificate "Expert for Regulatory Compliance and Certification Strategies".



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Further Information
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Learning goals

Overall programme goals

- High-level know-how and methods on the strategically relevant regulatory topics for obtaining a company and product development in the medical life sciences.
- Interconnected knowledge of the relevant strategic topics.
- Minimization of fear of contact regarding Regulatory Affairs and Quality Management Systems.
- Understanding of the positive impact of a Regulatory Thinking approach and the associated high strategic value for product and company development.
- Minimization of expensive consulting costs by getting to know the primary literature and establishing a contextual understanding.
- Empowerment to build a QMS/RA department and develop a sense of the proper selection of personnel in this area.
- Orienting participants to the complex world of regulatory compliance and allowing them to independently develop their own path.

Learning goals certificate course 1 “Regulatory Thinking Basics”

The participants know the essential building blocks for obtaining a product and company approval. Furthermore, the participants have understood that many processes have to be started in parallel and from the beginning. The purpose statement was introduced as a key strategic anchor document.
After the course, participants are familiar with essential primary literature (e.g. MDR).
After the course, participants have developed a sense of essential tasks and have shed fears of contact. A mind-set has emerged that sees regulatory as an opportunity for a strategic competitive advantage and not as a cumbersome backpack.

Traget group

- Beginners in regulatory affairs and product approval,
- Founders and managing directors of smaller companies
- "Generalists" who have to answer questions from company and product approval in their own start-up environment

Methodology

Experts impart relevant knowledge on the topic of certification for life science startups and always put this into direct practice with interactive and individual involvement of the participants: **input - exercise - presentation - feedback and discussion.**

Methodological competencies: Regulatory Canvas, Medical Device Regulation, ISO 13485, Persona Definition, Value Proposition Canvas, Intended Use, DIDO-Matrix, Stakeholder Request, Stakeholder requirement, Product requirement, Product Specification, Usability Engineering (IEC 62304), Risk Management (ISO 14971).

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About the course

Certificate course 1 "Regulatory Thinking Basics":

- **Module 1** Overview of the world of regulations in medical technology, digital health and in-vitro diagnostics
- **Module 2** From stakeholder requirements to product requirements
- **Module 3** Introduction to design & development according to MDR and ISO 13485
- **Module 4** Introduction to quality management systems and the risk-based approach

Per module: 1 day/8h online session + 0.75 days/6h self-study/homework.

The course contents were compiled and reviewed in coordination with the Faculty of Applied Chemistry at Reutlingen University.

About the lectures

Dr. Dietmar Schaffarczyk
- Managing Partner of StimOS GmbH
- Lecturer at GdCH, ETH, University Tübingen
- External Auditor Medtech (Diplom SAQ), Certified Quality Auditor (EOQ) and Lead Auditor for Medical Devices (Certfication Body QS International Ltd.)

Ingo Hämmerle
- Managing Director of Medical Innovations Incubator GmbH and Incubator Invest GmbH, as well as founder and CEO of the startup Fysor
- Industrial engineer, previously in various management positions, e.g. in the in-vitro diagnostics industry

Wolfgang Vogt
- teaches B2B Marketing for International Management at ESB/Reutlingen University, was previously Director Strategy & Marketing at IBM.
- has been training and coaching startups for over 10 years, respectively in the "MedTech Startup School" of the University of Tübingen and the "4C Accelerator Tübingen" of the Foundation for Medical Innovation.

Format	*Certificate course with certificate of participation; in combination with successful completion of certificate course 2 "Regulatory Deep Dives" and final examination/project: award of the programme certificate "Expert for Regulatory Compliance and Certification Strategies".		
Requirements for participation	Being keen on workshop formats		
Lecture mode	online	**Instruction language**	English
Dates/duration	4 days (+ 3 days self study): 17 and 24 June 2022, 1 and 8 July 2022	**Cost**	3.900 € (excl. examination fee of 360 € for programme certificate)
Participants	min. 4, max. 8 (companies/startups)	**Registration**	Online Registration Regulatory Thinking Basics

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