



# CAS ETH in Regulatory Thinking

Learning to use regulatory thinking as a business development tool for healthtech products.

# Shaping your regulatory strategy

In the CAS ETH in Regulatory Thinking continuing education programme, experts in the field will teach you how to transform a research idea into a compelling product, to navigate through different regulatory landscapes, and how to develop convincing certification strategies for different healthtech products. We also teach the principles of artificial intelligence to innovate and navigate development and approval of healthtech products.

Participants in this CAS will become experts by mastering the creation and execution of a regulatory strategy, a key element in effectively navigating the entire business development journey for a healthtech product.

This programme offers students with their own product ideas the unique opportunity to develop a compelling certification approach with the support of from academia and industry.

## Professional perspectives

The CAS ETH in Regulatory Thinking can be described as a „studium generale“ that will promote you to a generalist in the field of regulation and certification. You will get an overview in a rapidly changing healthtech market and be able to identify and guide different specialists. Regulatory generalists are in increasing demand in the health sector: whether as an executive seeking to

drive a business forward, a government official seeking to ensure the safety of health products or a payer defining new re-imbursement pathways.

## Structure and format

The programme consists of 8 modules that will guide you through the definition of regulatory thinking to a business and certification strategy for healthtech products. We offer interactive learning methods, such as group exercises and case studies, to give you the opportunity to deepen your understanding of the concepts.

## Target group

The CAS ETH in Regulatory Thinking is aimed at (non-)healthcare professionals who want to master the regulatory challenges in a rapidly changing healthtech market.



**Regulatory Thinking: A critical factor for success**

The programme gives insight in the various disciplines, principles and instruments in regulatory affairs activities and compiles these in a unique approach, defined as „Regulatory Thinking“.

**Regulatory Thinking can be applied to:**

Software as medical device, artificial intelligence, digital biomarkers, biotech, medical devices, in-vitro diagnostic devices, medicinal products and combination products.

**Start**

Autumn Semester (September)

**Duration**

10 months part-time

**Location and weekday**

Live sessions are on Wednesdays, either online or at ETH Zurich

**Tuition language**

English

**Programme fee**

CHF 13,900



**YOU want to...**

- > understand different regulatory landscapes
- > know how to set up design and development processes
- > use and evaluate validation tools
- > use artificial intelligence in the design and approval process
- > learn how to develop a clinical strategy
- > know about different certification and reimbursement strategies

**Develop your skills today!**



**„A smart regulatory strategy will make the difference between success and failure of an idea for a medical product. Regulatory Thinking helps to anticipate regulatory challenges and to plan ahead accordingly.“**

Professor Jörg Goldhahn  
Programme Director, CAS ETH in Regulatory Thinking



„Understanding the regulatory requirements of the health-tech market as a strategic opportunity and integrating them into one’s own business development - that is what Regulatory Thinking means. By introducing this way of thinking, we want to enable science, industry and start-ups to master the market launch of their healthtech innovations faster, more efficiently and more sustainably.“

Dietmar Schaffarczyk

Lecturer CAS ETH RT, CEO stimOS GmbH

Lead Auditor HealthTech, Lead Technical Assessor MedTech, IVD

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