

Kite-mentoring training

Training on Regulatory Affairs

Date: Monday 28.04.2025 (9:00 – 17:00)

Location: Faculty of Engineering, Univ. Freiburg, Georges-Köhler-Allee, building 080 - seminar room

Invited trainer: Dr. Thorben Bonarius (Switzerland) - <https://www.bonariusconsult.ch>

Registration: <https://terminplaner6.dfn.de/p/c2b7b51ad71ac292db5e2adcae2408a2-1076661>

Certificate will be provided!

Target Group

The target group for the workshop includes students from natural sciences such as Chemistry, Pharmacy, or Biology, as well as Medicine, who are at the end of their studies or PhD and looking for career orientation. Participants will gain comprehensive insights into the field of Regulatory Affairs with the following key topics:

Fundamentals of Product Development and the Role of Regulatory Affairs (RA)

- Career Profile of Regulatory Affairs:
 - What does a typical workday look like?
 - What qualities and skills are required?
 - Career opportunities and further education options.
- Case Studies:
 - Practical examples from professional life in industry, e.g., handling safety-critical issues, market entry strategies, and challenges in international markets.
 - Discussion and solution approaches for real-life scenarios.
- Negotiations with Authorities:
 - Strategies and methods for successful communication and negotiation with regulatory agencies.
 - Tips for researching and interpreting laws and guidelines.
- Practical Exercises:
 - Systematic research on regulatory requirements.
 - Use of AI tools to support regulatory work.
- Networking and Experience Exchange:
 - Opportunities to connect with other participants and the lecturer.

- Tips for entering the Regulatory Affairs profession.

Workshop Benefits

The workshop provides participants with motivation and inspiration by offering a diverse insight into the dynamic field of Regulatory Affairs through practical examples. They will gain a comprehensive understanding of the fundamentals of Regulatory Affairs and product development, insights into daily tasks, and core responsibilities through case studies, as well as recommendations for further reading and online resources.

Additionally, participants will acquire practical skills such as strategies for effective communication and negotiation with regulatory authorities, as well as methods for systematic research on regulatory requirements and laws. The workshop also offers career orientation by clarifying the necessary qualities and skills for a career in Regulatory Affairs and providing information on training and career paths. Moreover, participants will have the opportunity to network and exchange ideas with other attendees and the lecturer, receive tips for entering the field, and learn how to build a professional network. Practical tools and resources, such as the use of AI tools to support regulatory work and access to relevant guidelines, laws, and dossiers, complete the offering.

About the Lecturer: Dr. Thorben Bonarius

The workshop is led by Dr. Thorben Bonarius, a seasoned Senior Regulatory Affairs expert with over 20 years of professional experience in the pharmaceutical and chemical industries. He has extensive experience in leading global teams, managing product approvals, and overseeing product lifecycle management. Dr. Bonarius has negotiated with various health authorities and regulatory bodies worldwide and specializes in organizational development, as well as training and coaching employees and executives.

Education:

- Diploma in Chemistry and PhD in Chemistry, University of Marburg (1991–2000)
- Certificate in Quality Management (ISO 9000 and EN45000) (2000)
- Advanced Training in Organizational Development at the Artop Institute, Humboldt University Berlin (2021)

Professional Background:

- Founder and Owner of Dr. Bonarius Consult GmbH (since 2018)
- Global Head of Regulatory Affairs at Siegfried AG (2016–2019)
- Regulatory Affairs Project Manager at Knoell Consult GmbH (2002)
- Scientific Researcher in Drinking Water Surveillance (1997–2002)

Expertise:

- Organizational Development and Training in Regulatory Affairs
- Personal and Professional Development of Employees
- Support in Product Development and Lifecycle Management

Dr. Bonarius brings not only profound technical knowledge but also practical experience from a variety of projects and industries, making him a highly competent and experienced lecturer in Regulatory Affairs.