bonarius consult
Your guide through the jungle of regulations.

Dr. Bonarius Consult GmbH | Bärengasse 23 | CH-4800 Zofingen

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Regulatory Affairs Basic Course (Pharma)

- 4 webinars, each ca. 1:30h, ~1 webinar per week
- 4 case studies for participants to work on, including individual feedback

Curriculum

Grundlagen der Chemikalien-, Pflanzenschutzmittel-, Biozid- und Pharmazulassung in der EU

Module 1: Fundamentals Part 1

- Introduction: Why is regulatory affairs important for society?
- What criteria are used to authorise products?
- The market and R&D costs
- Core tasks of a Regulatory Affairs department
- Job profiles
- Interest groups
- Basic principles and common elements of all authorisation procedures
- Regulatory authorities worldwide

Literature and links to Module 1

- For self-study

Case study to Module 1

- For self-study (required to obtain the certificate)

Module 2: Fundamentals Part 2

- Tasks of the Competent Authorities
- The dossier
    - Common elements of contents and formats
    - The authorisation dossier for pharmaceutical products in detail
    - Data requirements for pharmaceuticals
    - The authorisation dossier for plant protection products and biocides
    - Comparison of data requirements between plant protection products and pharmaceutical products
- Structure of the regulations
- The EU legislative process
- Fact sheets
    - Human pharmaceuticals
    - Veterinary pharmaceuticals

    - Plant protection products
    - Biocides
    - Chemicals

Literature and links to Module 2

- For self-study

Case study to Module 2

- For self-study (required to obtain the certificate)

Module 3: Pharmaceuticals

- Authorisation procedures for new products
    - Overview
    - Example: Decentralised procedure (DCP) of a pharmaceutiscl product
- Variations: life-cyle management of existing authorisations
    - Overview
    - Example: variation for a product authorised via DCP or MRP
- Further Regulaotry activities during the life-cycle management phase of a medicinal product
- Packaging and labelling

Literature and links to Module 3

- For self-study

Case study to Module 3

- For self-study (required to obtain the certificate)

Module 5: Medical Devices and In-vitro Diagnostic Devices

- History of Medical Devices and In-vitro Diagnostic Devices
- Definitions of Medical Devices and In-vitro Diagnostic Devices
- Key Principles of the Regulations
- Notified Bodies and Conformity Assessment
- Requirements
- Borderline Products
- Dossier Structure
- Transition Periods and Implementation

Literature and links to Module 5

- For self-study

Case study to Module 5

- For self-study (required to obtain the certificate)

External Quality Control

The contents of the curriculum have been reviewed and approved by the Continuing Education Committee of the German Chemical Society (GDCh).

Language

German, English

Customer feedback

"Mr. Bonarius made the content very vivid through his practical experience." (Anon.)

"Many thanks, Thorben Bonarius, for the interesting course and the insight into the depths of regulatory approval." (Marcel Werner, Coltène/Whaledent)

"Good overview/insight into the topic of Regulatory Affairs. Practice-oriented case studies; realistic insight into the professional profile of an RA manager." (Christian Breuer, Central Office for Health Protection in Medicinal Products and Medical Devices)

"Very informative course on Regulatory Affairs with illustrative examples and good materials. The lecturer addressed all questions in detail." (Dr. Sascha Shuxia Zhu, BASF)

“During the last year, I was coached by Thorben in every aspect of my future career and I wholeheartedly recommend him. Everything I have achieved this year would not have been possible without his great support. From the very beginning, I found a very trustworthy level of communication with Thorben. Regular video calls formed the basis of the coaching and enabled me to work on a wide range of topics. Thorben was at my side as an advisor at all times, but always made sure that I formed my own opinion and worked on the topics independently.” (Matthias Klimpel, ETH Zurich, Ph.D. candidate)

“During the last year, I was coached by Thorben in every aspect of my future career and I wholeheartedly recommend him. Everything I have achieved this year would not have been possible without his great support. From the very beginning, I found a very trustworthy level of communication with Thorben. Regular video calls formed the basis of the coaching and enabled me to work on a wide range of topics. Thorben was at my side as an advisor at all times, but always made sure that I formed my own opinion and worked on the topics independently.” (Amrita Möhl-Raj, Novartis Internship)

“I´d like to thank German Chemical Society (GDCh) for organizing this very interesting and fun course, and especially Thorben Bonarius for his excellent teaching!” (Dr. Berhard C. Richard, MDRA, Biotest AG)

Sufficient opportunities for exchange of experiences among the participants and with the speaker	100% ++
Did the practical exercises meet your expectations? Entsprachen praktische Übungen Ihren Vorstellungen?	100% ++
Comprehensibility:Verständlichkeit	80% ++ 20% +
Relevance to practice Bezug zur Praxis	100% ++
Motivation by the speaker Motivation durch Referenten	100% ++
Accompanying materials Begleitmaterial	100% ++
Overall rating Gesamtbewertung	5/5 Stars