Virtual Bio[M] Crash Course

Drug Development 2024

Date and Time

Wednesdays, 24 April until 26 June 2024, 7 week-course evenings, 4 p.m. to 6 p.m. CET
Venue: Online via Zoom Meeting® (*Zoom access details will be provided upon registration.*)

Please note that this course will be held entirely in English.

Overview

This crash course offers you a sound overview of clinical drug development from the study idea to marketing authorization. The content is structured according to the development phases of a drug and includes legal and strategic aspects.

Target Groups

This course is ideally suited for junior staff in clinical research, employees at biotech and pharma companies, clinics, and research-based organizations, academic students, graduates, researchers, consultants, and anyone interested in gaining a comprehensive understanding of drug development.

Speakers and Main Topics ***(extended version see next page)***

Learn from the best in the field, with speakers boasting years of experience in the biopharmaceutical and healthcare sectors, specializing in various areas of clinical development. Main topics will be the following:

- *Introduction to the pharmaceutical market*
- *From preclinical to clinical trial*
- *Design of development programmes and clinical trials*
- *Preparation, implementation and project management of clinical trials*
- *Pharmacovigilance and risk management of clinical trials*
- *Quality management of clinical trials*
- *Approval procedure and life cycle management*

Participation Details

Fee: 980 Euro (+VAT) *including*

- *access to online course materials*
- *a certificate of attendance at the end of the course*
- *an extended access for networking after each session (30 minutes)*

Registration Deadline: Wednesday, 10 April 2024
Please also note our cancellation deadlines in accordance with our General Terms and Conditions.

Registration

Organisation

Melanie Greitl | Bio[M] Biotech Cluster Development GmbH | Email: greitl@bio-m.org | P +49 (0) 89-899679-35

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Drug Development 2024 / Agenda

Timeframe:

4.00 pm – Welcome **/ 4.05 pm** – Program I **/ 5.00 pm** – Break **/ 5.15 pm** – Program II **/ 6.00 pm** – End
(optional networking after each course date latest until 6.30 pm)

1st Evening: Introduction to the Pharmaceutical Market / Wednesday, 24 April 2024

Speaker: Dr. Samson Fung

Topics: Overview of Healthcare Systems, Drug development - economic aspects, Basics of Pharmacotherapy, Drug development, Terms & Definitions

Calendar week 18 - 1 week break due of public holiday (1st May)

2nd Evening: From preclinical to clinical trial / Tuesday, 7 May 2024

Speaker: Prof. Dr. Ralf Huss

Topics: The basis of successful clinical development, Stumbling blocks of clinical development, Quality requirements (GCP), Implementation of clinical data in the regulatory dossier

3rd Evening: Design of development programmes and clinical trials / Wednesday, 15 May 2024

Speaker: Dr. Birgit Glasschröder

Topics: Clinical development programmes, Designing a development strategy, Planning and designing a clinical trial

Calendar week 21+22 - 2 weeks break due of holidays (21.05.-01.06.)

4th Evening: Preparation, implementation & project management of clinical trials / Wed., 5 June 2024

Speaker: Dr. Birgit Glasschröder

Topics: Preparation of a clinical trial, Study start and implementation, Study completion, Project management for clinical trials, Project monitoring and completion

5th Evening: Pharmacovigilance and risk management of clinical trials / Wednesday, 12 June 2024

Speaker: Dr. Silke Ostermann

Topics: Drug safety, Risk management and risk minimization

6th Evening: Quality management of clinical trials / Wednesday, 19 June 2024

Speaker: Annette Schuster

Topics: Quality assurance measures by the sponsor, Verification of quality by authorities, Results of audits and inspections, Trial Master File & archiving of documents

7th Evening: Approval procedure and life cycle management / Wednesday, 26 June 2024

Speaker: Karsten Binder

Topics: Approval and documentation, Special features of marketing authorization, Reimbursement and market access