Bio[M] Course: ICH E6(R3) & GCP Refresher 2026

Tuesday, 1 December 2026, Certificate Course

Date and Time

Tuesday, 1 December 2026, 09.00 am – 05.00 pm

Venue: Bio[M] Biotech Cluster Development GmbH,
Am Klopferspitz 19a, IZB West II, 82152 Martinsried

Room: *Bio[M] Conference Room „Munich" at 3rd floor*

Contents

The first "hot topic" of this course is ICH E6(R3). With R3, Good Clinical Practice has undergone its most substantial revision in many years. The new guideline responds to the increasing complexity of clinical trials, new technologies and data sources, and evolving approaches to trial design and conduct. **In the EU, the ICH E6(R3) Principles and Annex 1 have been effective since July 2025.**

While the fundamental objectives of GCP remain unchanged – protecting the rights, safety and well-being of trial participants and ensuring reliable trial results – the way in which these objectives should be achieved is evolving. ICH E6(R3) places much greater emphasis on **Quality by Design**, **Critical-to-Quality factors**, **proportionality and risk-based approaches**. Rather than applying the same processes and controls to every trial, sponsors are expected to focus their resources on the aspects that truly matter for participant protection and the reliability of trial results.

Other important changes include strengthened expectations regarding **data governance and computerized systems, sponsor and investigator oversight**, **service providers, informed consent, essential records and risk-based monitoring.** All these changes have a direct impact on the sponsor's GCP Quality Management System (QMS). Existing SOPs, processes, responsibilities and oversight mechanisms need to be reviewed to determine whether they adequately reflect the principles and expectations of ICH E6(R3).

Other "hot topics" of this course lead us to more national and regional aspects of clinical trials.

Germany adopted the Medical Research Act (**Medizinforschungsgesetz – MFG**) at record speed in 2024, with the aim of making Germany a more attractive location for research. A number of promising changes, including amendments to the German Medicinal Products Act (AMG) and the Radiation Protection Act (Strahlenschutzgesetz), have since entered into force and will also be addressed in this seminar.

There is also a great deal happening at EU level. On 16 December 2025, the proposal for the **EU Biotech Act** was published, which is expected to have a significant impact on the EU Clinical Trials Regulation (CTR). A summary of the proposed amendments to the CTR will bring you up to date with the latest developments and ongoing discussions.

Overall, the aim is to make not only Germany, but the EU as a whole, a more attractive environment for clinical research. The initiatives currently underway are multifaceted and far-reaching. All in all, these are once again exciting times for clinical research and its regulatory framework – and plenty of good reasons not to miss this GCP Update.

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***Content* (Continued)**

After the course, participants will be up to date with ICH GCP, and current developments in Germany and the EU. This course is suitable for both GCP beginners and GCP professionals who would like (or need) to refresh their knowledge.

According to the requirements of ethics committees (EC), individuals involved in clinical trials with medicinal products (or medical devices) should demonstrate regular participation in a certified GCP course including an update on the legal situation. This course mainly covers GCP, however also provides a comprehensive overview of legislative changes, both in Germany and the EU, which either already happened or are planned to be implemented in the not-too-distant future.

You will receive a **certificate of attendance** as proof of qualification, e.g., for audits/ inspections or for presentation to ethics committees.

Target group

This course is designed for individuals involved in clinical trials with drugs from biotech companies, pharmaceutical companies and CROs, e.g. CRA/monitor/project leader, project management, data management, quality assurance and study teams. Members of the study team of investigator sites (e.g. study nurses, study coordinators), can also register (specific GCP investigator courses are given for investigators - program on request).

Speaker

Dr. Dagmar Chase

After studying computer science (with a minor in theoretical medicine), Dagmar Chase initially worked in the computer industry. In 1983, she founded the contract research organization GMI with the biometrician Professor Albrecht Neiß and soon developed the company into a "full service CRO". The work on the company's quality management system as well as the development of many training programs for the drug development industry are - in addition to the management of GMI - among the focal points of Dagmar Chase's work. After receiving her doctorate from the Medical Faculty in Ulm in 1995 and the sale of GMI in 1997 to the American CRO Kendle (now Syneos Health), Dagmar Chase served for many years as Vice-President and Project Director for international development programs at Kendle. In 2004, she founded Clinrex, a clinical trial quality management consulting firm. In addition to training, her responsibilities include gap analysis of GCP SOP systems.

Ms. Chase co-founded the Bundesverband Medizinischer Auftragsinstitute (BVMA e.V.) in 1991 and served as the association's president from 2001 until the end of 2017. In 2005, the corresponding European association was launched under her participation (EU CRO Federation, EUCROF), which she has actively accompanied since its foundation.

In 2019, Dagmar Chase was appointed Senior Expert by the German Pharmaceutical Industry Association (BPI e.V.).

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Agenda

Timetable:

08.45 am | Arrival & Coffee

09.00 – 09.05 am | Welcome

10.45 – 11.00 am | Coffee Break

01.00 – 01.45 pm | Lunch Break

03.00 – 03.15 pm | Coffee Break

04.30 pm | Success control & Certificate

05.00 pm | End

Participation Fee:

590,00 Euro (+ VAT) *incl. materials, catering, and a certificate of participation*

Registration Link:

http://bio-m.org/biom-course-ich-e6r3-and-gcp-refresher-2026

Registration Deadline:

Tuesday, 17 November 2026

Please also note our cancellation policies as set forth in our GTC.

Organisation:

Melanie Greitl, Bio[M] Biotech Cluster

Email: events@bio-m.org

Topic Overview:

ICH Guideline E6 (R3) (ICH-GCP Principles and Annex I)

- ***History of ICH E6***
- ***New Structure, Scope and Summary of Changes***
- ***Principles of ICH GCP***
- ***Investigators, in particular***
  - ***Responsibilities***
  - ***Protocol Deviations***
  - ***Participant Medical Care and Safety Reporting***
  - ***Informed Consent of Trial Participants***
  - ***Investigational Product Management***
  - ***Records (Source and Case Report Forms)***
- ***Sponsors, in particular***
  - ***Agreements***
  - ***Sponsor Oversight***
  - ***Risk-based Quality Management / Risk-based Monitoring***
  - ***Safety Assessment and Reporting***
  - ***Investigational Product***
  - ***Data and Records***
  - ***Reports***
- ***Data Governance – Investigator and Sponsor***
- ***Essential Records (TMF / eTMF)***
- ***Brief Overview of Annex II of ICH E6 (R3)***

Medical Research Act (Medizinforschungsgesetz (MFG)) and its Impact on the German Medicinal Product Act (AMG) and the Radiation Protection Act (Strahlenschutzgesetz)

Overview of the proposed EU Biotech Act with regard to Changes of the EU Clinical Trials Regulation 536/2014