

ADAX ICH E6 GCP Investigator Site Training

Workshops for up to 8 attendees

Training for larger audience

Training at your location

Individual trainings

Combined GCP & Regulatory training

ABOUT OUR TRAINERS

Our GCP trainers have over 5 years experience in clinical research with deep knowledge in GCP requirements. Trainers completed GCP Certification and Trainer Accreditation.



www.adax.si

Earn your GCP
certificate from
120,00 EUR + DDV on.

We offer discounts for
companies/institutions
with more attendees.

We will deliver our
training in consensus
with your preferences!

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The ADAX logo is written in a blue, lowercase, cursive font. It is set against a background of a white honeycomb or hexagonal pattern.



ICH E6 GCP Investigator Site Training

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Our ICH E6 GCP Investigator Site training gives Investigators and their clinical teams all the knowledge required for running clinical trials in compliance with Good Clinical Practice. The GCP training is available in Slovenian and English language and can be delivered at your preference.

The following topics are covered in the training:

1. The Principles of ICH GCP
2. Investigator's Qualifications and Agreements
3. Adequate Resources
4. Medical Care of Trial Subjects
5. Communication with IRB/IEC
6. Compliance with Protocol
7. Investigational Products
8. Randomization and Unblinding
9. Informed Consent of Trial Subjects
10. Records and Reports
11. Progress Reporting / Final Reports
12. Safety Reporting
13. Premature Termination or Suspension of Trial

Training duration is approximately 6 hours and it includes a knowledge test at the end of the training. Training can be delivered as an interactive workshop for groups up to 8. For larger groups the training is in form of a lecture.

CERTIFICATION

Our GCP Training includes a knowledge check at the end of the training which consists of 20 questions. One must achieve 80% of correct responses to earn the training certificate. Training certificate is **valid for 3 years**. After this period a refresher training on GCP should be completed to extend the certification.

RECOGNITION BY TRANSCCELERATE BIOPHARMA

Our ICH-GCP Training meets the Minimum Criteria for ICH GCP Investigator Site Personnel Training identified by TransCelerate BioPharma as necessary to enable mutual recognition of GCP training among trial sponsors. TransCelerate members have developed guidelines to give innovative drug companies the comfort necessary to recognize and rely on another member's or Training Provider's investigator site personnel GCP training meeting the identified Minimum Criteria. ADAX ICH E6 GCP Investigator Site Training meets all these minimum criteria and is recognized by all TransCelerate members as a training provider.