Your Certified GMP/GDP Excellence!

ECA Academy
Your GMP/GDP Information Source

New!

GMP/GDP Training & Conferences

OVERVIEW OF ALL EVENTS ON-SITE AND LIVE ONLINE

Education Courses & Conferences

Live Online Training Courses & Webinars

Welcome

Dear readers,

Concept Heidelberg is by far the largest provider of training and information services in Europe in the areas of GMP and GDP. We organise more than 350 conferences and seminars in 10 countries every year. Our team of speakers consists of over 500 experts from industry and regulatory authorities. This enables us to offer training courses on all topics related to pharmaceutical quality assurance.

We look forward to welcoming you to our events!

Oliver Schmidt, Managing Director

What we offer

On-Site

Our on-site events are held in sustainable hotels throughout Europe. These events provide valuable opportunities to engage not only with the speakers but also with fellow participants. Some selected seminars even include a practical component, for example in a laboratory.

Live Online

Live online seminars have become an integral part of our event repertoire in recent years. Thanks to modern software and location independence, professional development has never been so easy! Workshops and question-and-answer sessions ensure active dialogue with the experts.

Recordings

Our seminar recordings offer maximum flexibility. You decide when and where you want to conduct your training and set the pace yourself. No additional software is required—the videos run directly in your browser.

EACH PARTICIPATION INCLUDES A CERTIFICATE AS OFFICIAL PROOF OF YOUR PROFESSIONAL QUALIFICATION.

How to quickly find your seminar

The seminar number makes it quick and easy to find your seminar: simply enter the number from the catalogue into the search field at www.gmp-compliance.org to find and book the right event straight away!

nvironment

Course No. 22436

Content

We have organised our events for you by topic – information about our certification programmes can be found at the beginning of each topic area and on our website.

The ECA Academy

The ECA Academy is the ECA Foundation's educational organisation. It has been developing and conducting comprehensive training courses and a certification programme (education courses, conferences and webinars) in the GMP/GDP and regulatory compliance environment since the organisation was established in 1999. Together with the ECA Foundation and its ten Interest Groups, it has become the leading European provider of information and training services in the areas of pharmaceutical Quality Assurance and GMP/GDP compliance.

To learn more about the ECA Academy, please visit **www.gmp-compliance.org.**

ECA Academy
Your GMP/GDP Information Source

Training Fees

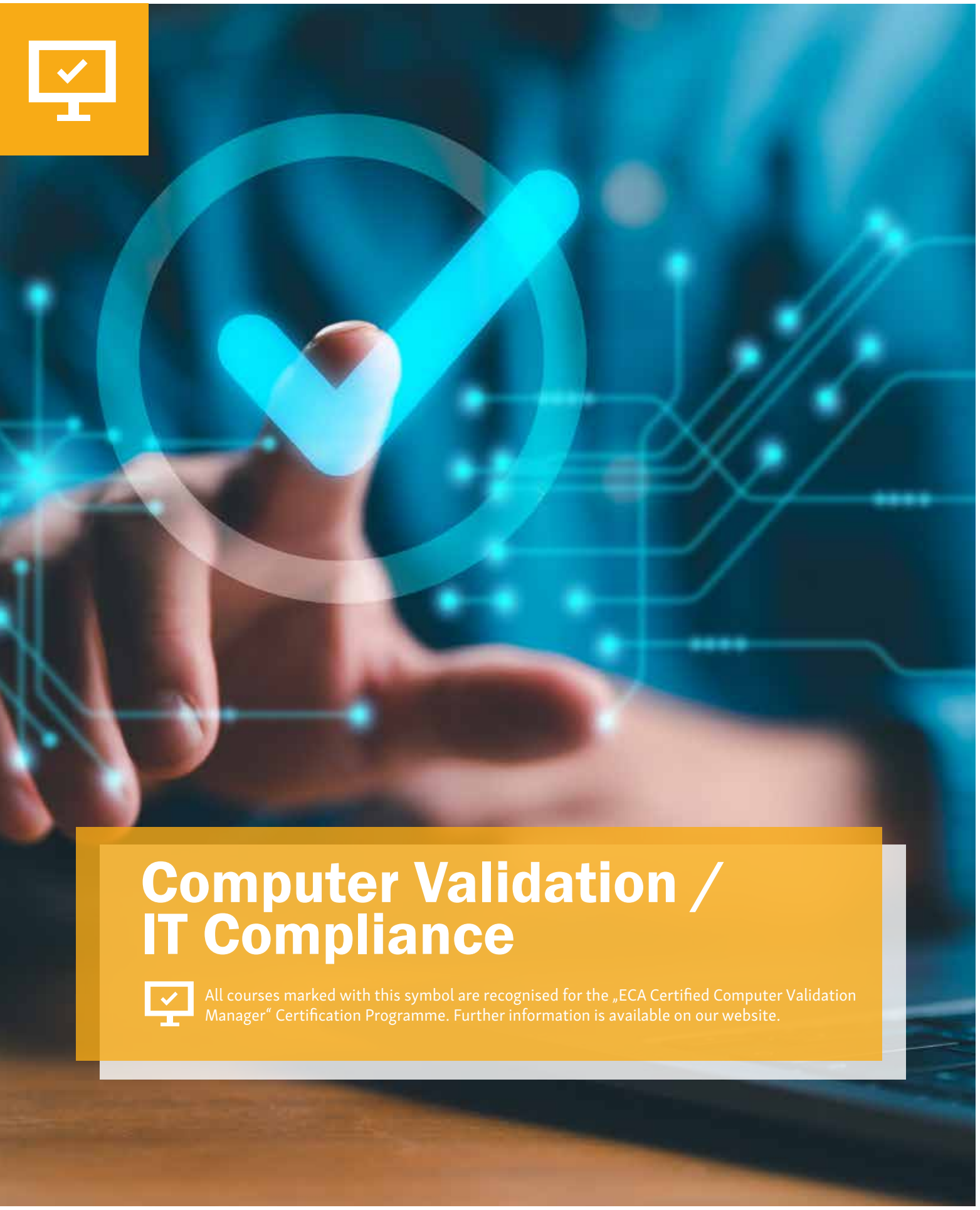
The standard fees for ECA training courses and conferences (on-site and live online), webinars, and recordings are as follows:

1-day course	€1,290
2-day course/conference	€2,090
3-day course/conference	€2,490
webinars	€399

Discounts apply to ECA Members, EU/GMP Inspectorates, and APIC Members. Rebates are also available for the combination of specific training courses. Please see the website for applicable registration fees.

The ECA Certification Programme

One reason for the ECA Academy's excellent reputation is its high-quality Certification Programme – which builds on your college or univerity education. In the past years, thousands of GMP and GDP professionals already have relied on the programme to advance their knowledge, gain an additional qualification, and achieve the ECA Certification Level.
The comprehensive qualification curriculum comprises 15 programmes, allowing you to combine several seminars according to your fields of interest.
For more information and the individual programmes, please see **www.gmp-certification.org**



Computer Validation / IT Compliance

All courses marked with this symbol are recognised for the „ECA Certified Computer Validation Manager“ Certification Programme. Further information is available on our website.

Cloud Computing in a GxP Environment

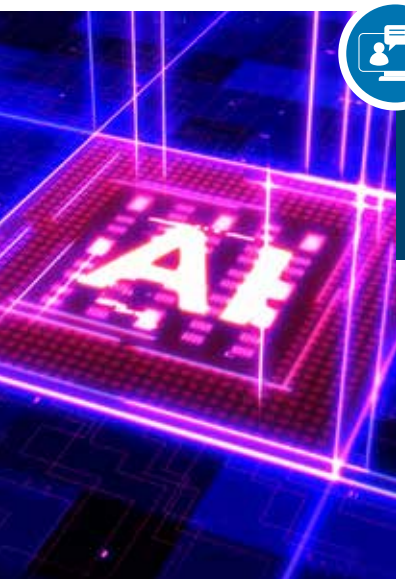
11-13 February 2026, Live Online Training — Course No. 22716

Highlights:

- Compliance Requirements for Cloud Computing
- Use of Cloud Computing in a GxP Environment
- IT Security and Data Protection Requirements

Speakers:

Robert Gärtner, Veeva Systems, Germany | Dr Wolfgang Schumacher, SPC, Switzerland | Dr Arno Terhechte, GMP Inspector, Germany | Michael Wegmann, F. Hoffmann-La Roche, Switzerland



GMP meets AI

How to use Artificial Intelligence in Quality Assurance and Quality Control

17/18 February 2026, Live Online Training — Course No. 22452

Highlights:

- AI in the GxP Environment
- How to train a GPT; Prompt Engineering
- How to Use GPT and digital Tools to Support Daily Work in QA; Application Examples

Speakers:

Frank Hanakam, QuaSyCon | Peter Hackel, Takeda, Austria | Manfred Karner, Takeda, Austria | Torsten Kneuß, Bayer | Philip Lienbacher, Takeda, Austria | Dr Simon Schäfermann, GMP Inspector, RPR Tübingen, Germany

Annex 22 / AI Conference

07/08 October 2026

With a Pre-Conference Course on **Basics of AI** on 06 October 2025

Further information about the conference will be available at a later date.
You can then search and register directly at **www.gmp-compliance.org** under the **course number 22695**.

Computerised System Validation: Introduction to Risk Management

21 April 2026, Barcelona, Spain — Course No. 22308
24 November 2026, Live Online Training — Course No. 22405

Highlights:

- The use of GAMP® 5 Second Edition
- The EU GMP Guide Annex 11 including Draft 2025
- 21 CFR Part 11

Speakers:

Frank Behnisch, formerly of of CSL Behring, Germany | Yves Samson, Kereon, Switzerland | Dr Robert Stephenson, Rob Stephenson Consultancy, UK

The GAMP® 5 Approach

22-24 April 2026, Barcelona, Spain — Course No. 22310
25-27 November 2026, Live Online Training — Course No. 22407

Highlights:

- The GAMP® 5 Lifecycle: Software Categorisation, Specifications, Verification / Testing
- Practical Risk Management – ICH Q9 (R1) and FMEA Methodology
- Change Control & Test Incident Management

Speakers:

Frank Behnisch, formerly of CSL Behring, Germany | Yves Samson, Kereon, Switzerland | Dr Robert Stephenson, Rob Stephenson Consultancy, UK

A discount of €600 applies when booking both courses together.

IT / OT Infrastructure Qualification and Operation in a GxP Environment

27-29 May 2026, Copenhagen, Denmark — Course No. 22281

Highlights:

- Information Technology (IT) / Operation Technology (OT) Infrastructure Enterprise Model
- Regulatory Requirements
- IT Compliance for the IT Infrastructure

Speakers:

Frank Behnisch, formerly of CSL Behring, Germany | Bob McDowall, R.D.McDowall, UK | Yves Samson, Kereon, Switzerland

Computerised System Validation: Auditing and Leveraging IT / OT Suppliers and Service Providers

19 May 2026, Vienna, Austria — Course No. 22282

Highlights:

- Regulatory Update
- Auditing and Leveraging Suppliers: Supplier Selection Process, Leveraging Audit Findings
- Good Validation Practices

Speakers:

Yves Samson, Kereon, Switzerland | Dr Robert Stephenson, Rob Stephenson Consultancy, UK

Computerised System Validation Master Class

20-22 May 2026, Vienna, Austria — Course No. 22284

Highlights:

- Validation Planning Activities
- Design Activities
- Testing Activities

Speakers:

Frank Behnisch, formerly of CSL Behring, Germany | Yves Samson, Kereon, Switzerland | Dr Robert Stephenson, Rob Stephenson Consultancy, UK

A discount of €600 applies when booking both courses together.

SAP – Validation and GMP Compliance

02/03 June 2026, Live Online Training — Course No. 22396

Highlights:

- Specific Focus on SAP S/4HANA Implementation and Validation
- SAP Cloud Solutions – Legal Challenges and Compliance in Practice

Speakers:

Andreas Busse, Carl Zeiss, Germany | Károly Földesi, SAP Deutschland, Germany | Christian Gasper, DHC Dr. Herterich & Consultants, Germany | Robert Geiger, SAP SE, Germany | Christina Kiefer, Reusch Rechtsanwalts-gesellschaft, Germany | Thomas Pauly, DHC Dr. Herterich & Consultants, Germany | Dr Wolfgang Schumacher, SPC, Switzerland | Stefan Staub, DHC, Switzerland | Nicole Steffensky, DHC Dr. Herterich & Consultants, Germany | Christian Vogler, Raumedic, Germany

Computerised System Validation: GMP-Compliant Documentation

15-17 September 2026, Copenhagen, Denmark — Course No. 22398

Highlights:

- Which Documents for the Validation of Computer-based Systems are Required by Regulation?
- Which Documents are Checked in the Course of an Inspection?
- What Level of Detail must Documents Have?

Speakers:

Dr Rainer Gnibl, District Government of Upper Bavaria, Germany | Uwe Mai, Bayer, Germany | Yves Samson, Kereon, Switzerland

Computerised System Validation: How to Handle Legacy Systems?

29 September 2026, Live Online Training — Course No. 22402

Highlights:

- Regulatory requirements for the qualification / validation of legacy systems
- Considerations in the context of legacy system audits
- Legacy systems compliance from a QA perspective

Speakers:

Yves Samson, Kereon, Switzerland | Uwe Mai, Bayer, Germany | Dr Robert Stephenson, Rob Stephenson Consultancy, UK

Maintaining Compliance During Operation

30 September - 02 October 2026, Live Online Training — Course No. 22404

Highlights:

- Requirements from the EU GMP Guide Annex 11 and GAMP®5 2nd Edition
- The GAMP 5 Risk-Based Approach to Operation of GxP Computerized Systems Good Practice Guide
- Handover and Establishing Support Services

Speakers:

Frank Behnisch, formerly of CSL Behring, Germany | Yves Samson, Kereon, Switzerland | Dr Robert Stephenson, Rob Stephenson Consultancy, UK

A discount of €600 applies when booking both courses together.

IT for Non IT-Professionals

22/23 October 2026, Live Online Training — Course No. 22693

Highlights:

- The Technology behind your IT
- Requirements for Data Handling, Data Life Cycle and Data Management
- IT System Landscapes

Speakers:

Stefan Münch, Körber Pharma Consulting, Germany | Yves Samson, Kereon, Switzerland

COMMUNITY CELEBRATION

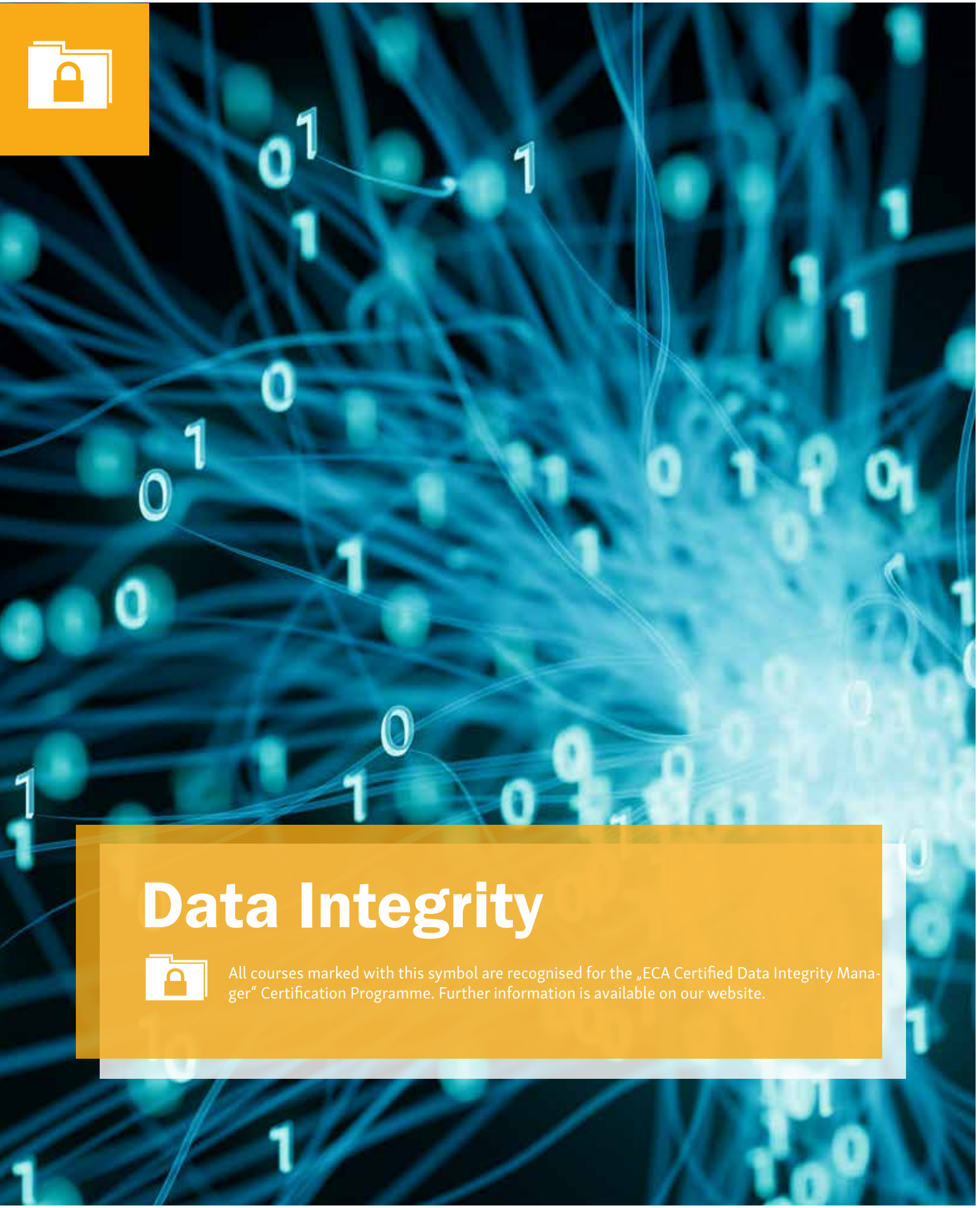
GET 2 CONGRESS TICKETS AND ECA MEMBERSHIPS WITH ONLY 1 REGISTRATION

Digital Transformation & Artificial Intelligence

24/25 March 2026, Wiesbaden, Germany
Part of GMP-PharmaCongress

GMP-PHARMA CONGRESS
www.pharma-congress.com

CONCEPT HEIDELBERG Supported by ECA Academy
Your GMP/GDP Information Source



Data Integrity

All courses marked with this symbol are recognised for the „ECA Certified Data Integrity Manager“ Certification Programme. Further information is available on our website.

Good Documentation Practice and Data Integrity

GMP-compliant instructions and records

14-16 April 2026, Munich, Germany — Course No. 22340

Highlights:

- Updates to EU GMP Chapter 4 (Documentation), Annex 11 (CSV) and USP<1029> Good Documentation Practice
- Principles of Good Documentation Practice and Data Integrity
- Instructions, blank forms and records – Life Cycle and Data Integrity considerations

Speakers:

Bob McDowall, McDowall Ltd. | Dr Stephan Dresen, D|Consulting | Dr Wolfgang Schumacher, SPC

Data Integrity

Requirements for a GMP-compliant data life cycle

06-08 May 2026, Berlin, Germany — Course No. 22287
28-30 October 2026, Live Online Training — Course No. 21649

Highlights:

- Understand the Regulatory Requirements for an Audit Trail (review)
- Identifying GMP-relevant Data
- Review of Audit Trail Entries

Speakers:

Bob McDowall, R.D.McDowall, UK | Yves Samson, Kereon, Switzerland | Dr Franz Schönfeld, GMP Inspector, Germany

Optional full-day pre-course session: Audit Trail Review

05 May 2026, Berlin, Germany — Course No. 22285
27 October 2026, Live Online Training — Course No. 21647

Highlights:

- FDA Draft Guidance for Industry 'Data Integrity and Compliance with cGMP'
- WHO, MHRA and GAMP Data Integrity Guidances - Key Points
- Data Integrity – EU Requirements

Speakers:

Bob McDowall, R.D.McDowall, UK | Yves Samson, Kereon, Switzerland

A discount of €600 applies when booking both courses together.

Data Integrity Master Class

26-28 August 2026, Copenhagen, Denmark — Course No. 22290

Highlights:

- Data Integrity in the PQS / Data Governance
- Metrics for Data Integrity
- Data Integrity Inspection / Preparing your Company for a Data Integrity Inspection

Speakers:

Bob McDowall, R.D.McDowall, UK | Yves Samson, Kereon, Switzerland | Dr Franz Schönfeld, GMP Inspector, Germany | Dr Wolfgang Schumacher, SPC, Switzerland

With an optional full-day pre-course session on

Raw Data - Understanding, Defining, and Managing

25 August 2026, Copenhagen, Denmark — Course No. 22288

Highlights:

- What are Raw Data? Understanding GMP Definitions and Regulations
- Interpretation of Raw Data
- True Copy vs. Raw Data

Speakers:

Bob McDowall, R.D.McDowall, UK | Yves Samson, Kereon, Switzerland

A discount of €600 applies when booking both courses together.

Audit Trail Review for Computerised Systems in Analytical Laboratories

22/23 September 2026, Live Online Training — Course No. 22411

Highlights:

- Regulations and Guidance for Audit Trails and their Review
- Audit Trail Review as Part of a Data Integrity Strategy
- Validation of Audit Trail Functionality

Speakers:

Dr Markus Dathe, F. Hoffmann-La Roche, Switzerland | Dr Bob McDowall, Member of the ECA IT Compliance Interest Group | Dr Frank Sielaff, Regional Authority, Darmstadt, Germany

Pharmaceutical Technology

All courses marked with this symbol are recognised for the „ECA Certified Technical Operations Manager“ Certification Programme. Further information is available on our website.

Fundamentals of Visual Inspection

Best practice for manual and automated visual inspection of parenterals

12 February 2026, Live Online Training — Course No. 22301

Highlights:

- Understanding the US/EU Pharmacopeial Requirements
- Ensuring GMP Compliance in Manual Inspection
- Categorisation of Defects

Speakers:

Dr Helmut Gaus, WinSol, formerly of Boehringer Ingelheim | Felix Krumbein, Head ECA Visual Inspection Group

Cross Contamination Control

Implementation of a cross-contamination control strategy

17/18 March 2026, Live Online Training — Course No. 22205

Highlights:

- Regulatory Requirements: Contamination Control Strategy & Cross Contamination
- Sources of Cross Contamination
- Containment Solutions – Avoiding Exposure – Minimizing Cross Contamination

Speakers:

Nikolaus Ferstl, Facility Engineering Services | Dr Andreas Flückiger, formerly of F. Hoffmann La-Roche | Dr Markus Keller, Fraunhofer Institute for Manufacturing Engineering and Automation (IPA) | Dr Jean Denis Mallet, Former Head of the French Pharmaceutical Inspection Dpt. AFSSAPS, France | Robert G. Schwarz, GXP TrainCon, Vienna

Cleanrooms & HVAC Systems

21/22 April 2026, Live Online Training — Course No. 22293

Highlights:

- GMP-Guidance for Clean Rooms and HVAC Systems
- Implementation of the Clean Room Requirements of EU GMP Annex 1
- Zone Concepts for sterile, non-sterile and highly potent Products

Speakers:

Nikolaus Ferstl, Facility Engineering Services, Germany | Dr Lars Kreye, Boehringer Ingelheim, Germany | André Lourenco, Novo Nordisk, Denmark | Dr Jean Denis Mallet, Former Head of the French Pharmaceutical Inspection Dpt. AFSSAPS, France | Andreas Nuhn, D&B Pharmadesign, Germany

GMPs for Equipment, Utilities, and Facilities

Good engineering practice for pharmaceutical companies and suppliers

16-18 June 2026, Live Online Training — Course No. 22471

Highlights:

- Regulations in the Technical GMP Environment
- Understanding Risk Analyses

Speakers:

Lucas Davenport, Dockweiler | Nikolaus Ferstl, Facility Engineering Services | Dr Markus Keller, Fraunhofer Institute for Manufacturing Engineering and Automation (IPA) | Dr Jean Denis Mallet, Former Head of the French Pharmaceutical Inspection Dpt. AFSSAPS | Markus Multhauf, Senior Consultant GMP-Engineering | Dr Jan Rau, Dockweiler | Dr Ingrid Walther, Former Head of the Business Unit iv Drugs, Fresenius

Product Transfer

Organisation of a GMP-compliant site change

22/23 September 2026, Live Online Training — Course No. 22437

Highlights:

- Development of a regulatory transfer strategy
- Handling of process changes during the transfer
- Handling of GMP and regulatory gaps at the donor site

Speakers:

Dr Reinhard Adam, formerly of BIPSO | Dr Eva Keller, Ferring | Christof Langer, OSConsulting | Dr Jean-Denis Mallet, Former Head of the Pharmaceutical Inspection Dpt. AFSSAPS | Dr Lisa Matzen, Boehringer Ingelheim | Dr Harald Stahl, Romaco

Image: Spray Drying Facilities at Hovione

Spray Drying

Solutions for the pharmaceutical industry

29/30 September 2026, Live Online Training — Course No. 22520

Highlights:

- Fundamentals of Spray Drying
- Development of a Spray Drying Process
- Advanced Characterisation of Spray Dried Particles

Speakers:

Dr Sune Klint Andersen, Janssen Pharmaceutica | Dr Inês Matos, Hovione | Simon Phillips, Nova Laboratories | Dr Thomas Quinten, Janssen Pharmaceutica | Dr Inês Ramos, Hovione | Dr Harald Stahl, Romaco | Dr João Vicente, Hovione | Dr Ann-Cathrin Willmann, Boehringer Ingelheim Pharma

Granulation & Tableting

13-15 October 2026, Live Online Training — Course No. 22472

Highlights:

- Fundamentals & Scale-Up of granulation processes: Fluidbed-Granulation, High-Shear Granulation, Roller Compaction
- Fundamentals of commercial compression processes
- Global GMP requirements for the manufacture of oral solid dosage forms

Speakers:

Dr Michael Braun, Boehringer Ingelheim Pharma | Dr Jean-Denis Mallet, Former Head of the French Pharmaceutical Inspection Dpt. AFSSAPS | Dr Harald Stahl, Romaco | Prof Dr Karl G. Wagner, University of Bonn | Dr Lars Reinders, Romaco | Dr Kristina Steffens, University of Bonn

COMMUNITY CELEBRATION

GET 2 CONGRESS TICKETS AND ECA MEMBERSHIPS WITH ONLY 1 REGISTRATION

Biotechnology / Blood / ATMP

All courses marked with this symbol are recognised for the „ECA Certified Biotech Manager“ Certification Programme. Further information is available on our website.

Protein Analytics

Evaluation, implementation, and use of suitable technologies

03/04 February 2026, Live Online Training — Course No. 22131

Highlights:

- Regulatory Aspects
- Available Methods e.g. HPLC, MS, Biophysical Methods, Immunochemical Methods, (non-cellular) Bioassays

Speakers:

Dr Markus Fido, Mfi Bio-Consulting, Austria | Dr Ulrike Herbrand, Charles River Laboratories, Germany | Dr Wolf Hagen Holtkamp, Paul-Ehrlich Institut, German Federal Agency for Vaccines and Biomedicines | Dr Henno van den Hooven, MSD, The Netherlands | Dr Michael Leiss, Roche Diagnostics, Germany | Dr Dietmar Reusch, Roche Diagnostics, Germany | Markus Roucka, VelaLabs, Austria

Tissue – QC, Inspections, and other Challenges

Special handling and applications

26 February 2026, Live Online Training — Course No. 22161

Highlights:

- Donor Eligibility
- How to handle Process Changes
- Regulatory Requirements for Transportation and Storage

Speakers:

Dr Katja Aschermann, Astator | Dr Verena Plattner, Austrian Agency for Health and Food Safety (AGES) | Dr Pia Strasser, Austrian Agency for Health and Food Safety (AGES)

Handling Biological Raw Materials & APIs

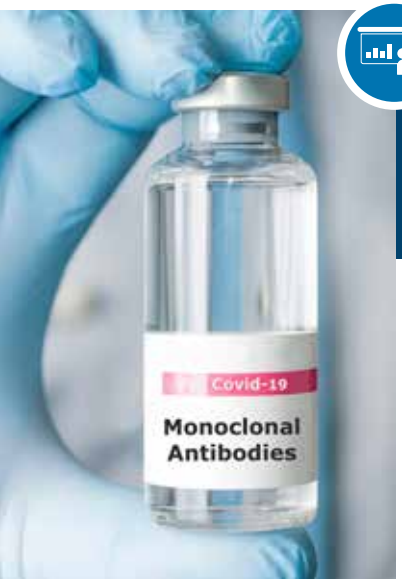
10/11 March 2026, Live Online Training — Course No. 22336

Highlights:

- Regulatory and Quality Requirements
- E&L and Biologics Containment
- Microbiological Safety and Control

Speakers:

Dr Katja Aschermann, Astator | Melanie Braun, Labor LS | Stefan Gärtner, Labor LS | Dr Armin Hauk, Sartorius Stedim Biotech | Dr Ana Kuschel, West Pharmaceuticals Deutschland | Anna Liznar, PathoQuest | Raphael Parusel, Tetec



Monoclonal Antibodies

From concept to approval

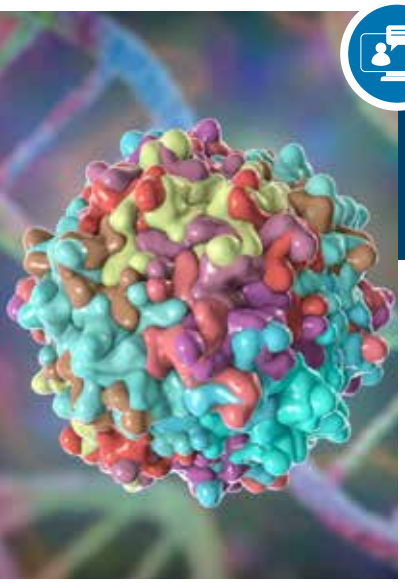
14/15 April 2026, Heidelberg, Germany — Course No. 22477

Highlights:

- Bacterial vs Mammalian Cell Production
- Antigen Affinity Purification
- Analytical Concepts and Methods for Testing, LCMS and more

Speakers:

Dr Zulfaqar Ahmad Arfi, Freelance Consultant | Dr Ghazaleh Gouya, Gouya Insights | Markus Haberger, Roche Diagnostics | Dr Andrea Hawe, Coriolis Pharma Research | Stefan Iarusso, ProBioGen | Dr Andreas Nechansky, VelaLabs | Markus Roucka, VelaLabs



AAV Analytics

Suitable analytical methods to assess AAV quality

16 April 2026, Live Online Training — Course No. 22504

Highlights:

- Case Studies
- Establishing Specifications & Acceptance Criteria
- Method and Formulation Optimization

Speakers:

Dr Kerstin Brack, Charles River Laboratories | Dr Sabine Hauck, Chair of ECA ATMP Interest Group | Dr Ulrike Herbrand, Charles River Laboratories | Anna Liznar, PathoQuest | Dr Roland Pach, Roche

Advanced GMP for ATMPs

Perfect your skills in the ATMP world of GMP and Annex 1

29/30 April 2026, Live Online Training — Course No. 22522

Highlights:

- Regulatory Overview Part IV
- Impact of Annex 1 in the Aseptic Manufacturing of HCGTP
- Creation of a CCS

Speakers:

Dr Katja Aschermann, Astator | Dr Rainer Gnibl, Local Government of Upper Bavaria | Dr Sabine Hauck, Chair of ECA ATMP Interest Group | Kati Kebbel, Fraunhofer Institute for Cell Therapy und Immunology | Dr Wolfgang Schumacher, SPC

GMP for Biopharmaceuticals

12/13 May 2026, Live Online Training — Course No. 22521

Highlights:

- Regulatory Requirements on Biopharmaceuticals
- Validation of Analytical Methods and Biotech Processes
- Process Transfer from Development to Commercial Production

Speakers:

Dr Markus Fido, Mfi Bio-Consulting | Dr Marcel Günther, GMP Inspector, Local Government Tübingen | Dr Matthias Leitritz, Rentschler Biopharma | Stephan Löw, CSL | Friederike Wedelich, GMP Inspector, Local Government Tübingen

mRNA & Non-Viral Delivery

19/20 May 2026, Live Online Training — Course No. 22136

Highlights:

- RNA-based Technologies and Applications
- Advances in Cell Therapies without Viral Transduction
- Latest Technologies in Cell Engineering and Manufacturing

Speakers:

Dr Mohamad Toutounji, Molgenium | Dr Christoph Peter, Peter Auditing | Selina Roth, Lonza | Dr Julia Schüler, Charles River Laboratories

GMP for ATMPs

Basic training for beginners & newcomers

30 September/01 October 2026, Live Online Training — Course No. 22587

Highlights:

- Definitions and Key Regulations of ATMP and GMP
- Risk-based Approach
- Environmental Monitoring and (Cross) Contamination

Speakers:

Dr Rüdiger Alt, Novartis | Dr Rainer Gnibl, Local Government of Upper Bavaria | Dr Sabine Hauck, Chair of ECA ATMP Interest Group | Dr Ulrich Kissel, Chair of ECA ATMP Interest Group

Development

All courses marked with this symbol are recognised for the „ECA Certified Pharmaceutical Development Manager“ Certification Programme. Further information is available on our website.

ICH Q8 Training Course

From QbD to process validation

28/29 April 2026, Live Online Training — Course No. 22388

Highlights:

- Quality by Design (QbD)
- Quality Target Product Profile (QTPP)
- Critical Quality Attributes (CQA) and Critical Process Parameters (CPP)

Speakers:

Dr Steffen Groß, PEI, Germany | Dr Line Lundsberg-Nielsen, NNE, Denmark | Dr Martin Maus, Boehringer Ingelheim, Germany | Dr Christian Palmes, Bayer, Germany | Dr Andrea Staab, Boehringer Ingelheim, Germany

GMP meets GCP

Management, supply and quality assurance of clinical trials

16-18 June 2026, Live Online Training — Course No. 22303

Highlights:

- Rules and Regulations: Applicable legislation and GMP/GCP interfaces, Duties and responsibilities
- Supply Management: Packaging, Labelling, Distribution, Shelf-life extensions, Handling of comparators
- Study Management: Key tasks and responsibilities, The role of the hospital pharmacy

Speakers:

Thomas Becker, Dr Thomas Becker Pharma & Biotech Consulting | Pascal Brendelberger, Pharma Packaging Expert | Patryk Jegorow, Takeda | Gabriela Schallmeiner, Inspection Ready Consulting | Gerlinde Schmitter, CureVac | Gabriele Schwarz, BfArM | Dr Lenka Taylor, Heidelberg University Hospital

Auditing / Inspections

All courses marked with this symbol are recognised for the „ECA Certified GMP Auditor“ Certification Programme. Further information is available on our website.

Self-Inspection

Compliant and successful self-inspections and internal audits

24 February 2026, Live Online Training — Course No. 22379

Highlights:

- Regulatory Requirements
- Expectations regarding planning, implementation and follow-up
- The Implementation of Self-Inspections

Speakers:

Dr Rainer Gnibl, District Government of Upper Bavaria, Germany | Dr Felix Kern, Merck, Germany

Efficient Supplier Qualification

15/16 April 2026, Hamburg, Germany — Course No. 22148

Highlights:

- Regulatory Background and Expectations of the Agencies
- How to increase Efficiency in Supplier Qualification: Quality Risk Management, Third Party Audits
- Integration of Suppliers, Logistic Providers, Contract Manufacturers and Laboratories in the Quality System

Speakers:

Melanie Distl, Roche | Mukesh Patel, CommQP | Philipp Reusch, Reuschlaw Wolfgang Schmitt, Concept Heidelberg | Dr Franz Schönfeld, GMP Inspector | Dr Reto Theiß, Merck Healthcare

With an optional pre-course Session on

What You Need to Know About Suppliers in China and India

Highlights:

- Sourcing from Asia: What Procurement and QA should Know
- India and China: Cultural Aspects to Consider when Doing Business
- The Indian and Chinese Pharma Market: an Overview (Legal Structures, Authorities)

Speakers:

York Moeller, J.A.Moeller Chongqing | Mukesh Patel, CommQP

A discount of €400 applies when booking both courses together.

The GMP-Auditor

Initial and continuous professional training for GMP Auditors

05-07 May 2026, Berlin, Germany — Course No. 22137
20-22 October 2026, Live Online Training — Course No. 22519

Highlights:

- Expectations of the Authorities
- Risk-based Audit Planning
- Categorisation of Audit Findings

Speakers:
Dr Christian Hösch, GMP Inspector | Stefan Reintgen, Team Connex | Charis Schmidt, Ferring | Thomas Højsholm Schmidt, CSL Behring

GMP Auditor Practice

An advanced auditor course with many interactive sessions and practical examples

10-12 November 2026, Hamburg, Germany — Course No. 22489

Highlights:

- Understand and discuss: Root Causes in poor personal Behaviour, Challenging Personalities in the Audit
- How to audit: Quality Systems, Solid Dosage Forms, Parenteral Dosage Forms, ...

Speakers:
Energy Kristina Hansen, Novo Nordisk, Denmark | Ágnes Kis, form. GMP-Inspector at OGYÉI, Hungary | Christof Langer, OSConsulting, Austria | Thomas Højsholm Schmidt, CSL Behring, Switzerland

GMP-Auditor Forum 2026

A conference for GMP auditors to exchange experience

23/24 June 2026 | Barcelona, Spain

More details: www.gmp-auditor.gmp-compliance.org

Packaging

All courses marked with this symbol are recognised for the „ECA Certified Packaging Manager“ Certification Programme. Further information is available on our website.

Extractables & Leachables

Challenges and solutions for packaging / devices & single-use systems

05/06 May 2026, Live Online Training — Course No. 22425

Highlights:

- Current Regulatory Requirements
- Practical Approaches for E&L Testing
- Evaluation of E&L Data

Speakers:

Dr Katrin Buss (invited), Quality Assessor | Marcel Dörkes, Eurofins BioPharma | Dr Armin Hauk, Sartorius Stedim Biotech | Dr Dennis Jenke, Triad Scientific Solutions, USA | Dr Ana Kuschel, West Pharmaceutical Services | Dr Andreas Nixdorf, SGS Institut Fresenius | Gaby Reckzügel, Boehringer Ingelheim Pharma

Design Controls for Drug-Device Combination Products

23/24 June 2026, Live Online Training — Course No. 22507

Highlights:

- Regulatory Requirements (USA/EU), Quality System requirements (USA/EU)
- Standards, process and guidance for: Usability Engineering, Risk Management, Design Planning, ...
- Case Studies

Speakers:

Dr Gerhard Bauer-Lewerenz, GBL-Consulting, Germany | Andrew Fiorini, Cambridge Design Partnership, UK | Torsten Kneuss, Bayer, Germany | Urs Widmer, confinis, Switzerland | Lee Wood, medHF, Switzerland

Avoiding Non-Compliance in Packaging Operations

04/05 November 2026, Live Online Training — Course No. 20643

Highlights:

- GMP Requirements & Guidelines for Packaging Operations
- Requirements for Packaging Facilities
- Cleaning and Hygienic Concepts for Packaging Areas

Speakers:

Alexandra Wengerter , Merz, Germany | Daniel Guirao Navarro | Reig Jofre, Spain | Dr Rainer Kahlich, GMP Inspector, Germany | Sergio Cuevas Luján, Teva | Dr Stephan Schwarze, StepS Consulting, Germany | Ana Cláudia Pinho Bial, Portugal | Alexander Gutbrod, Vetter, Germany

Microbiology / Hygiene

All courses marked with this symbol are recognised for the „ECA Certified Microbiological Laboratory Manager“ Certification Programme. Further information is available on our website.


Photo: Courtesy Sartorius Stedim Biotech S.A.

Virus Safety – Best Practices and Emerging Trends

03/04 March 2026, Heidelberg, Germany — Course No. 22295

Highlights:

- Overview about Regulatory Background
- The Impact on the Manufacture of Biopharmaceuticals/Biologics
- Current Detection, Inactivation and Removal Techniques

Speakers:

Dr Johannes Blümel, Paul-Ehrlich-Institute (Federal Agency for Vaccines and Biomedicines) | Dr Albrecht Gröner, PathoGuard Consult | Dr Michael Ruffing, Boehringer Ingelheim Pharma | Michael Schiffer, CSL Behring

Low Endotoxin Recovery / Masking (LER)

Hands-on Laboratory Training Course

10/11 March 2026, Munich/Bernried, Germany — Course No. 22499

Highlights:

- Interpretation of Interference during Endotoxin Detection
- Understanding Low Endotoxin Recovery (LER)
- Setup of hold-time Studies

Speakers:

Dr Christian Faderl, bioMérieux | Dr Holger Kavermann, Roche | Alessandro Pauletto, bioMérieux | Georg Schumm, Lonza Cologne | Veronika Wills, Associates of Cape Cod | Marc Zechmann, Microcoat | Luis Barthelmes, Labor LS

Monocyte Activation Test

Hands-on laboratory training course

12/13 March 2026, Munich/Bernried, Germany — Course No. 22500

Highlights:

- Explanation of the MAT Principle
- Available MAT Kits and Methods
- Understanding pharmacopoeial Requirements

Speakers:

Marc Juraschitz, Microcoat | Fabian Nürnberger, Labor LS | Dr Ruth Röder, Microcoat | Dr Ingo Spreitzer, Paul-Ehrlich-Institut, German Federal Agency for Vaccines and Biomedicines | Dr Sandra Stoppelkamp, University Tübingen and South Westphalia University of Applied Sciences | Delphine Trelat, Sanofi Pasteur

Microbiology for Non-Microbiologists

Understand the “true” meaning of microbiological findings

14/15 April 2026, Live Online Training — Course No. 22502

Highlights:

- Acquire a Basic Knowledge in Microbiology
- Develop an Understanding for the Meaning of Microbiology for the Quality of Medicinal Products
- Get familiar with Typical Microbiological Tests in the Pharmaceutical Industry

Speakers:

Dr Hans-Joachim Anders, Novartis Stein, Switzerland | Dr Stefanie Bayer, Labor LS, Germany | Arjan Langen, MSD, The Netherlands | Axel H. Schroeder, Concept Heidelberg, Germany

COMMUNITY CELEBRATION GET 2 CONGRESS TICKETS AND ECA MEMBERSHIPS WITH ONLY 1 REGISTRATION

European Microbiology Jubilee Conference

24/25 March 2026, Wiesbaden, Germany

Part of GMP-PharmaCongress

GMP-PHARMA CONGRESS

www.pharma-congress.com

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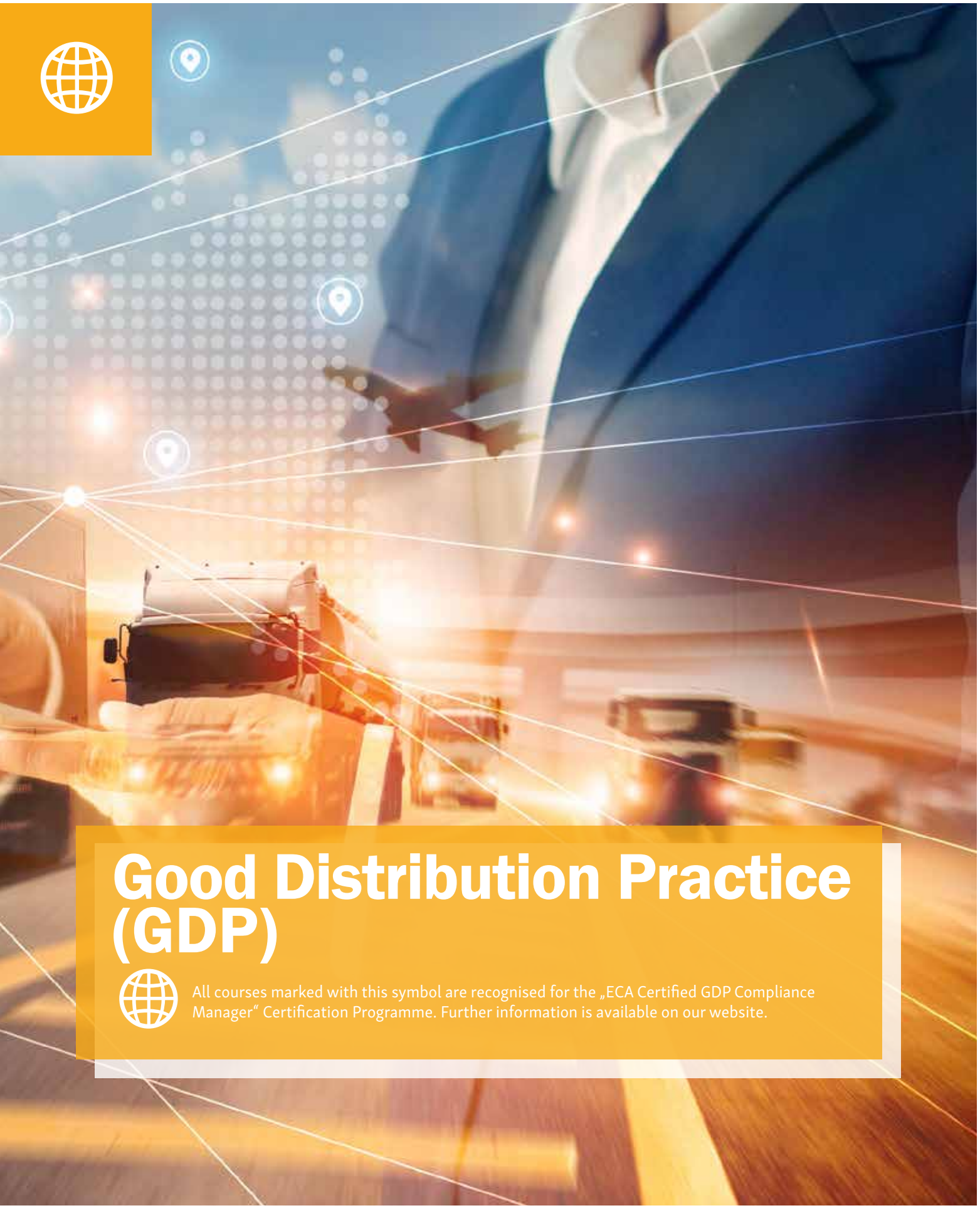

Good Distribution Practice (GDP)

All courses marked with this symbol are recognised for the „ECA Certified GDP Compliance Manager“ Certification Programme. Further information is available on our website.

GDP Audits

How to audit logistics service providers

18 February 2026, Live Online Training — Course No. 22416

Highlights:

- Audit methodology for different transport modes
- How to Audit: Road transport Vendors, Forwarders on airfreight Service, Forwarders on ocean freight service
- How to host and prepare for a Quality and Risk Management System and GDP audit

Speaker:
Dr Zvonimir Majic, IATA Senior Consultant for Healthcare, Croatia

GDP Update 2026

From development to batch release

12 March 2026, 14:00-16:30 CET, Live Webinar — Course No. 22165

Highlights:

- Regulatory updates – Changes in regulations, guidelines, and publications from authorities and organizations over the past 12 months
- Insights from the European GDP Association
- GDP Compliance – Overview of key requirements, responsibilities, and essential documents/SOPs

Speaker:
Dr Christian Grote-Westrick, B. Braun Avitum

The Responsible Person for Good Distribution Practices (GDP)

06/07 May 2026, Copenhagen, Denmark — Course No. 22241

Highlights:

- The EU GDP Guidelines
- Roles and Responsibilities of the Responsible Person
- What to learn from GMP/GDP Inspections and Audits

Speakers:
Alfred Hunt, Hunt Pharma Solutions, Ireland | Dr Daniel Müller, GMP/GDP Inspector, Germany | Jonathan Riley, Takeda UK | Dr Torsten Schmidt-Bader, moveproTec, Germany

Stability Studies to Support Shipping / Distribution of Pharmaceuticals and Biopharmaceuticals

17/18 June 2026, Live Online Training — Course No. 22564

Highlights:

- Stability Programs and Storage Statements
- Mean Kinetic Temperature (MKT) and World Climatic Zones
- Stress Studies of Pharmaceuticals

Speakers:

Dr Raphael Bar, BR Consulting, Israel | Dr Thomas Fürst, Boehringer Ingelheim, Germany

GDP in Switzerland

Specifics in the distribution of medicinal pand APIs

08 September 2026, Basel, Switzerland — Course No. 22238

Highlights:

- Legal Bases for the Distribution of Medicinal Products
- Tasks, Responsibilities and Liability
- Practical Implementation in Switzerland

Speakers:

Dr Ina Bach, Dr Bach | Dr Johannes Fröhlich, Akroswiss | Dr Felix Kesselring, Bratschi | Dr Matthias Schwebe, Roche Pharma

Pharma Supply Chain: GDP Requirements and Certification for Logistics Vendors

06 October 2026, Live Online Training — Course No. 22567

Highlights:

- Mastering Supply Chain Risks
- Quality and Risk Management Systems
- Standards and Guidance in Supply Chain (GDP meets ISO; Certification and Selection of Logistics Suppliers)

Speakers:

David Abraham, Quality Resource Solutions | Dr Zvonimir Majic, IATA Senior consultant for Healthcare, Croatia

GDP for APIs

22 October 2026, Live Online Training — Course No. 22242

Highlights:

- Regulatory requirements
- GDP-compliant transport of active substances (human and veterinary), GDP-compliant storage
- Monitoring of suppliers and the supply chain from the perspective of the Qualified Person

Speakers:

Dr Marcel Günther, Regierungspräsidium Tübingen, Germany | Dr Martin Melzer, gempex GmbH, Germany | Dr Ulrich Kissel, KisselPharmaConsulting, Germany

APIs / Excipients

All courses marked with this symbol are recognised for the „ECA Certified API Production Manager“ Certification Programme. Further information is available on our website.

GMP for Excipients

03 February 2026, Live Online Training — Course No. 22346

Highlights:

- EU GMP Requirements for Excipients – View of an Inspector
- Formalized Risk Assessment for Excipients

Speakers:

Emerich Grassinger, Takeda, Austria | Dr Franz Schönfeld, German GMP and GDP Inspector at the District Government of Upper Franconia

APIC ACTIVE PHARMACEUTICAL INGREDIENTS COMMITTEE a sector group of cefic ECA Academy Your GMP/GDP Information Source

www.ichq7-week.org

Handling of Foreign Particles in APIs and Excipients

10/11 February 2026, Live Online Training — Course No. 22174

Highlights:

- Key Preventive Measures to Minimise Foreign Particles
- How to Deal with Technically Unavoidable Particles in Excipients
- Acceptance Criteria for Particles in APIs

Speakers:

Karl Heinz Freitag, Takeda Manufacturing Austria | Rajnish Kumar, QAR Solutions, The Netherlands | Martin Melzer, gempex, Germany | Robert G. Schwarz, GXP-TrainCon, Austria

How to Register APIs in Brazil

Focus on CADIFA and obtaining a Brazilian GMP certificate

24 February 2026, Live Online Training — Course No. 22188

Highlights:

- How to handle Brazilian registrations and changes
- Content of the registration file
- Obtaining the Brazilian GMP (CBPF) certificate

Speakers:

Marieke van Dalen, MARA Consultancy, The Netherlands | Susan Swiggers, Aspen Oss, The Netherlands

APIC a sector group of ceflc In cooperation with ECA Academy Your GMP/GDP Information Source

api-conference.org

ECA GMP/GDP Certification Programmes

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Highly qualified personnel are a crucial factor in the GMP-compliant manufacturing of APIs, medicinal products, and medical devices. While your college or university education provides the scientific basis, the ECA GMP/GDP Certification Programme complements your professional training with a well-established certification.

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- ECA Certified Validation Manager
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- ECA Certified Quality Control Manager
- ECA Certified Technical Operations Manager
- ECA Certified Computer Validation Manager
- ECA Certified Regulatory Affairs Manager
- ECA Certified Microbiological Laboratory Manager
- ECA Certified Sterile Production Manager
- ECA Certified Pharmaceutical Development Manager
- ECA Certified Biotech Manager
- ECA Certified GMP Auditor
- ECA Certified GDP Compliance Manager
- ECA Certified Packaging Manager
- ECA Certified Data Integrity Manager

For more information please visit
www.gmp-certification.org

Quality Assurance / Qualified Person

All courses marked with this symbol are recognised for the „ECA Certified Quality Assurance Manager“ Certification Programme. Further information is available on our website.

Combination Products

Medicinal products / drugs meet medical devices

10/11 February 2026, Heidelberg, Germany — Course No. 22201

Highlights:

- Regulatory Requirements Medicinal Products/Drugs
- Regulatory Requirements Medical Devices
- Classification of Medical Devices in the USA

Speakers:

Harald Rentschler, mdc, medical devices certification | Dr Peer Schmidt, AbbVie | Dr Andrea Weiland-Waibel, Explicat

Pharmaceutical Contracts: GMP and Legal Compliance

04/05 March 2026, Live Online Training — Course No. 22163

Highlights:

- GMP requirements: Duties and responsibilities, Expectations of the authorities
- Legal and juristic Knowledge: International law, Structure of Agreements, Content of agreements
- Practical perspective: What is needed? Who is involved?

Speakers:

Dr Carsten Coors, Vetter Development Services, Austria | Dr Rainer Gnibl, EU-GMP Inspector, Local Government, Germany | Dr Monika Hupfauf, Attorney-at-Law, Austria

GMP and Quality Requirements for Radiopharmaceuticals

17/18 March 2026, Copenhagen, Denmark — Course No. 22420

Highlights:

- Regulatory Developments and Authorities' Expectations
- Radiopharmaceuticals in Ph. Eur. and Annex 1
- QRM – Challenge Quality Risk Management

Speakers:

Dr Dirk Freitag-Stechl, CUP Laboratorien, Germany | Marlous van der Hooft, Qualificiency Consulting, Germany | Thijs Kroon, M2K2 radiopharma consultancy, The Netherlands | Arjan Langen, MSD Animal Health, The Netherlands | Dr Franz Schönfeld, Government of Upper Franconia, Germany

GMP-Update: Reform of EU Pharmaceutical Legislation

17 March 2026, Live Online Training — Course No. 22608

Highlights:

- Professionals involved in GMP-relevant activities within the pharmaceutical industry
- Personnel responsible for preparing for or implementing regulatory updates in their organisations
- Anyone who wants an overview of the expected GMP-related changes proposed in the revision of EU Medicines Legislation

Speakers:
Dr Fatima Bicane, Pharma Deutschland | Dr Ulrich Kissel, European QP Association

Right-sizing GMP and Compliance

How to implement lean GMP systems

25/26 March 2026, Berlin, Germany — Course No. 22332

Highlights:

- Basics of Lean Thinking
- Case studies: Linking Lean and Quality, Lean Documentation Systems, Lean and Kaizen in the Quality System
- Interactive Sessions: A3 Lean Thinking Approach, Lean Process Management, Right-sizing GMP/Compliance

Speakers:
Dr Anke von Harpe, QProgress, Germany | Cecilie Hejlskov, Ferring, Denmark | Arnoud Herremans, Lean Kaizen Consultant, The Netherlands | Christof Langer, OSConsulting, Austria | Dr Frank Seibel, Roche Diagnostics, Germany

GMP for Beginners

Understanding the importance of GMP

21-22 April 2026, Live Online Training — Course No. 22384
20-21 October 2026, Live Online Training — Course No. 22462

Highlights:

- GMP History & Trends
- Basic Principles of GMP
- Elements of a QA System

Speakers:
Dr Christoph Prinz, BioNTech, Germany | Dr Heinrich Prinz, PDM Consulting, Germany | Dr Wolfgang Schumacher, SPC, Switzerland

Efficient Batch Record Design and Review

Batch manufacturing documents: from preparation to operational excellence

27/28 May 2026, Live Online Training — Course No. 22210

Highlights:

- Background and GMP Requirements: Regulatory requirements, Good Documentation Practice
- Practical Implementation: From design to final approval, Examples
- Process Improvement: Efficiency in the review process, Electronic Batch Record, AI, ...

Speakers:

Dr Bernhard Böhm, Boehringer Ingelheim Vetmedica | Jakub Čierný, SOTIO Biotec | Ingo Ebeling, Abbott Laboratories | Maria Thai Hien Nguyen Heimbürger, Ascendis Pharma | Dr Felix Kern, Merck | Dr Monika Schlapp, Boehringer Ingelheim Vetmedica

Deviation Management and CAPA

Mastering root cause analysis, (non-)human error and CAPA

02/03 June 2026, Hamburg, Germany — Course No. 22149

Highlights:

- Rules and Regulations
- CAPA System Implementation
- Root Cause Analysis

Speakers:

Marcus Heinbuch, B.Braun Melsungen, Germany | Mick Hopper, GxPpro, UK | Dr Jens-Uwe Rengers, JeRo Consulting, Switzerland | Sandra Schäffler, GMP/GDP Inspectorate, Germany | Charis Schmidt, Ferring, Germany

Quality Oversight

Supervision of the pharmaceutical quality system: challenges and opportunities

17/18 June 2026, Copenhagen, Denmark — Course No. 22249

Highlights:

- FDA and EU Expectations
- Managing Quality Oversight
- Case Studies: Gap Analysis and Implementation, Performance Review and Monitoring, CMO Business, ...

Speakers:

Dr Panagiotis Fakitsas, F. Hoffmann-La Roche | Dr Rainer Gnibl, GMP Inspector | Dr Alexander Pontius, Bayer | Dr Frank Seibel, Roche Diagnostics | Dr Georg Sindelar, Recipharm | Hans Steier, Vetter Pharma-Fertigung

Improve Your Quality Reviews

PQR, APR, management review, quality metrics

25/26 June 2026, Live Online Training — Course No. 22211

Highlights:

- Quality Reviews in the Context of FDA, EU and ICH
- Expectations of the Agencies
- AI/ Machine Learning Tools

Speakers:

Simone Baisi, Kedrion Biopharma, Italy | Cheryl Chia, BeOne Medicines, The Netherlands | Dr Rainer Gnibl, GMP Inspector for EMA, Germany | Dr Jean-Denis Mallet, NNE Pharmaplan, France | Dr Jens-Uwe Rengers, JeRo Consulting, Switzerland

Root Cause Analysis

A CAPA workshop on successful failure investigation

02/03 September 2026, Copenhagen, Denmark — Course No. 22618

Highlights:

- Regulations and Background
- Human Error
- Tools presented: 5 Whys, Ishikawa (Fishbone), Comparative Analyses, Bow-Tie Risk Management, ...

Speakers:

Energy Kristina Hansen, MilCor Consulting | Cecilie Hejlskov, Syntese | Tim Ohlrich, Gempex | Wolfgang Schmitt, Concept Heidelberg

Quality Risk Management

An ICH Q9 training course

16/17 September 2026, Barcelona, Spain — Course No. 22509

Highlights:

- ICH Q9 Implementation
- Expectations of the Inspector
- QRM Tools

Speakers:

Alexandra Bauloye, Johnson & Johnson Innovative, Medicine, Belgium | Christof Langer, OSConsulting, Austria Aidan Madden, FivePharma, Ireland | Dr Franz Schönfeld, GMP Inspector, Germany

The GMP-Compliance Manager

27/28 October 2026, Berlin, Germany — Course No. 22530

Highlights:

- Current Regulatory Requirements and Expectations
- Deviations and CAPA
- Documentation Systems, Review and Approval

Speakers:

Ingo Ebeling, Abbott | Melanie Kinzner, Sandoz | Katja Kotter, Vetter Pharma-Fertigung | Sue Mann, Sue Mann Consultancy | Sebastian Rögner, Croma Pharma

CMO Oversight

Quality oversight of pharmaceutical contract manufacturing organisations

14/15 October 2026, Vienna, Austria — Course No. 22558

Highlights:

- Requirements and Responsibilities
- Challenges and possible Solutions
- Quality System Aspects

Speakers:

Energy Kristina Hansen, MilCor Consulting, Denmark | Canice Kearney, Takeda, Ireland | Sue Mann, Sue Mann Consultancy, UK | Jette Petersen, Roche, Switzerland

Quality Culture

People empowerment in GMP

03/04 November 2026, Hamburg, Germany — Course No. 22555

Highlights:

- What is Quality Culture?
- How to implement Quality Culture in Business
- Knowledge Management

Speakers:

Thaleia Aikaterini Darmi, Boehringer Ingelheim Hellas, Greece | Arnoud Herremans, Y47 Consultancy, The Netherlands | Dr Thomas Krieger, KU-Pharma, Germany | Aidan Madden, FivePharma, Ireland | Francois Vandeweyer, VDWcGMP Consulting, Belgium

ECA | QP ASSOCIATION
An ECA Foundation Interest Group

Qualified Person Education Course: Module A

Understand the implications of becoming a QP

11/12 March 2026, Hamburg, Germany — Course No. 22103
08/09 October 2026, Live Online Training — Course No. 22515

Highlights:

- The Legal and Professional Duties of the Qualified Person
- Update on European Requirements
- Delegation of Duties and Responsibilities

Speakers:

Julia Gudd, GMP and GDP Inspector, Hamburg, Germany | Dr Ulrich Kissel, European QP Association | Savvas Koulouridas, Fagron BV, The Netherlands | Aidan Madden, FivePharma, Ireland | Sue Mann, Sue Mann Consultancy, UK | Lance Smallshaw, UCB Biopharma, Belgium

With an optional pre-course session on

Investigational Medicinal Products (IMP) QP Education Course

10 March 2026, Hamburg, Germany — Course No. 22101

Highlights:

- Principles of Clinical Trials
- Specific Legal Requirements for IMPs
- GMP meets Clinical Trials – Differences between IMPs and Commercial Products

Speakers:

Dr Susanne Ding, Boehringer Ingelheim, Germany | Patryk Jegorow, Takeda, Ireland | Sue Mann, Sue Mann Consultancy, UK

A discount of €400 applies when booking both courses together.

Qualified Person Education Course: Module B

Mastering the QP role in daily practice

20/21 May 2026, Barcelona, Spain — Course No. 22183

Highlights:

- QP Interfaces
- Import – Export – Product Flow
- Interpretation of Data (with a Focus on Batch Documentation and the PQR)

Speakers:

Georg Göstl, Qualified Person, Takeda, Austria | Dr Ulrich Kissel, European QP Association | Sue Mann, Sue Mann Consultancy, UK | Jens-Uwe Rengers, JeRo Consulting, Switzerland | Ewa Rybak, JJP Biologics, Poland

With an optional pre-course session on

Soft Skills for the QP: Leadership with Impact

19 May 2026, Barcelona, Spain — Course No. 22118

Highlights:

- Introduction and objectives
- Situational leadership and leadership skills for the QP
- How a QP needs to demonstrate leadership

Speakers:

Arnoud Herremans, Y47 Consultancy, The Netherlands | Sue Mann, Sue Mann Consultancy, UK

A discount of €400 applies when booking both courses together.

The QP in Switzerland

Role, accountability and liability of the Responsible Person

04/05 March 2026, Bern, Switzerland — Course No. 22104

Highlights:

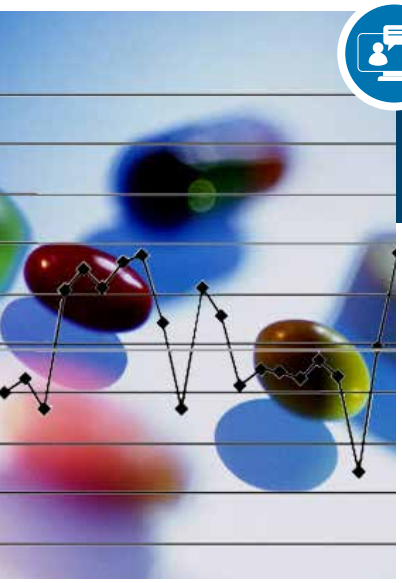
- EU Regulations and their Implementation in Switzerland
- Revision of the Therapeutic Products Act and Amendments to Ordinances
- Tasks and Responsibilities in the Supply Chain

Speakers:

Dr Ina Bach, Dr Bach, former RHI | Dr Karin Hofstetter, BioAtrium | Dr Felix Kesselring, Bratschi Rechtsanwälte | Dr Ulrich Kissel, European QP Association | Dr Carsten Meininghaus, dsm-firmenich | Jette Petersen, Roche

Validation / Qualification

All courses marked with this symbol are recognised for the „ECA Certified Validation Manager“ Certification Programme. Further information is available on our website.



Statistical Process Control in the Pharmaceutical Industry

05/06 February 2026, Live Online Training — Course No. 22184

Highlights:

- Six Sigma, Process Capability, Process Improvement
- Case Study SPC and Trending of Microbiological Data
- Case Study Sanofi-Aventis SPC as tool for Continued Process Verification

Speakers:

Dr Ingolf Stückrath, Sanofi, Germany | Dr Sven Wedemeyer, Merck, Germany | Dr Björn Wiese, Janssen Cilag, Switzerland

The Validation Manager

in the pharmaceutical industry

25-27 March 2026, Barcelona, Spain — Course No. 22370

Highlights:

- Cleaning Validation, Computer Validation
- Risk Assessment
- Case Studies Qualification/Validation

Speakers:

Lynn Bryan, Ballygan Consulting, UK | Dr Line Lundsberg-Nielsen, Lundsberg Consulting, UK | Dr Wolfgang Schumacher, formerly of F. Hoffmann-La Roche, Switzerland | Dr Norbert Skuballa, Biologische Arzneimittel Heel, Germany

Cleaning Validation during the Manufacturing of Medical Devices

14 April 2026, Live Online Training — Course No. 22582

Highlights:

- Fundamental regulatory and normative requirements regarding the cleaning of medical devices
- Differences from pharmaceuticals and practical approaches for implementing cleaning validation in the field of medical devices

Speakers:

Robert G. Schwarz, GXP-TrainCon | Marc Seegers, mdc

Cleaning Validation

Current GMP for cleaning validation

28/29 April 2026, Live Online Training — Course No. 22432
24/25 November 2026, Live Online Training — Course No. 22688

Highlights:

- Sampling
- Hygienic Equipment Design
- Cleaning Process Development

Speaker:
Robert G. Schwarz, FH Campus Vienna, Austria

With an optional post-course session on

Impact of Annex 1 Revision on Cleaning Validation

30 April 2026, Live Online Training — Course No. 22434
26 November 2026, Live Online Training — Course No. 22690

Highlights:

- Regulatory requirements of Annex 1 regarding Cleaning Validation & Cleaning
- Annex 1, Annex 15 and EMA "Shared facilities Guideline"
- Annex 1 & Cleaning Validation – practical approaches

Speaker:
Robert G. Schwarz, FH Campus Vienna, Austria

A discount of €200 applies when booking both courses together.

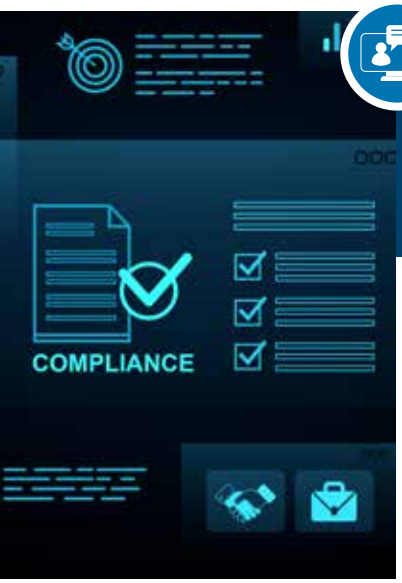
Validation / Qualification for Beginners

05 May 2026, Live Online Training — Course No. 22430

Highlights:

- Change Control
- Risk Assessment
- Qualification
- Process Validation

Speaker:
Dr Wolfgang Schumacher, SPC, Switzerland



Process Validation

12/13 May 2026, Live Online Training — Course No. 22628
29/30 September 2026, Live Online Training — Course No. 22627

Highlights:

- EU Inspector's and FDA's Point of View
- The link between Quality by Design and Process Validation
- Establishing the Control Strategy

Speakers:
Madeleine Fritzsche, EU Inspector, Germany | Dr Line Lundsberg-Nielsen | Dr Thomas Schneppe Sarah Zimmet, Boehringer Ingelheim Pharma, Germany

Ongoing / Continued Process Verification

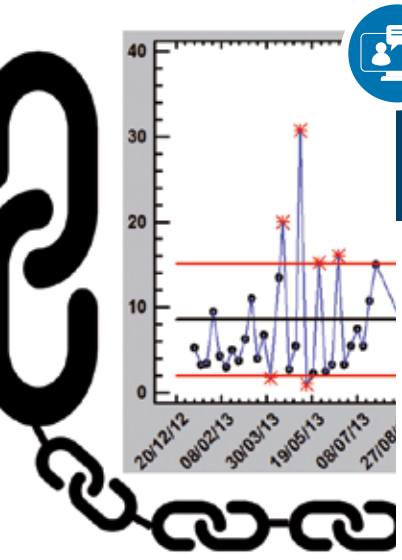
From the control strategy to product quality review

02/03 June 2026, Live Online Training — Course No. 22450

Highlights:

- FDA's Process Validation Guide and the Principles behind
- View of an EU Inspector
- 4 Case Studies

Speakers:
Dr Rainer Gnibl, GMP Inspector for EMA | Dr Line Lundsberg-Nielsen, Lundsberg Consulting | Dr Thomas Schneppe | Dr Ingolf Stückrath, Sanofi-Aventis Deutschland | Dr Chris Watts, VoPal, formerly of FDA | Sarah Zimmet, Boehringer Ingelheim



Trending of Process Data for OPV/CPV

14-16 October 2026, Advanced Level Live Online Training — Course No. 22641

Highlights:

- Overview of control charts
- Process Stability & Capability
- Why fundamental requirements for control charts are not met in real-life process data

Speaker:
Dr Raphael Bar, BR Consulting

Quality Control / Analytics

All courses marked with this symbol are recognised for the „ECA Certified Quality Control Manager“ Certification Programme. Further information is available on our website.

CAPAs in QC Laboratories

10 February 2026, Live Online Training — Course No. 22096

Highlights:

- Regulatory requirements for CAPAs and CAPAs in quality control
- Understand and prevent human error
- Measures to avoid and prevent OOS results
- Practical examples & exercises

Speaker:
Dr Karl-Heinz Bauer, Trainer - Consultant - Coach (previously of Boehringer Ingelheim)

QC Compliance Manager

Focus on small-molecule APIs and drug products

03/04 March 2026, Live Online Training — Course No. 22228

Highlights:

- Regulatory Requirements for Analytical Labs (EU and U.S.)
- Analytical Instrument Qualification
- Chromatographic Reference Standards

Speakers:
Dr Thomas Backensfeld, Berlin, Germany | Dr Raphael Bar, BR Consulting, Israel | Dr Thomas Fürst, Boehringer Ingelheim, Germany | Sue Mann, Sue Mann Consultancy, UK | Dr Ralph Nussbaum, Omega Pharma, Germany

Quality Control of Starting Materials

(APIs and excipients)

18/19 March 2026, Vienna, Austria — Course No. 22168

Highlights:

- Regulatory Requirements for APIs and Excipients
- Current GMP Requirements for APIs, Excipients and Drug Products
- Pharmacopoeias

Speakers:
Emerich Grassinger, Takeda, Austria | Veronika Käser, Merck Healthcare, Germany | Dr Reto Theiss, Merck Healthcare, Germany

Analytical Instrument Qualification

05-07 May 2026, Vienna, Austria — Course No. 22341

Highlights:

- Regulatory Aspects of Analytical Instrument Qualification
- USP General Chapter <1058> - Analytical Instrument Qualification
- Risk Assessment in Analytical Laboratories

Speakers:

Jörg Kastenschmidt, Merck, Germany | Philip Lienbacher, Takeda, Austria | Roland Miksche, MiRo Consulting, Austria

Analytical Methods for Cleaning Validation

Development, validation & control

09-11 June 2026, Live Online Training — Course No. 22506

Highlights:

- Cleaning Method Characteristics
- Calculation of MAC
- Sampling Techniques of Cleaning Residues

Speakers:

Dr Raphael Bar, BR Consulting, Israel | Walid El Azab, QP Pro Services, Belgium

Transfer of Analytical Procedures

11 June 2026, Live Online Training — Course No. 22366

Highlights:

- Management of the Transfer Process
- Root Causes of Issues during Transfer
- Risk-based Design of Transfer Studies
- Evaluation of Results

Speaker:

Dr Joachim Ermer, Ermer Quality Consulting, Germany


Image: ERWEKA GmbH, Germany

Dissolution Testing

Development / quality control and *in vivo* relevance

23/24 June 2026, Live Online Training — Course No. 22491

Highlights:

- Importance of Dissolution Testing in Drug Development and for a Commercial Product
- *In vivo* Relevant Dissolution Testing
- Discriminatory Power of a Dissolution Method

Speakers:

Dr Corinna Bode, Bayer | Dr Jan Joseph, Bayer | Dr Gerd Michael Maier, Boehringer Ingelheim | Dr Johanna Milsmann, Boehringer Ingelheim

EU GMP-/FDA-Compliant Sampling

22/23 September 2026, Live Online Training — Course No. 22565

Highlights:

- Regulatory and Compendial Requirements
- Acceptance Sampling and Sampling by Variables
- Classification of Nonconformities and allocating AQL to Classes

Speakers:

Dr Raphael Bar, BR Consulting, Israel | Dr Gerald Kindermann, GxP Consulting, Switzerland | Philip Lienbacher, Takeda, Austria

Ph. Eur., USP and Other Pharmacopoeias

Dealing with different compendial methods

06/07 October 2026, Live Online Training — Course No. 22463

Highlights:

- Structure of Ph. Eur. and USP and their enforcement
- Additional Pharmacopoeias around the world – Japan, China, India, Int. Ph. (WHO)
- Harmonisation of Ph. Eur., USP, JP

Speakers:

Dr Raphael Bar, BR Consulting, Israel | Dr Ulrich Rose, Former Deputy Head of the European Pharmacopoeia Department, EDQM | Dr Lance Smallshaw, UCB, Belgium

Validation of Analytical Test Procedures & Measurement Uncertainty

13-15 October 2026, Barcelona, Spain — Course No. 22245

Highlights:

- Analytical Instrument Qualification
- Measurement Uncertainty and its Impact on Analytical Methods Validation
- Practical Determination of Validation Characteristics

Speakers:

Dr Christopher Burgess, Burgess Analytical Consultancy, UK | Trevor J. Coomber, Pharmaceutical Development, Consultant, UK | Dr Xaver Schratt, GBA Pharma, Germany

Practical Statistical Tools for Analytical Laboratories

20/21 October 2026, Live Online Training — Course No. 22246

Highlights:

- Participants should gain an understanding of: basic statistical fundamentals, distribution of data and its Parameters, accuracy and precision
- Participants will be shown how to: apply statistical principles scientifically and pragmatically in their day-to-day Business, use statistical simulations

Speakers:

Dr Christopher Burgess, Burgess Analytical Consultancy, UK | Dr Joachim Ermer, Ermer Quality Consulting, Germany

Setting Specifications and Acceptance Criteria

03/04 November 2026, Barcelona, Spain — Course No. 22573

Highlights:

- Principles for Setting of Release and Shelf-life Specifications throughout Development
- Regulatory Requirements for Specifications (ICH Q6A)
- Specifications of Biopharmaceuticals

Speakers:

Dr Ulli Backofen, Boehringer Ingelheim, Germany | Dr Thomas Fürst, Boehringer Ingelheim, Germany | Dr Josef Hofer, EXDRA, Germany | Dr Cornelia Nopitsch-Mai, former Quality Assessor, Germany | Dr Bettina Pahlen, Quality x Pharma Consulting, Germany | Dr Thomas Uhlich, Bayer, Germany

Stability Testing for Drug Substances and Drug Products

04/05 November 2026, Barcelona, Spain — Course No. 22574

Highlights:

- Stability Testing from Early Development to Product Launch
- Guidelines for Stability Testing
- Stability Testing for: Biologicals, Drug Substances

Speakers:

Dr Ulli Backofen, Boehringer Ingelheim, Germany | Dr Heiko Brunner, Hamburg, Germany | Dr Thomas Fürst, Boehringer Ingelheim, Germany | Dr Josef Hofer, EXDRA, Germany | Dr Cornelia Nopitsch-Mai, former Quality Assessor, Germany | Dr Thomas Uhlich, Bayer, Germany

A discount of €400 applies when booking both courses together.

System Suitability Tests (SST) and Troubleshooting for HPLC Methods

10 November 2026, Live Online Training — Course No. 22685

Highlights:

- Importance of the system suitability test (SST) and regulatory requirements of chromatographic analytical methods
- Current changes in the pharmacopoeial SST chapters
- SST parameters and their acceptance criteria with a focus on chromatographic methods

Speakers:

Dr Heiko Brunner, Hamburg, Germany | Dr Gerd Jilge, Retired Head of a Method Development Laboratory at Boehringer Ingelheim Pharma, Germany

Regulatory Affairs

§ All courses marked with this symbol are recognised for the „ECA Certified Regulatory Affairs Manager“ Certification Programme. Further information is available on our website.

API Regulatory Starting Materials

25/26 February 2026, Live Online Training — Course No. 22189

Highlights:

- Defining an API Starting Material
- Starting Materials in the CEP Application Procedure
- Risk Assessment and Criticality Analyses

Speakers:

Marieke van Dalen, MARA Consultancy, The Netherlands | Gerd Jilge, formerly of Boehringer Ingelheim, Germany Cornelia Nopitsch-Mai, former Quality Assessor, Germany | Matthias Schneider, BASF, Germany | Francois Vandeweyer, VDWcGMP Consultancy, Belgium

GMP Meets Regulatory Affairs

24/25 March 2026, Hamburg, Germany — Course No. 22232

Highlights:

- Drug Approvals in the ICH Countries: Prerequisites and Procedures
- Structure of the CTD: Module 1,3,4,5
- Relevant GMP Documents for a Marketing Authorisation Application

Speakers:

Marieke van Dalen, MARA Consultancy, The Netherlands |Dr Rainer Gnibl, EU-GMP Inspector, Bavarian Government, Germany | Dr Josef Hofer, EXDRA GmbH, Germany | Dr Cornelia Nopitsch-Mai, former Quality Assessor, Germany

Global Registration and Life Cycle Management of APIs

21-23 April 2026, Heidelberg, Germany — Course No. 22233

Highlights:

- Dossier Requirements for the Drug Substance
- Requirements for the Certificate of Suitability
- ASMF Procedure

Speakers:

Marieke van Dalen, MARA Consultancy, The Netherlands | Alma Kiso, European Directorate for the Quality of Medicines (EDQM & Health Care), France | Cristina Jimenez Sala, Centrient Pharmaceuticals, Spain | Dr Wilhelm Schlumbohm, Berlin, Germany

How to Write the Quality Part of an IMPD

12/13 May 2026, Live Online Training — Course No. 22345

Highlights:

- Drug Substance Information
- IMP Dossier Quality Drug Product
- Substantial Amendments and Notification Obligations

Speakers:

Marieke van Dalen, MARA Consultancy, The Netherlands | Dr Wolfram Eisenreich, Boehringer Ingelheim Pharma, Germany | Dr Jörg Engelbergs, Paul-Ehrlich-Institut, Germany | Sonja Estermann, F. Hoffmann-La Roche, Switzerland | Dr Josef Hofer, EXDRA, Germany

Drug Master File Procedures in the EU, the US, and Japan

6/7 October 2026, Live Online Training — Course No. 22344

Highlights:

- Requirements of the European ASMF procedure
- Different types of Drug Master Files in the US
- How to document drug substance stability

Speakers:

Marieke van Dalen, MARA Consultancy, The Netherlands | Dr Cornelia Nopitsch-Mai, former Quality Assessor, Germany | Wilhelm Schlumbohm, Berlin, Germany

Handling Changes and Variations

10/11 November 2026, Vienna, Austria — Course No. 22356

Highlights:

- Also covering: Updated Variations Regulation and Veterinary Medicinal Products Variations
- The European Variations Procedure
- The CMDh Best Practice Guides and Explanatory Notes

Speakers:

Dr Peter Bachmann, BfArM, Germany | Dr Josef Hofer, exdra, Germany | Dr Wilhelm Schlumbohm, Berlin, Germany | Cristina Jimenez Sala, Centrient Pharmaceuticals

Sterile Manufacturing

All courses marked with this symbol are recognised for the „ECA Certified Sterile Production Manager“ Certification Programme. Further information is available on our website.

Isolator Technology Workshop

Engineering – validation – operation

10/11 November 2026 Course No. 22114

Highlights:

- Regulatory Requirements and Trends
- New Annex 1 Requirements
- From the Conceptual Design to the Validated Equipment

Speakers:

Tarik Cheema, F. Hoffmann-La Roche | Theresa Ladwig, SKAN | Ruben Rizzo, SKAN | Yves Scholler, SKAN | Alexandra Stärk, Novartis Pharma Stein | Eva-Maria Wolz, Labor LS

Picture: MS 2.0 – Microbiology and Biokinetik

Environmental Monitoring

Compliant and reasonable

11/12 June 2026, Copenhagen, Denmark Course No. 22505

Highlights:

- Environmental Monitoring. Why Do We Do It – What Does it Tell Us?
- Relevant Guidelines Including the New EU GMP Annex 1
- Non-viable (particulate) Air Monitoring

Speakers:

Arjan Langen, MSD Animal Health, The Netherlands | Chris Randell, CooperVision, UK | Dr Björn Wiese, Janssen Cilag, Switzerland

Annex 1 Intensive Training

Requirements for aseptic manufacturing and approaches for implementation

30 June/01 July 2026, Live Online Training Course No. 22577

Highlights:

- Revision Background and Relevant New Requirements

Speakers:

Dr-Ing. Jürgen Blattner, BSR | Dr Rainer Gnibl, GMP Inspector, Government of Upper Bavaria | Dr Philip Hörsch, Vetter | Arjan Langen, GE HealthCare | Stephan Löw, CSL | Carsten Moschner, CMC3 | Dr Daniel Müller, GMP Inspector | Dr Bettina Rietz-Wolf, GMP Inspector | Matthias Schaar, Novartis | Robert G. Schwarz, GXP-TrainCon | Dr Ingrid Walther, Pharma Consulting Walther, Chair ECA Annex 1 Task Force

Other Topics

Single-Use Systems – What You Need to Know

12 March 2026, Live Online Training — Course No. 22381

Highlights:

- Available SU Technology: Possibilities and Limitations
- GMP Requirements for the Usage of SU Equipment
- Quality Assurance for Manufacture of Single-Use Equipment

Speakers:

Dr Simone Biel, Merck | Prof Dr Regine Eibl, Zürcher University of Applied Science | Dr Daniel Müller, GMP Inspector | Nicola Rutigliani, Merck

Cleaning Validation in the Manufacturing of Medical Devices

14 April 2026, Live Online Training — Course No. 22582

Highlights:

- What are the requirements?
- Where can you find assistance in regulations and standards?
- Differences compared to medicinal products

Speakers:

Robert G. Schwarz, GXP-TrainCon | Marc Seegers, mdc

Quality Statistics in the Pharmaceutical Industry - Hands-On with Minitab

19/20 May 2026, Hamburg, Germany — Course No. 22700

Highlights:

- Pharma-focused real-world case studies
- Introduction to Minitab and its Quality Toolbox
- Demystification of key statistical concepts: p-value, significance testing, power, correlation, regression analysis

Speakers:

Dr Raluca Ilinca Schmitt, Bayer, Germany | Dr Christian Palmes, Bayer, Germany

GMP for Cannabis – what You Need to Know

19/20 May 2026, Live Online Conference — Course No. 21905

Highlights:

- GACP/GMP Requirements for Medical Cannabis
- How to get a MA-, Import-License (MIA) / How to get a GMP Certificate
- Experiences from Current Inspections
- Aspects to Consider for CBD
- Update from the German Cannabis Agency
- How to get GMP certified for Export
- Decontamination
- Qualification/Validation
- Lessons learned

Speakers:

Dr Viviana Braude, Cronos Israel, ECA Cannabis Working Group
Tina Cacanoska, PharmaRolly, North Macedonia, ECA Cannabis Working Group
Joaquín Dell'Acqua, Agronomist, Spain
Dr Rainer Gnibl, GMP Inspector, District Government of Upper Bavaria, Germany
Luis Meirinhos Soares, Auditor and Consultant, former GMP Inspector at INFARMED, Portugal, ECA Cannabis Working Group
Dr David Surjo, GOC NEXUS, Germany
Dr Giorgia Tossi, Linnea, Switzerland, ECA Cannabis Working Group
Dr Ingrid Walther, Pharma Consulting Walther, Germany, Chair of the ECA Cannabis Working Group
Dr Anne Wolf (invited), German Cannabis Agency, BfArM

Download for participants only:
non-official English translation of the German Pharmacopoeia (DAB) monograph "Cannabis Extract"

Drug Shortage Policy in the EU: How to Deal with Regulatory Requirements?

09 June 2026, Live Online Training — Course No. 22493

Highlights:

- Challenges with the European Regulatory Strategy for Managing and Monitoring Drug Shortages
- New Requirements like Reporting, SMP, SPP, i-SPOC
- Collaborative Solutions for Drug Shortage Management and Preventive Measures

Speakers:

Dr Fatima Bicane, Pharma Deutschland e.V. | Dr Ulrich Kissel, KisselPharmaConsulting

Excel in the GxP-Regulated Environment

16 September 2026, Live Online Training — Course No. 22236

Highlights

- Regulatory, technical, and data integrity requirements
- Life cycle approach according to GAMP 5
- Classification (criticality and complexity)

Speaker:
Roland Miksche, MiRo Consulting, Vienna, Austria

Also planned in 2026:

22357	China GMP and Registration of APIs
22585	Navigating ATMP Development
22127	Reference Standards
22676 22674	Visual Inspection of Parenterals & Fundamentals of Visual Inspection
22588	Pharmaceutical Biotechnology for Non-Biotechnologists
22589	Lyophilisation 2026
22590	GMP for Vaccine Manufacturers
22591	Quality Oversight in Sterile Manufacturing
22468 22467	Pharmaceutical Packaging Systems – Development & Pharmaceutical Packaging Systems – Quality Control
22365	The Impurities Workshop Part I-III
22594 22597	GMP for Beginners in Sterile Manufacturing & Aseptic Process Simulation
22699	Efficient GMP Training Systems
22576	GMP/FDA-Compliance in Analytical Laboratories
22244	The GDP Compliance Manager
19367	How to Provide Process Validation Data in a Regulatory Submission
21890	The GDP Audit
22023	Ambient Transport and Cold Chain
20097	Toxicological, Microbiological, and Pyrogen Safety of Medical Devices
22705	The New GMP for Veterinary Medicinal Products
22600	Supply Chain of ATMPs
22599	SoHO Regulation - Overview and Impact -
22601	Validation of Analytical Methods in Biotechnology

Training Courses and Conferences 2026

All the latest information and details of more than 300 further events, both on-site and live online, can be found on our web-site at
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