



Academy  
*Your GMP/GDP  
Information Source*

# European Events

- Live Online and on Site -

2023/2024

Quality Assurance  
Quality Control  
Sterile/Aseptic Manufacturing  
APIs/Excipients  
Computer Validation  
Data Integrity  
Production/Engineering  
Microbiology  
Biopharmaceuticals  
Validation  
GDP  
Others

[www.gmp-compliance.org](http://www.gmp-compliance.org)

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## ECA GMP/GDP Certification Programme

One reason for the ECA Academy's excellent reputation is its high-quality Certification Programme. In the past years, thousands of GMP and GDP professionals already relied on the programme to advance their knowledge and to get an additional qualification - and completed the ECA Certification Level.

This comprehensive qualification curriculum comprises 15 programmes, allowing professionals to combine several seminars according to their fields of interest.

### New – Attend Online Courses for Certification

Many of our training courses are offered live online. Also some training courses will be offered on demand (recording of live online training courses). These online courses will be recognized for the ECA GMP/GDP Certification Programme as well!

### Objectives

Highly qualified personnel is crucial within the field of GMP-compliant manufacturing of APIs and drugs. Although college and university education provide the scientific basis, a continuous advanced training is essential.

And this is where the ECA Academy GMP Certification Programme fills the gap. It offers modular training with an industry-known certification at the end. For most of the Certification Options you will need to attend 3 training courses of a comprehensive number of events. You can:

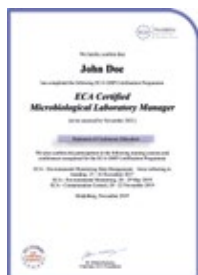
- select courses according to your individual professional demands
- suit the course registration to your company's necessities, i.e. usually there is a period of several months between the courses. If two dates are too close together, you can attend one course in the following year.

### Recognition of the Certification Programme

The ECA Academy enjoys an excellent reputation within Europe's pharmaceutical industry. The Certification Programme represents a useful completion of your college and university education. The ECA Certification Programme is the largest programme of its kind in Europe.

### Which Training Courses are Recognized for the Certification Programme?

To find out which training courses are recognized for the certification program, please click on the different certification options listed below. There you will find a link to the currently recognized training courses. Please note: On each program flyer for the Training Courses you will find an indication for which certification it is recognized.



### How to Obtain the Certificate?

To obtain the certificate, please send an e-mail prior or after the 3rd event you attended to [info@gmp-compliance.org](mailto:info@gmp-compliance.org). This e-mail should also list the courses you attended in the past. You will then get your certificate during the 3rd course. The Certificate will not only include the title of the Certification Programme, but also lists all ECA courses and conferences you attended. Thus, it will serve as a valid documentation for your continuous GMP and GDP education.

### Continuous GMP/GDP Certification – a service offered by the ECA Academy

In order to reflect the development of a continuous advanced education for GMP and GDP professionals from 2014 on the ECA Academy will issue the Certificates of the Certification Programme with a validity date. Every new Certificate (see list of the Certificates below) will be valid for two years. To renew it the applicant has to join one ECA Training Course or Conference within that period. Applicants are quite flexible in selecting training courses or conferences for the renewal. For example, a Validation Training Course or one on OOS Results will also be recognised for the renewal of the ECA Certified QA Manager Certificate, although these courses are not specifically recognized for the QA Manager Certificate (the same applies to all other certificates). This flexibility takes into account that applicants will broaden their knowledge in GMP Compliance.

The renewal process is easy and will be managed by the ECA Academy. If you have obtained one of the Certificates below in 2014 or later you will automatically receive a new version of your certificate which contains the new two years Certification statement every time you will participate in an ECA Training Course or Conference. Please contact us at [info@gmp-compliance.org](mailto:info@gmp-compliance.org) if you have any further question.

### We offer the following modules:



**ECA Certified Biotech Manager**



**ECA Certified Pharmaceutical Development Manager**



**ECA Certified Sterile Production Manager**



**ECA Certified Computer Validation Manager**



**ECA Certified Microbiological Laboratory Manager**



**ECA Certified Technical Operations Manager**



**ECA Certified Regulatory Affairs Manager**



**ECA Certified API Production Manager**



**ECA Certified QA Manager**



**ECA Certified Validation Manager**



**ECA Certified Quality Control Manager**



**ECA Certified GMP Auditor**



**ECA Certified GDP Compliance Manager**



**ECA Certified Packaging Manager**



**ECA Data Integrity Manager**

## ECA Certified Computer Validation Manager

- **(AI) Artificial Intelligence in a GxP Environment**  
Live Online Training on 9/10 October 2023
- **Computerised System Validation: Maintaining Control of Operation**  
Live Online Training on 11 - 13 October 2023
- **SAP – Validation and GMP Compliance**  
Live Online Training on 7/8 November 2023
- **Computerized System Validation: Introduction to Risk Management**  
Live Online Training on 21 November 2023
- **The GAMP 5 Approach**  
Live Online Training on 22 - 24 November 2023
- **Computerised System Validation: GMP Compliant Documentation**  
Live Online Training from 13-15 December 2023
- **Cloud Computing in a GxP Environment**  
Live Online Training from 21 - 23 February 2024
- **IT / OT Infrastructure Qualification and Operation in a GMP Environment**  
22 - 24 May 2023, Copenhagen, Denmark
- **Computerised System Validation Master Class**  
12 - 14 June 2024, Vienna, Austria  
With optional Pre-Course Session „Leveraging Suppliers“, 11 June 2024

## ECA Certified Data Integrity Manager

- **Data Integrity - Requirements for a GMP-compliant Data Life Cycle**  
29 November - 1 December 2023, Heidelberg, Germany  
Optional Full-Day Pre-Course Session „Audit Trail Review“:  
28 November 2023, Heidelberg, Germany
- **Lab Data Integrity**  
A Practical Approach for Generating and Auditing Laboratory Records  
Live Online Training on 05 - 07 December 2023
- **HPLC Data Integrity**  
Live Online Training on 24/25 January 2024
- **Audit Trail Review for Computerised Systems in Analytical Laboratories**  
Live Online Training on 07/08 May 2024
- **Data Integrity and Good Documentation Practice**  
GMP-compliant instructions and records  
18 - 20 June 2024, Vienna, Austria

## ECA Certified Technical Operations Manager

- **Product Transfer**  
Organisation of a GMP-compliant Site Change  
10 - 12 October 2023, Munich, Germany
- **Renovation and Upgrading of GMP Facilities**  
Live Online Training on 15/16 November 2023
- **GMP-compliant Equipment Design**  
Live Online Conference on 22/23 November 2023
- **GMPs for Equipment, Utilities and Facilities**  
Live Online Training from 9 - 11 April 2024
- **Granulation & Tableting**  
Live Online Training from 17-19 September 2024

## ECA Certified Biotech Manager

- **GMP for Vaccine Manufacturers**  
Live Online Training on 29/30 November 2023
- **Pharmaceutical Biotechnology for Non-Biotechnologists**  
Live Online Training on 14/15 December 2023
- **Annex 2 & Co - GMP Compliance for Biopharmaceuticals**  
Live Online Training on 07/08 May 2024
- **Protein Analytics**  
Evaluation, Implementation and Use of Suitable Technologies  
Live Online Training on 22/23 May 2024
- **Blood, Plasma and Stem Cells – Audits and Inspections**  
Live Online Training on 05/06 November 2024

## ECA Certified Development Manager

- **Emulsions & Gels**  
Live Online Training on 10/11 October 2023
- **GMP meets Development**  
Live Online Training on 6 - 8 November 2023
- **GMP meets GCP**  
Live Online Training from 27 - 29 February 2024
- **ICH Q8 Training Course**  
Live Online Training on 10/11 April 2024

## ECA Certified GMP Auditor

- **Inspection Management**  
How to pass global GMP Inspections  
Live Online Training on 18/19 October 2023
- **The GMP Auditor**  
Live Online Training on 21 - 23 November 2023
- **Efficient Supplier Qualification**  
13/14 March 2024, Barcelona, Spain  
With an optional pre-course Session on 12 March 2024:  
What you need to know about Suppliers in China and India
- **The GMP-Auditor**  
Initial and Continuous Professional Training for GMP Auditors  
15 - 17 May 2024, Berlin, Germany

## ECA Certified Packaging Manager

- **Serialization/Aggregation**  
Live Online Training on 15/16 November 2023

## ECA Certified Microbiological Laboratory Manager

- **Modern Microbiology Laboratory**  
„Best Lab Practice“  
07 - 09 November 2023, Barcelona, Spain
- **Microbiology for Non-Microbiologists**  
Live Online Training on 06/07 February 2024
- **Virus and TSE Safety made simple**  
All you need to know  
05/06 March 2024, Barcelona, Spain

## ECA Certified GDP Compliance Manager

- **The GDP Compliance Manager**  
Live Online Training on 4/5 October 2023

- **Ambient Transport and Cold Chain**  
24/25 October 2023, Vienna, Austria
- **GDP for Beginners**  
Storage - Transportation - Cold Chain  
Live Online Training on 31 January/01 February 2024
- **The Responsible Person for Good Distribution Practices (GDP)**  
17/18 April 2024, Hamburg, Germany

## *ECA Certified API Production Manager*

- **Handling of Foreign Particles in APIs and Excipients**  
Live Online Training on 28/29 February 2024

## *ECA Certified Quality Assurance Manager*

- **Quality Culture**  
People Empowerment in GMP  
05/06 October 2023, Heidelberg, Germany
- **GMP for Beginners**  
Live Online Training on 24/25 October 2023  
Live Online Training on 13/14 March 2024  
Live Online Training on 15/16 October 2024
- **The GMP Compliance Manager**  
24/25 October 2023, Berlin, Germany
- **GMP for Medical Devices**  
EU versus USA  
Live Online Training on 21/22 November 2023
- **Complaint Handling and Recall Management**  
Live Online Training on 21/22 November 2023
- **Root Cause Analysis**  
A CAPA Workshop on Successful Failure Investigation  
13/14 December 2023, Berlin, Germany
- **Combination Products**  
Medicinal Products/Drugs meet Medical Devices  
Live Online Training on 06/07 February 2024
- **Efficient Batch Record Design and Review**  
Live Online Training on 15/16 February 2024
- **Pharmaceutical Contracts: GMP and Legal Compliance**  
Live Online Training on 21/22 February 2024
- **Deviation Management and CAPA**  
Live Online Training on 20/21 March 2024
- **Improve your Quality Reviews**  
PQR, APR, Management Review, Quality Metrics  
Live Online Training on 10/11 April 2024
- **KPIs and Quality Metrics**  
How to foster Continual Quality Improvement  
07/08 May 2024, Vienna, Austria
- **Quality Oversight**  
Supervision of the Pharmaceutical Quality System: Challenges and Opportunities  
28/29 May 2024, Copenhagen, Denmark

## *ECA Certified Validation Manager*

- **Trending of Process Data for OPV/CPV**  
Advanced Level Live Online Training on 04/05 October 2023
- **Process Validation**  
Live Online Training on 30/31 October 2023

- **Cleaning Validation**  
Live Online Training on 09/10 November 2023  
With optional Pre-Course Session „Impact of Annex 1 Revision on Cleaning Validation“, 08 November 2023
- **Qualification and Validation Forum - Update 2023**  
Live Online Conference on 14/15 November 2023
- **Process Understanding**  
Statistical Process Control (SPC) as a tool to get there  
Live Online Training on 15/16 February 2024
- **The Validation Manager**  
in the Pharmaceutical Industry  
Live Online Training on 20/21 March 2024
- **Ongoing/Continued Process Verification**  
From the Control Strategy to Product Quality Review  
Live Online Training on 22/23 May 2024

## *ECA Certified Quality Control Manager*

- **Validation of Analytical Test Procedures & Measurement Uncertainty**  
10 - 12 October 2023, Barcelona, Spain
- **Reduced Sampling / Reduced Testing**  
17/18 October 2023, Heidelberg, Germany
- **Practical Statistical Tools for Analytical Laboratories**  
25/26 October 2023, Vienna, Austria
- **The Impurities Forum**  
Part I: Identification and Control of Impurities in Drug Substances and Drug Products, Live Online Training on 09 November 2023  
Part II: Nitrosamines and other Mutagenic Impurities  
Live Online Training on 10 November 2023
- **Setting Specifications and Acceptance Criteria**  
Live Online Training on 05/06 December 2023
- **Stability Testing for Drug Substances and Drug Products**  
Live Online Training on 07/08 December 2023
- **Stability by Design**  
Live Online Training on 12 - 14 December 2023
- **Quality Control of Starting Materials (APIs and Excipients)**  
21/22 February 2024, Berlin, Germany
- **QC Compliance Manager**  
Focus on Small-Molecule APIs and Drug Products  
Live Online Training on 24/25 April 2024
- **EU GMP-/FDA-compliant Sampling**  
Live Online Training on 07/08 May 2024
- **Dissolution Testing**  
Development/Quality Control and in vivo Relevance  
26/27 June 2024, Hamburg, Germany
- **Analytical Methods for Cleaning Validation**  
Development, Validation & Control  
Live Online Training on 25 - 27 June 2024

## *ECA Certified Regulatory Affairs Manager*

- **ICH Q12 Training Course - How to use the PACMP in Practice**  
Live Online Training on 5/6 October 2023
- **Handling Changes and Variations**  
10/11 October 2023, Vienna, Austria



- **GMP meets Regulatory Affairs**  
20/21 February 2024, Munich, Germany
- **API Regulatory Starting Materials**  
22/23 February 2024, Munich, Germany
- **Drug Master File Procedures in the EU, the US and Japan**  
Live Online Training on 17 – 18 September 2024

## ECA Certified Sterile Production Manager

- **GMP for Beginners in Sterile Manufacturing**  
Live Online Training on 7/8 November 2023
- **Aseptic Process Simulation (APS) / Media Fills**  
Live Online Training on 9/10 November 2023
- **Isolator Technology Workshop**  
14/15 November 2023, Basel, Switzerland
- **Environmental Monitoring**  
18/19 June 2024, Copenhagen, Denmark

## On behalf of European Qualified Person Association

- **QUALIFIED PERSON FORUM 2023**  
12/13 October 2023, Vienna, Austria (with online options)  
PRE-CONFERENCE SESSIONS on 11 October 2023  
Specific Requirements for IMPs (full day)  
Quality Culture (1/2 day)  
New QPs meet experienced QPs (1/2 day)
- **Qualified Person Education Course (Module A)**  
Understand the Implications of becoming a QP  
29/30 November 2023, Live Online
- **Qualified Person Education Course (Module A)**  
Understand the Implications of becoming a QP  
05/06 June 2024, Munich, Germany
- **Qualified Person Education Course (Module B)**  
Mastering the QP Role in daily Practice  
19/20 June 2024, Barcelona, Spain  
With an optional pre-course Session: "Interpersonal and Soft Skills for the QP" on 18 June 2024

## On behalf of APIC/CEPIC

- **26th Global GMP & Regulatory API Conference**  
25/26 October 2023 in Berlin or live online  
With Pre-Conference Session  
"GMP approaches for your day to day API work"  
24 October 2023 in Berlin or live online
- **ICH Q7 Training Courses**  
20 - 24 November 2023 - Live Online -
  - ICH Q7 Compliance for APIs Manufactured by Chemical Synthesis
  - ICH Q7 Compliance for APIs Manufactured by Cell Culture/Fermentation
  - ICH Q7 Auditor Training Course

## Other Training Courses/Conferences

- **Transfer of Analytical Procedures**  
Live Online Training on 04 October 2023
- **Computer Validation & Data Integrity GxP Basics**  
Live Online Training on 12 October 2023
- **Quality Oversight in Sterile Manufacturing**  
Live Online Training on 31 October 2023

- **China GMP and Registration of APIs**  
Live Online Training on 02 November 2023
- **Quality Oversight for Virtual Companies**  
Live Online Training on 09 November 2023
- **Qualification and Validation Forum – Update 2023**  
Live Online Conference on 14/15 November 2023
- **Japan Quality**  
Live Online Training on 21 November 2023
- **Raw Materials, Excipients and APIs Used for Biological Medicinal Products**  
21/22 November 2023, Neuss/Düsseldorf, Germany
- **11th PharmaLab Congress & Exhibition**  
21/22 November 2023, Düsseldorf, Germany
  - GMP Compliance Trends in Analytical Laboratories/Outsourcing in Pharmaceutical Laboratories
  - Laboratory Optimization, Automation and Digitalization
  - Analytical Method Validation and Life Cycle Management - ICH Q14/Q2 (R2)
  - Endotoxin and Pyrogen Testing
  - Alternative and Rapid Microbiological Methods
  - Cell and Gene Therapies/ATMPs - Quality and Safety
- 20 November: Pre-Conference Event  
4th International Mycoplasma qPCR Testing User Day
- **Fundamentals of AQL Testing in Packaging Control**  
Live Online Training on 23 November 2023
- **The GDP Audit**  
How to conduct and pass GDP Audits and Inspections  
Live Online Training on 13/14 December 2023
- **CAPAs in QC Laboratories**  
Live Online Training on 15 January 2024
- **Glass Packaging Systems**  
Live Online Training on 1 February 2024
- **Single-Use Disposables**  
Live Online Training on 20 February 2024
- **Fundamentals of Visual Inspection**  
Live Online Training on 21 February 2024
- **IT for Non-IT Professionals**  
Live Online Training on 27/28 February 2024
- **How to register APIs in Brazil**  
Focus on CADIFA and obtaining a Brazilian GMP certificate  
Live Online Training on 27 February 2024
- **Reference Standards**  
Establishment, Use and Maintenance of Analytical Reference Substances  
Live Online Training on 12 March 2024
- **Validation in Pharmaceutical Analysis**  
ICH Q2 Revision, Lifecycle Concept, Precision, and Accuracy, Live Online Training on 13 March 2024  
Specificity/Selectivity, Response (Calibration Model), Impurities and Quantitation Limit, Live Online Training on 14 March 2024
- **Pharma Supply Chain: GDP Requirements and Certification for Logistics Vendors**  
Live Online Training on 30 April 2024
- **Excel in the GxP-regulated Environment**  
Live Online Training on 02 May 2024

- **Validation/Qualification for Beginners**  
Live Online Training on 28 May 2024

## **GMP Webinars**

- **GMP Update 2023/2024**  
Live Webinar on Tuesday, 12 December 2023, 14.00 – 16.00 h CET
- **GDP Update 2024**  
Live Webinar on Tuesday, 12 March 2024, 14.00 – 16.00 h CET