



Academy  
*Your GMP/GDP  
Information Source*

# European Events

- Live Online and on Site -

2024

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

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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:

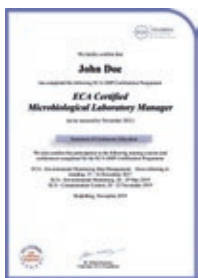
- select courses according to your individual professional demands
- suit the course registration to your company's necessities, i.e. usually there is a period of several months between the courses. If two dates are too close together, you can attend one course in the following year.

### 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

- **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
- **Computerized System Validation: Introduction to Risk Management**  
Live Online Training on 26 November 2024  
**The GAMP 5 Approach**  
Live Online Training on 27-29 November 2024
- **Computerised System Validation: GMP Compliant Documentation**  
Live Online Training from 11 - 13 December 2024

## ECA Certified Data Integrity Manager

- **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
- **Data Integrity Master Class**  
28 - 30 August 2024, Copenhagen, Denmark  
With an optional full-day pre-course session on 27 August 2024:  
„Raw Data - Understanding, Defining and Managing“
- **Data Integrity - Requirements for a GMP-compliant Data Life Cycle**  
Live Online Training on 20-22 November 2024  
With an optional full-day pre-course session „Audit Trail Review“,  
19 November 2024
- **Lab Data Integrity**  
12 - 14 November 2024, Barcelona, Spain
- **HPLC Data Integrity**  
Live Online Training on 22/23 January 2025

## ECA Certified Technical Operations Manager

- **Granulation & Tableting**  
Live Online Training from 17 - 19 September 2024
- **Spray Drying - Solutions for the Pharmaceutical Industry**  
24 - 26 September 2024, Lisbon, Portugal
- **Container-/Closure-Integrity Testing**  
Live Online Training on 24 October 2024
- **Product Transfer - Organisation of a GMP-compliant Site Change**  
Live Online Training on 29/30 October 2024
- **Visual Inspection of Parenterals**  
State-of-the-art Visual 100% Inspection  
6/7 November 2024, Berlin, Germany
- **Pharmaceutical Water**  
Generation, Monitoring & Compliance  
Live Online Training on 28/29 January 2025

## ECA Certified Biotech Manager

- **Blood, Blood Products, and Plasma**  
Quality, Safety, SoHO and recent Developments  
14/15 May 2024, Berlin, Germany
- **Protein Analytics**  
Evaluation, Implementation and Use of Suitable Technologies  
Live Online Training on 22/23 May 2024
- **Advanced GMP for ATMPs**  
Live Online Training on 02/03 July 2024
- **Pharmaceutical Biotechnology for Non-Biotechnologists**  
09/10 October 2024, Berlin, Germany
- **Blood, Plasma and Stem Cells – Audits and Inspections**  
Live Online Training on 05/06 November 2024

## ECA Certified Development Manager

- **GMP meets Development**  
05 - 07 November 2024, Hamburg, Germany

## ECA Certified GMP Auditor

- **The GMP Auditor**  
Initial and Continuous Professional Training for GMP Auditors  
15 - 17 May 2024, Berlin, Germany  
Live Online Training on 15 - 17 October 2024
- **GMP Auditor Forum**  
Release of ECA's new GMP Auditor Guide  
25/26 June 2024, Barcelona, Spain
- **GMP Auditor Practice**  
An advanced Auditor Course with many interactive Sessions and practical Examples  
08 - 10 October 2024, Barcelona, Spain

## ECA Certified Packaging Manager

- **Extractables & Leachables**  
Challenges and Solutions for Packaging and Single Use Systems  
Live Online Training on 07/08 May 2024
- **Serialization/Aggregation - Live Online Training**  
Live Online Training on 23/24 October 2024
- **GMP Pre-Sterilized Packaging Material**  
Requirements and Challenges for RTU / RTS Products  
Live Online Training on 14 November 2024

## ECA Certified Microbiological Laboratory Manager

- **EUROPEAN MICROBIOLOGY CONFERENCE**  
26/27 June 2024, Munich, Germany  
+ Pre-Conference Workshop – Next Generation Sequencing (NGS) on 25 June 2024, Munich
- **Bioburden - Regulatory Expectations and Practical Experiences**  
- Lessons and Panel Discussion -  
Live Online Training on 15/16 October 2024
- **Contamination Control Strategies**  
Requirements, Measures and Strategies  
05 - 07 November 2024, Berlin, Germany  
with an optional Post-Conference Workshop „Risk Assessment in Contamination Control“ on 08 November 2024, Berlin, Germany

➤ **Environmental Monitoring - Trending, Analysis and Data Management**

Live Online Training on 12/13 November 2024

➤ **Microbiology for Non-Microbiologists**

Understand the „true“ meaning of microbiological findings  
11/12 March 2025, Berlin, Germany

## ECA Certified GDP Compliance Manager

➤ **Ambient Transport and Cold Chain**

Live Online Training on 06/07 November 2024

➤ **The GDP Compliance Manager**

Live Online Training on 19/20 November 2024

➤ **The GDP-Audit**

Live Online Training on 03/04 December 2024

## ECA Certified API Production Manager

➤ **Handling of Foreign Particles in APIs and Excipients**

Live Online Training on 05/06 February 2025

## ECA Certified Quality Assurance Manager

➤ **KPIs and Quality Metrics**

How to foster Continual Quality Improvement  
Live Online Training on 07/08 May 2024

➤ **Quality Oversight**

Supervision of the Pharmaceutical Quality System: Challenges and Opportunities  
28/29 May 2024, Copenhagen, Denmark

➤ **Lean GMP Systems**

27/28 June 2024, Barcelona, Spain

➤ **Quality Risk Management**

04/05 September 2024, Munich, Germany

➤ **Quality Culture**

17/18 September 2024, Berlin, Germany

➤ **Ph. Eur., USP and other Pharmacopoeias**

Live Online Training on 17/18 September 2024

➤ **GMP for Beginners**

Live Online Training on 15/16 October 2024

➤ **The GMP Compliance Manager**

19/20 November 2024, Hamburg, Germany

➤ **GMP for Medical Devices**

Live Online Training on 19/20 November 2024

➤ **Root Cause Analysis**

A CAPA Workshop on Successful Failure Investigation  
04/05 December 2024, Berlin, Germany

➤ **Combination Products**

11/12 February 2025, Heidelberg, Germany

## ECA Certified Validation Manager

➤ **Process Validation**

Live Online Training on 02/03 May 2024  
Live Online Training on 01/02 October 2024

➤ **Ongoing/Continued Process Verification**

From the Control Strategy to Product Quality Review  
Live Online Training on 22/23 May 2024

➤ **Trending of Process Data for OPV/CPV**

Advanced Level Live Online Training on 08/09 October 2024

➤ **Cleaning Validation**

Live Online Training on 13/14 November 2024  
**Pre-Course: Impact of Annex 1 Revision on Cleaning Validation**  
Live Online Training on 12 November 2024

➤ **Process Understanding - Statistical Process Control (SPC) as a tool to get there**

Live Online Training on 06/07 February 2025

## ECA Certified Quality Control Manager

➤ **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

➤ **Practical Statistical Tools for Analytical Laboratories**

01/02 October 2024, Barcelona, Spain

➤ **The Impurities Workshop**

Practical Approaches for assessing the Risks of Impurities  
08 - 10 October 2024, Hamburg, Germany

➤ **Validation of Analytical Test Procedures & Measurement Uncertainty**

15 - 17 October 2024, Copenhagen, Denmark

➤ **Setting Specifications and Acceptance Criteria**

22/23 October 2024, Barcelona, Spain

➤ **Stability Testing for Drug Substances and Drug Products**

23/24 October 2024, Barcelona, Spain

➤ **GMP/FDA Compliance in Analytical Laboratories**

23 - 25 October 2024, Barcelona, Spain

➤ **Complaint Handling and Recall Management**

Live Online Training on 19/20 November 2024

➤ **Quality Control of Starting Materials (APIs and Excipients)**

Live Online Training on 05/06 February 2025

➤ **Reference Standards**

Establishment, Use and Maintenance of Analytical Reference Substances  
Live Online Training on 04 February 2025

## On behalf of APIC/CEFIC

➤ **ICH Q7 Training Courses 2024**

ICH Q7 Compliance for APIs Manufactured by Chemical Synthesis, 01 - 03 July 2024  
ICH Q7 Compliance for APIs Manufactured by Cell Culture/Fermentation, 01 - 03 July 2024  
ICH Q7 Auditor Training Course, 03 - 05 July 2024

➤ **27th APIC/CEFIC Global GMP & Regulatory API Conference**

23/24 October 2024 in Vienna  
+ Pre-Conference "From theory to practice: implementing API Process Knowledge" on 22 October 2024

## ECA Certified Regulatory Affairs Manager

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

Live Online Training on 17/18 September 2024

➤ **Handling Changes and Variations**

06/07 November 2024, Barcelona, Spain



- **API Regulatory Starting Materials**  
18/19 February 2025, Munich, Germany

- **GMP meets Regulatory Affairs**  
19/20 March 2025, Barcelona, Spain

## ECA Certified Sterile Production Manager

- **Environmental Monitoring**  
18/19 June 2024, Copenhagen, Denmark
- **Annex 1 Intensive Training**  
Requirements on Aseptic Manufacturing and Approaches for Implementation  
Live Online Training on 03/04 July 2024
- **GMP for Beginners in Sterile Manufacturing**  
Live Online Training on 24/25 September 2024
- **Aseptic Process Simulation (APS) / Media Fills**  
Live Online Training on 26/27 September 2024
- **Isolator Technology Workshop**  
12/13 November 2024, Basel, Switzerland

## On behalf of European Qualified Person Association

- **Qualified Person Education Course (Module A)**  
Understand the Implications of becoming a QP  
05/06 June 2024, Munich, Germany  
– With an optional Pre-Course Session –  
“Investigational Medicinal Products (IMP) QP Education Course”  
on 04 June 2024
- **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
- **Qualified Person Education Course (Module A)**  
Understand the Implications of becoming a QP  
Live Online Training on 12/13 November 2024
- **QUALIFIED PERSON FORUM 2024**  
28/29 November 2024, Amsterdam, The Netherlands  
WITH SIX PARALLEL SESSIONS TO FOSTER INTERACTION  
Pre-conference sessions on 27 November 2024:  
Specific Requirements for IMPs (full day)  
QP Oversight for “Virtual Companies” (1/2 day)  
QP Liability and Indemnification (1/2 day)

## Other Training Courses/Conferences

- **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 for Cannabis – what you need to know**  
Live Online Conference on 05/06 June 2024
- **GDP Audits**  
How to Audit Logistics Service Providers  
Live Online Training on 13 June 2024
- **Transfer of Analytical Procedures**  
Live Online Training on 19 June 2024
- **The ICH Q9 Training Package - What is behind it?**  
Live Online Training on 19 June 2024
- **5s-Optimization in Offices & QC Laboratories**  
Live Online Training on 19 June 2024

- **Procurement and Purchase meet GMP**  
Live Online Training on 25/26 June 2024

- **Self Inspection**  
Compliant and Successful Self-Inspections and Internal Audits  
Live Online Session on 12 September 2024

- **Stability Studies to Support Shipping/Distribution of Pharmaceuticals and Biopharmaceuticals**  
Live Online Training on 12/13 September 2024

- **Cost of Quality**  
**Understand, Measure and Optimise Cost of Quality**  
Live Online Session on 19 September 2024

- **Focus on Tissue: A Multidisciplinary Approach**  
Live Online Training on 19 September 2024

- **Temperature-Sensitive Pharmaceuticals – Transport and Vehicle Qualification**  
Live Online Training on 10 October 2024, 09:00 – 12:30 h

- **China GMP and Registration of APIs**  
Live Online Training on 15 October 2024

- **Quality Oversight in Sterile Manufacturing**  
Live Online Training on 06 November 2024

- **Japan Quality**  
Live Online Training on 12 November 2024 09.00 – 17.00 h CET

- **Efficient GMP Training Systems**  
Live Online Training on 19/20 November 2024

- **CAPAs in QC Laboratories**  
Live Online Training on 14 January 2025 13.00 – 17.30 h CET

- **How to register APIs in Brazil**  
Focus on CADIFA and obtaining a Brazilian GMP Certificate  
Live Online Training on 13 February 2025

- **Fundamentals of Manual Visual Inspection**  
100 % Inspection of Parenterals  
Live Online Training on 15 May 2025

## GMP Webinars

- **Ethylene and Diethylene Glycol Testing**  
Pharmacopoeial Activities, Regulatory Developments and Analytical Testing -  
Tuesday, 28 May 2024, 15.30 - 17.30 h CEST
- **Statistical Simulations for Enhanced Understanding of Analytical Performance**  
Live Webinar on Monday, 09 Sept. 2024, 14.00 – 16.00 CEST  
*This webinar is included free of charge for all participants of the ECA course “Practical Statistical Tools for Analytical Laboratories” on 01/02 October 2024 in Barcelona, Spain. If you decide to book the course in Barcelona after attending the webinar, the webinar fee will be credited.*