GMP and GDP Certification Programme

Join more than 4,000 colleagues in the Academy!

15 Certification Modules

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

ECA Academy
Your GMP/GDP Information Source

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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.

Objectives

A highly qualified personnel is a crucial factor within the field of GMP/GDP-compliant manufacturing and distribution of APIs, drugs and medical devices. College and university education provide a scientific basis which needs to be completed. A continuous advanced training is therefore essential.

This is where the ECA Academy's GMP/GDP Certification Programme fills the gap. This programme offers modular training with an industry-known certification at the end. Its structure respects companies' interests, i.e. professionals can

1. select courses according to their individual professional demands
2. suit the course registration to their and their companies' needs. Usually there are several months between the courses in the individual programmes. However, if there are two courses too close to each other, one course can be attended in the following year.
3. By taking part in an education course, attendees become ECA members. During the membership, you enjoy
   - free access to the members' area where you always find the latest update of the "GMP Guideline Manager" online version – allowing you to access a GMP tree with guidelines sorted by topics or by authority. It lets you find relevant guidelines quick and easy. And as member you can also get to this detailed tree with the GMP WebApp on your smartphone or tablet PC.
   - a 200,- Euro rebate for any ECA course and conference, plus the opportunity to complete the GMP Certification Programme with an internationally recognised certificate.

Continuous Expansion of the Programme and Recognition of Past Events

The ECA Certification Programmes are not static. They are rather subject to a constant review, and current topics are added just as "outdated" topics are taken off the list. However, if you attended one or more seminars in the past, these seminars will of course be recognised.

Recognition

The courses of the ECA Academy enjoy an excellent reputation within Europe's pharmaceutical industry and regulatory authorities. This is proven by the large number of participants, the often booked-up courses and the fact that many speakers and participants come from European GMP Inspectorates.

What is essential for the recognition of a qualified training programme is the speakers' reputation. ECA employs up to 8 speakers for an education course - preferably representatives from industry and authorities. Frequently, experienced consultants with an exceptional track record complete the trainings.

How to Obtain the Certificate

To obtain the certificate, please send an e-mail prior or after the 2nd or 3rd event (depending on the certification you aim at) to info@concept-heidelberg.de. This e-mail should also list the courses you attended in the past. You will then get your certificate at the last course or within the following 2 weeks by post.

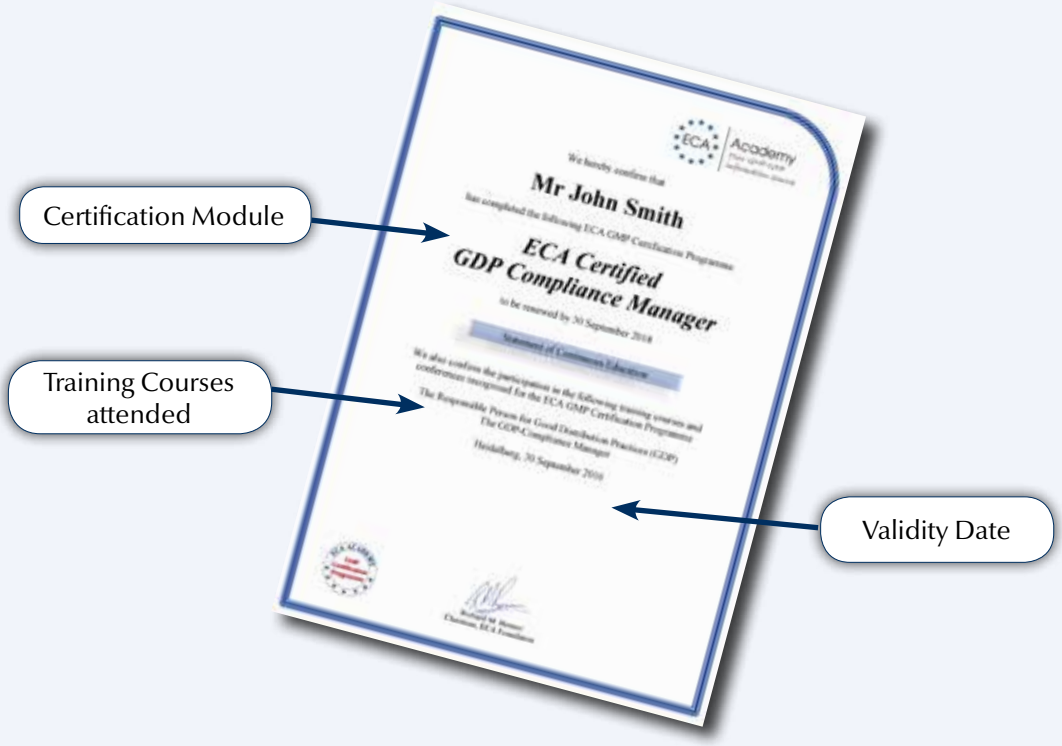
Continuous GMP Certification

In order to reflect the development of a continuous advanced education for GMP professionals the ECA Academy issues 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 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 if you have any further question.

The New Certificate – Confirmation of Continuous GMP Education

The new Certificates of the GMP Certification Programme will not only include the title of the certification programme but will also list all ECA GMP Training Courses and Conferences you have participated in. Thus, the Certificate will serve as a valid documentation for your continuous GMP Education.



To get to the calendar with all courses and conferences currently offered for these programmes - including a link to the contents and a booking form - please go to www.gmp-certification.org

Certified GDP Compliance Manager

The European Commission has published the revised EU Good Distribution Practice (GDP) Guideline in March 2013. The completely revised document contains comprehensive requirements for all stakeholders involved such as logistic service providers, wholesalers, storage facilities and for the manufacturer of the medicinal products.

Chapter 2 of the EU GDP Guideline defines that Personnel involved in GDP activities should "receive initial and continuing training relevant to their role, based on written procedures and in accordance with a written training programme." Furthermore the GDP Guide states that "a record of all training should be kept, and the effectiveness of training should be periodically assessed and documented."

The certification Programme of the ECA Academy aims to provide the necessary knowledge for personnel involved in GDP activities.

Courses and Conferences acknowledged

To receive the certificate, the applicant must attend two training courses. After attending the second course, the applicant can apply for an Internet-based exam with 20 multiple choice questions. If the applicant passes the GDP exam he/she obtains the certificate "ECA Certified GDP Compliance Manager".

- The Responsible Person for Good Distribution Practices (GDP)
- The GDP Compliance Manager (formerly GDP - How to get you there)
- How to implement the new GDP requirements for APIs
- GDP for APIs
- Ambient Transport and Cold Chain
- The GDP Audit
- GDP for Beginners (formerly GMP meets GDP)

Certified GMP Auditor

With Continuous professional training for auditors and lead auditors is of utmost importance as the authorities expect qualified personal performing audits. And GMP audits of suppliers, contract manufacturers and contract laboratories are a fundamental part of a Quality Management System to assure the quality of a drug product. Only knowledgeable and highly qualified auditors can guarantee audits that are useful for both the auditing company and the auditee. A continuous training in all GMP-related areas is therefore essential for all GMP auditors."

Recognising this need for further professional knowledge development, the ECA Academy has set up the programme for initial and continuous qualification.

In order to reflect a continuous professional development for GMP auditors, this Certificate can be extended for continuous training. Renewal is easy: the applicant can join any GMP-relevant ECA Training Course or Conference within two years. This flexibility takes into account that GMP auditors have to broaden their knowledge in various GMP topics.

Courses and Conferences acknowledged

To receive the certificate, the applicant must attend the following three courses:

- The GMP Auditor
- Efficient Supplier Qualification
- GMP Auditor Workshop

15 Certification Modules

Certified Packaging Manager

The programme ECA Certified Packaging Manager lets you qualify as a specialist for pharmaceutical packaging systems and packaging operations. It provides guidance on ways to attain best regulatory practice and compliance. In addition, it addresses tools for the efficient and effective development of packaging materials and systems, qualification of suppliers, setting of specifications, management of changes and deviations, and performance of quality control testing.

Courses and Conferences acknowledged

To receive the certificate, the applicant must attend three out of the following courses / conferences. After attending the third course, the applicant obtains the certificate "ECA Certified Packaging Manager".

- Avoiding non-Compliance in Packaging Operations
- Pharmaceutical Packaging Systems: Development / Quality Control
- Leachables & Extractables
- Design Control for Drug - Device Combination Products
- Track & Trace Training Course
- Plastic Packaging Materials

Certified Validation Manager

With FDA's new Process Validation Guidance validation requirements will become more complex. In addition to other requirements the revised Annex 15 also asks for a Process Validation Life Cycle. For 'ensuring that all necessary validation is carried out' (EU GMP Guide), many firms have introduced a position called validation manager. For this reason, the ECA has established the Certified Validation Manager Module. Attend a compulsory course, "The Validation Manager", as well as two further courses from our validation programme to obtain the certificate for this high-level additional qualification.

Courses and Conferences acknowledged

To receive the certificate, the applicant must attend three out of the following courses / conferences. After attending the third course, the applicant obtains the certificate "ECA Certified Validation Manager".

- Cleaning Validation
- SPC in the Pharmaceutical Industry
- Modern EU and FDA Validation
- Continued/Ongoing Process Verification
- Process Validation in the light of the Annex 15 and FDA requirements
- The Validation Manager in the Pharmaceutical Industry

Certified QA Manager

Quality Assurance Managers are internal specialists for various compliance topics. For this task, they need a wide-ranging knowledge. Depending on the main emphasis of their activities, they have to acquire diverse qualifications. The different seminars of this programme take this fact into account.

Courses and Conferences acknowledged

To receive the certificate, the applicant must attend three out of the following courses / conferences. After attending the third course, the applicant obtains the certificate "ECA Certified Quality Assurance Manager.

- Change Control
- Complaint Handling & Recall Management
- Deviation Management and CAPA
- Document Management
- Efficient Batch Record Design and Review
- KPIs and Quality Metrics
- Lean GMP Systems
- Pharmaceutical Contracts
- The GMP Compliance Manager
- Quality Oversight
- Quality Risk Management (ICH Q9 Training Course)
- Improve your Quality Reviews
- Inspection Management
- GMP for Beginners
- GMP for Medical Devices
- Pharmacopoeias for Beginners
- Combination Products

Certified API Production Manager

The requirements to the quality assurance of active pharmaceutical ingredients have increased enormously, among others, due to the establishment of the ICH Q7 "Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients". Therefore, highly qualified experts are necessary to put these requirements correctly into practice. The ECA Certified API Production Manager learns the rudiments in one of the 3-day intensive courses and can deepen this know-how according to his or her focus by means of two further seminars

Courses and Conferences acknowledged

To obtain the additional certificate, the applicant must attend three out of the following courses / conferences. After attending the third course, the applicant obtains the additional certificate "ECA Certified API Production Manager".

- ICH Q7 Compliance for APIs Manufactured by Chemical Synthesis (3 days)
- ICH Q7 Compliance for APIs Manufactured by Cell Culture/Fermentation (3 days)
- ICH Q7 Auditor Training Course
- Annual APIC/CEFIC European Conference on Active Pharmaceutical Ingredients, GMP Part
- API Regulatory Starting Materials
- Handling of foreign particles in APIs
- Quality by Design in API Manufacturing

Certified Quality Control Manager

The most frequently cited cGMP non-compliances are often found in analytical laboratories - showing the importance of the pharmaceutical quality control and the Quality Control Manager. Further, the QC Manager has to observe a multitude of GMP requirements (FDA, EMA, WHO, Pharmacopoeias, etc.). The programme "ECA Certified Quality Control Manager" lets you qualify as a specialist for analytical GMP laboratories. It provides guidance on ways of attaining best regulatory practice and compliance. In addition, it addresses tools for the efficient and effective management and performance of quality control laboratories today.

This programme will be of significant value to employees both in routine quality control and in analytical development laboratories, who are responsible for GMP compliance and laboratory organisations: analytical scientists, analytical laboratory managers / supervisors, employees working in the incoming goods control of APIs, excipients, and packaging materials, contract laboratories personnel, auditors responsible for assessing laboratory compliance and performance.

Courses and Conferences acknowledged

To receive the certificate, the applicant must attend three out of the following courses / conferences. After attending the third course, the applicant obtains the certificate "ECA Certified Quality Control Manager".

- Dissolution Testing
- FDA Compliance in Analytical Laboratories
- Impurities
- Analytical Instrument Qualification
- OOS Training Course
- Quality Control of Raw Materials
- Setting Specifications
- Stability Testing of Drug Substances and Drug Products
- Stability Testing for Biological / Biotechnological Drug Substances and Drug Products
- Validation of Analytical Test Procedures and Measurement Uncertainty
- New USP&FDA Approaches for HPLC
- Leachables and Extractables Testing and Assessment
- QC Compliance Manager
- Handling OOE and OOT Results
- Design Control for Drug Device Combination Products

15 Certification Modules

Certified Technical Operations Manager

In pharmaceutical and API production, ssential prerequisites for manufacturing in conformity with GMP. Here, it is important to combine technical know-how with the interpretation of pharmaceutical regulations and guidelines.

Image: Seidenader

On the other hand, the understanding of the process is very important to define risks for the product, to carry out a qualification/validation and to ensure a safe product. The Technical Operations Manager has the necessary skills for this task.

Courses and Conferences acknowledged

To receive the certificate, the applicant must attend three out of the following courses / conferences. After attending the third course, the applicant obtains the certificate "ECA Certified Technical Operations Manager".

- Spray Drying
- Handling of Highly Potent Compounds
- Pharmaceutical Water
- Visual Inspection Systems/Particles in Parenterals
- Cross Contamination
- Manufacture of oral solid dosage forms
- Product Transfer
- Re-Construction / Upgrade of GMP Facilities
- Lyophilization
- Single-Use Systems for Sterile & Biotech Applications
- GMPs for Equipment, Utilities and Facilities / Technical Compliance
- Clean Rooms and HVAC-Systems
- Granulation/Tabletting
- Container-/Closure Integrity Testing

Certified Computer Validation Manager

Computerised systems that illustrate or control quality-relevant processes are in widespread use throughout the pharmaceutical industry. Not only are they subject to the requirements of the various collections of pharmaceutical regulations for the validation of these systems, but since 1997 the US authority FDA lays down requirements concerning electronic records / electronic signatures in 21 CFR Part 11. Also, since 1994 the GAMP® Guide provides a worldwide acknowledged industry guideline for the validation of computerised systems - and is available as version 5 since 2008. The basic guideline was and still is constantly expanded by various Good Practice Guides concerning specific aspects.

In the GMP Certification Programme "Computer Validation Manager" participants obtain a comprehensive knowledge of the basic principles for the validation of computerised systems, the requirements of Part 11 and specific aspects of the validation of computerised systems.

Courses and Conferences acknowledged

To receive the certificate, the applicant must attend three out of the following courses / conferences. After attending the third course, the applicant obtains the certificate "ECA Certified Computer Validation Manager".

- Computer Validation: The GAMP 5 Approach
- Computer Validation: Leveraging Suppliers
- Computer Systems Validation Master Class
- Computer Validation: Maintaining Control of Operation
- Computer Validation: Introduction to Risk Management
- SAP: Validation and GMP Compliance
- Virtual IT Systems in a GxP Environment
- Cloud Computing in a GxP Environment

15 Certification Modules

Certified Regulatory Affairs Manager

Regulatory Affairs Managers are internal specialists for various regulatory affairs and regulatory compliance topics. For this task, they need a wide-ranging knowledge. Depending on the main emphasis of their activities, they have to acquire diverse qualifications. The seminars and conferences of this programme take this into account.

Courses and Conferences acknowledged

To receive the certificate, the applicant must attend three out of the following courses / conferences. After attending the third course, the applicant obtains the certificate "ECA Certified Regulatory Affairs Manager".

- APIC/CEFIC Conference on Active Pharmaceutical Ingredients, Regulatory Affairs Part
- Marketing Authorisation Procedures in the EU / US
- How to write the Quality Part of an IMPD
- Handling Changes and Variations
- Blood, Blood Products, and Plasma
- GMP meets Regulatory Affairs
- API Regulatory Starting Materials
- Drug Master File Procedures in the EU, the US and Japan
- How to provide Process Validation Data in a Regulatory Submission
- Global Registration and Life Cycle Management of APIs
- ICH Q 12 - Product Life Cycle Management

Certified Microbiological Laboratory Manager

Throughout the last years the role of pharmaceutical microbiology has been getting more and more important. This is also shown by the attention it receives from regulators during product submission and inspections. With the harmonisation of the different pharmacopoeias the harmonised methods have to be implemented. The challenge is, though, to satisfy regulatory requirements and at the same time management's financial expectations.

Furthermore, the field of Rapid Microbiological Methods developed very fast. Caused by the new European regulation for chemical products, like the EU Guideline 98/8 EG for Biocides or REACH, the new European Community regulation on chemicals and their safe use promises both new possibilities as well as classic topics - like cleaning and disinfection - to regain importance. ECA stays abreast of these changes. The Certification Programme "Certified Microbiology Manager" provides the opportunity to get the necessary knowledge and qualification to fulfil the current requirements in microbiology.

Courses and Conferences acknowledged

To receive the certificate, the applicant must attend three out of the following courses / conferences. After attending the third course, the applicant obtains the certificate "ECA Certified Microbiological Laboratory Manager".

- Contamination Control
- European Microbiology Conference
- European Mycoplasma / Endotoxin Conference
- Microbiology for Non-Microbiologists
- Rapid Microbiological Methods Conference
- Validation of Microbiological Methods
- Virus and TSE Safety made simple
- Modern Microbiology Laboratory
- Low Endotoxin Recovery – Hands on Laboratory Course
- Environmental Monitoring Data Management – from collecting to trending

Certified Sterile Production Manager

Sterile medicinal products, especially when manufactured under aseptic conditions, underlie a variety of GMP regulations; Regulations that are frequently adapted to the current state of knowledge and technology and that are by now are strongly harmonised internationally.

To manufacture sterile drugs compatible with GMP regulations, a proper technical environment, qualified staff and validated processes are required. For that reason this certification programme extensively covers the basics as well as the current matters of sterile production. In this GMP Certification Programme you will acquire comprehensive knowledge on all aspects of the manufacture of sterile medicinal products.

Courses and Conferences acknowledged

To receive the certificate, the applicant must attend three out of the following courses / conferences. After attending the third course, the applicant obtains the certificate "ECA Certified Sterile Production Manager".

- Environmental Monitoring
- Process Simulation / Media Fills
- GMP for Beginners in Sterile Manufacturing
- Particles in Parenterals
- Isolator Technology Workshop
- Lyophilization

Certified Biotech Manager

From a historical view, biopharmaceuticals are no new business. Antibiotics and vaccines have been well known for more than 60 years. But with the marketing authorisation of the first pharmaceutical product, produced by gene technology in the 80s, a new era of biopharmaceutical and biotechnological development and manufacturing started.

In 2007, 20% of all new released pharmaceuticals were biopharmaceuticals. In defiance of all throw-backs in the last years, a progression of new approvals of biopharmaceuticals is expected. Furthermore, after the end of the protection of patents, biotechnical generics will be added.

Due to the specifics in biotechnology, fulfilling the regulatory requirements in the manufacture and quality assurance of biotech products is a tremendous challenge, and industry as well as authorities are constantly treated with new and expected changes in the regulatory guidelines.

ECA stays abreast of these changes. The Certification Programme "ECA Certified Biotech Manager" provides you with the opportunity to acquire the necessary knowledge and qualification to fulfil the current requirements in GMP for pharmaceutical Biotechnology.

Courses and Conferences acknowledged

To receive the certificate, the applicant must attend three out of the following courses / conferences. After attending the third course, the applicant obtains the certificate "ECA Certified Biotech Manager".

- Biotechnology for Non-Biotechnologists
- Protein Analytical Technologies
- cGMP for Biopharmaceuticals
- GMP for Vaccine Manufacturers
- GMP for ATMPs
- Bioassays and Bioanalytics
- Stability Testing for Biological/Biotechnological Drug Substances and Drug Products

Certified Pharmaceutical Development Manager

Not only in the manufacturing of marketed products (c)GMP-Compliance is mandatory. Also in the manufacturing of IMP supplies, compliance with the applicable GMP Guidelines is obligatory. But which GMP and GCP requirements are the applicable ones? And do the requirements differ from clinical phase 1 to phase 3? And how do I apply them?

This Certification Programme has been designed by the ECA to broaden your knowledge and to consolidate the various aspects which need to be considered in a successful development of a new pharmaceutical product.

Courses and Conferences acknowledged

To receive the certificate, the applicant must attend three out of the following courses / conferences. After attending the third course, the applicant obtains the certificate "ECA Certified Pharmaceutical Development Manager".

- GMP meets GCP
- GMP meets Development
- ICH Q8/Q11 Training Course
- Lifecycle Management in Pharmaceutical Analysis
- Stability by Design
- Pharmaceutical Packaging Systems, Part 1 Development
- How to write the Quality Part of an IMPD
- Granulation / Tabletting
- Emulsions & Gels
- ICH Q 12 Life Cycle Management
- D.I.C.T. Data Integrity in Clinical Trials

ECA Certified Data Integrity Manager

NEW

Although Data Integrity has been one of the basic GMP requirements for decades it became the regulators' focus of attention over the last few years. In the course of inspections of the U.S American FDA and European competent authorities, a lot of deviations and failures on that topic were detected. Current FDA Warning Letters and European Non-Compliance reports reflect the situation and show the weak points of data management in pharmaceutical companies. Meanwhile, major international authorities like FDA, MHRA, WHO and PIC/S have developed new Guidelines and Guidances on Data Integrity and Data Governance to explain their expectations to the industry.

In the GMP Certification Programme "Data Integrity Manager", participants obtain a comprehensive knowledge of the basic principles of Data Integrity and Data Governance. Participants will understand the data lifecycle and how the regulatory expectations can be implemented into the companies' Quality System.

Courses and Conferences acknowledged

To receive the certificate, the applicant must attend three courses and/or conferences. After attending the third course, the applicant obtains the certificate "ECA Certified Data Integrity Manager". Please find some training courses below.

- Data Integrity
- GMP Data Governance - Principles for Data Integrity Assurance
- Data Integrity and Good Documentation Practices
- Laboratory Data Integrity: Meeting FDA & EU Concerns
- Data Integrity Master Class
- Audit Trail Review
- Audit Trail Review for Computerised Systems in Analytical Laboratories
- Data Integrity Quality Oversight in the QC Laboratory
- Lab Data Integrity Master Class
- D.I.C.T. - Data Integrity in Clinical Trials
- Raw Data_ Understanding, Defining and Managing
- D.I.C.T. Data Integrity in Clinical Trials

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