GMP and GDP Certification Programme






15 Certification Modules:

- Certified Data Integrity Manager
- Certified Validation Manager
- Certified Quality Assurance 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 Pharmaceutical Development Manager
- Certified Biotech Manager
- Certified GMP Auditor
- Certified GDP Compliance Manager
- Certified Packaging Manager

All upcoming dates for events can be found at the end of this brochure.

ECA Academy
Your GMP/GDP Information Source

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.

All upcoming dates for events can be found at the end of this brochure.

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.

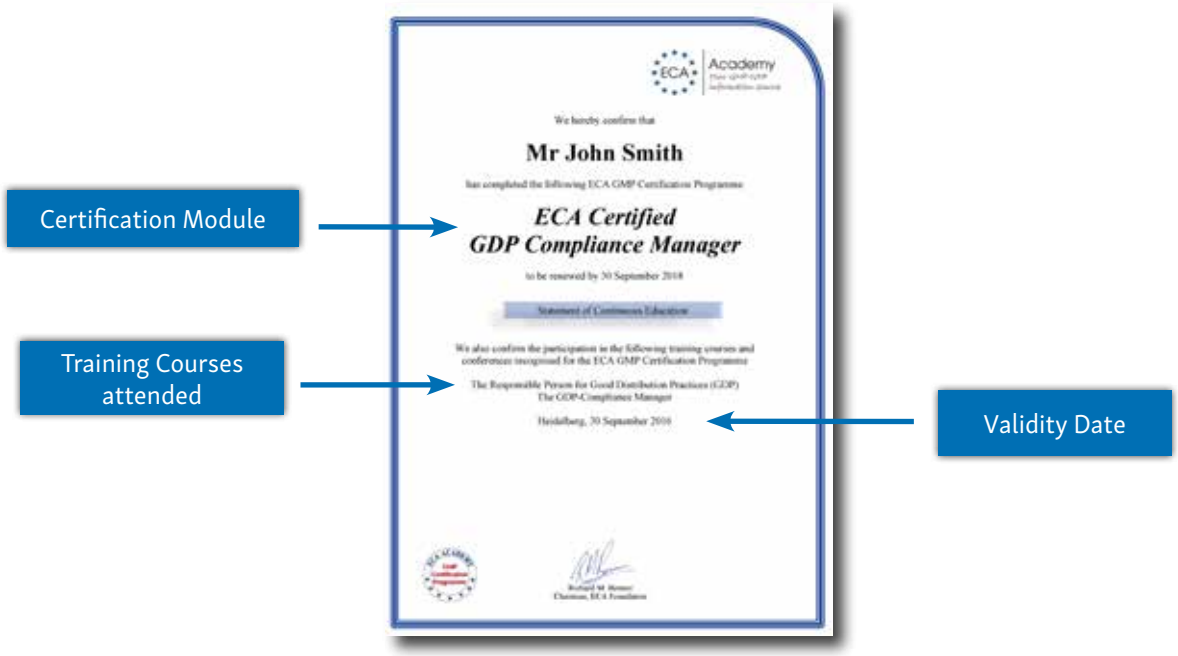
Continuous GMP Certification

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.

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 three out of the following courses/conferences. After attending the third course, the applicant obtains the certificate "ECA Certified GDP Compliance Manager".

- GDP for APIs
- The Responsible Person for Good Distribution Practices (GDP)
- The GDP-Compliance Manager
- Ambient Transport and Cold Chain
- GDP for Beginners
- The GDP Audit

Your questions
Dr Markus Funk is at your disposal for further information:
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Are you interested in this Certification Module?
Further information can be found online at
www.gmp-compliance.org/certification/gmp-gdp-certification-program/eca-certified-gdp-compliance-manager
or via the QR Code on the right.

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. After attending the third course, the applicant obtains the certificate "ECA Certified GMP Auditor".

- The GMP Auditor
- Efficient Supplier Qualification
- GMP Auditor Practice

Your questions
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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
- Serialization/Aggregation – Dealing with different global requirements
- Leachables & Extractables – Testing & Assessment
- Design Control for Drug-Device Combination Products
- Pharmaceutical Packaging Systems: Development
- Pharmaceutical Packaging Systems: Quality Control
- Plastic/Elastomeric Materials for Pharmaceutical Packaging and Production
- Glass meets Pharma
- GMP for Pre-Filled Syringes (PFS)

Your questions
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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
- Process Understanding – Statistical Process Control as a tool to get there
- Ongoing/Continued Process Verification
- Process Validation in the light of the Annex 15 and FDA requirements
- The Validation Manager in the Pharmaceutical Industry
- Equipment Qualification Forum
- Advanced Level Live Online Training: SPC rules in the real world for a Continued/Ongoing Process Verification Plan

Your questions
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Are you interested in this Certification Module?
Further information can be found online at
www.gmp-compliance.org/certification/gmp-gdp-certification-program/eca-certified-validation-manager
or via the QR Code on the right.

Certified Quality Assurance 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.

- Quality Risk Management (ICH Q9 Training Course)
- The GMP Compliance Manager
- Efficient Batch Record Design and Review
- Complaint Handling and Recalls
- Deviation Management and CAPA
- Quality Oversight
- Quality Culture
- Improve your Quality Reviews
- Lean GMP Systems
- GMP for Beginners
- Pharmaceutical Contracts
- GMP for Medical Devices
- KPIs and Quality Metrics
- Root Cause Analysis
- Inspection Management

Your questions
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Are you interested in this Certification Module?
Further information can be found online at
www.gmp-compliance.org/certification/gmp-gdp-certification-program/eca-certified-quality-assurance-manager
or via the QR Code on the right.

Certified API Production Manager

The requirements for the quality and purity 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 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
- ICH Q7 Compliance for APIs Manufactured by Cell Culture/Fermentation
- ICH Q7 Auditor Training Course
- APIC/CEFIC European Conference on Active Pharmaceutical Ingredients
- Handling of Foreign Particles in APIs and Excipients

Your questions
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Are you interested in this Certification Module?
Further information can be found online at
www.gmp-compliance.org/certification/gmp-gdp-certification-program/eca-certified-api-production-manager
or via the QR Code on the right.

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.

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".

- Analytical Instrument Qualification
- Handling OOT Results/Handling OOS Results
- Stability by Design
- EU GMP-/FDA-compliant Sampling
- Dissolution Testing
- QC Compliance Manager
- Reduced Sampling/Reduced Testing
- Analytical Methods for Cleaning Validation
- Ph. Eur., USP and other Pharmacopoeias – Dealing with different compendial methods
- FDA Compliance in Analytical Laboratories
- Validation of Analytical Test Procedures and Measurement Uncertainty
- Stability Studies to Support Shipping/Distribution of Pharmaceuticals and Biopharmaceuticals
- Setting Specifications and Acceptance Criteria
- Stability Testing for Drug Substances and Drug Products
- Practical Statistical Tools for Analytical Laboratories
- Bioassays and Bioanalytics
- Stability Testing for Biological/Biotechnical Drug
- Substances and Drug Products
- Leachables and Extractables

Your questions
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Are you interested in this Certification Module?
Further information can be found online at
www.gmp-compliance.org/certification/gmp-gdp-certification-program/eca-certified-quality-control-manager
or via the QR Code on the right.

Certified Technical Operations Manager

Image: Seidenader

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

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".

- Clean Rooms & HVAC Systems – GMP requirements for planning, qualification & operation
- Continuous Manufacturing of Oral Solid Dosage Forms
- GMPs for Equipment, Utilities and Facilities
- Pharmaceutical Water – Generation, Monitoring & Compliance
- Granulation & Tabletting – Process, Scale-Up, Trouble Shooting
- Lyophilization – Includes Workshop at GEA
- Container-/Closure Integrity Testing
- Visual Inspection Systems for Parenterals
- Renovation and Upgrading of GMP Facilities
- Single-Use Systems for Sterile & Biotech Applications
- Product Transfer – Organisation of a GMP-compliant Site Change

Your questions
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Are you interested in this Certification Module?
Further information can be found online at
www.gmp-compliance.org/certification/gmp-gdp-certification-program/eca-certified-technical-operations-manager
or via the QR Code on the right.

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.

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".

- Cloud Computing in a GxP Environment
- Computerised System Validation: Introduction to Risk Management
- Computerised System Validation: The GAMP 5 Approach
- Computerised System Validation: Leveraging Suppliers
- Computerised System Validation Master Class
- Computerised System Validation: How to Document CSV Activities
- Computerised System Validation: Maintaining Control of Operation
- SAP: Validation and GMP Compliance
- IT / OT Infrastructure Qualification and Operation in a GMP Environment

Your questions
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Are you interested in this Certification Module?
Further information can be found online at
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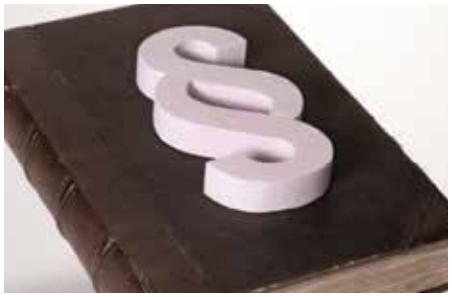
Certified Regulatory Affairs Manager



Regulatory Affairs Managers are 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".

- GMP meets Regulatory Affairs
- API Regulatory Starting Materials
- Drug Master File Procedures in the EU, the US and Japan
- ICH Q12
- Global registrations and Life Cycle Manage-ment for APIs
- How to write the Quality Part of an IMPD
- Handling Changes and Variations
- APIC/CEFIC European Conference on Active Pharmaceutical Ingredients, Regulatory Affairs Part
- How to provide Process Validation Data in a regulatory submission

Your questions
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Are you interested in this Certification Module?
Further information can be found online at
www.gmp-compliance.org/certification/gmp-gdp-certification-program/eca-certified-regulatory-affairs-manager
or via the QR Code on the right.

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.

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".

- European Microbiology Conference
- Monocyte Activation Test - Hands on Laboratory Course
- Microbiology for Non-Microbiologists
- Modern Microbiology Laboratory
- Contamination Control
- Low Endotoxin Recovery – Hands on Laboratory Course
- Environmental Monitoring Data Management
- Microbiological Identification – Hands on Laboratory Course
- Virus And TSE Safety Made Simple
- Bioburden - Regulatory Expectations and Practical Experiences

Your questions
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Are you interested in this Certification Module?
Further information can be found online at
www.gmp-compliance.org/certification/gmp-gdp-certification-program/eca-certified-microbiological-laboratory-manager
or via the QR Code on the right.

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 – Compliant and Reasonable
- Container/Closure Integrity Testing
- GMP for Beginners in Sterile Manufacturing
- Process Simulation / Media Fills – GMP Requirements on the Validation of Aseptic Processes
- Isolator Technology Workshop

Your questions
Dr Andreas Mangel is at your disposal for further information:
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Are you interested in this Certification Module?
Further information can be found online at
www.gmp-compliance.org/certification/gmp-gdp-certification-program/eca-certified-sterile-production-manager
or via the QR Code on the right.

Certified Biotech Manager

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".

- Protein Analytics
- GMP for Advanced Therapy Medicinal Products (ATMP)
- Annex 2 & Co. – GMP Compliance for Biopharmaceuticals
- Bioassays and Bioanalytics
- Stability Testing for Biological/Biotechnological Drug Substances and Drug Products
- Pharmaceutical Biotechnology for Non-Biotechnologists
- GMP for Vaccine Manufacturers – Current regulatory requirements and practical implementation
- Leachables and Extractables
- Blood and Plasma – Audits and Inspections

Your questions
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Further information can be found online at
www.gmp-compliance.org/certification/gmp-gdp-certification-program/eca-certified-biotech-manager
or via the QR Code on the right.

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".

- Stability by Design
- GMP meets Development
- ICH Q8 / ICH Q11 Training Course – From QbD to Process Validation
- How to write the Quality Part of an IMPD
- Lifecycle Management in Pharmaceutical Analysis
- Pharmaceutical Packaging Systems – Part 1 Development
- Granulation & Tableting
- GMP meets GCP – Management, Supply and Quality Assurance of Clinical Trials
- ICH Q12 – How to use the PACMP in Practice
- Emulsions & Gels

Your questions
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www.gmp-compliance.org/certification/gmp-gdp-certification-program/eca-certified-pharmaceutical-development-manager
or via the QR Code on the right.

ECA Certified Data Integrity Manager

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 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.

- HPLC Data Integrity
- Audit Trail Review for Comp. Systems in Analytical Laboratories
- Audit Trail Review
- Data Integrity
- Data Integrity Quality Oversight in the QC Laboratory AND Audit Trail Review for CDS/Laboratory Systems Workshop
- Raw Data: Understanding, Defining and Managing
- Data Integrity Master Class
- Lab Data Integrity: A Practical Approach for Gen-erating and Auditing Laboratory Records
- Lab Data Integrity Master Class
- Data Integrity and Good Documentation Practice
- D.I.C.T. - Data Integrity in Clinical Trials

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or via the QR Code on the right.