

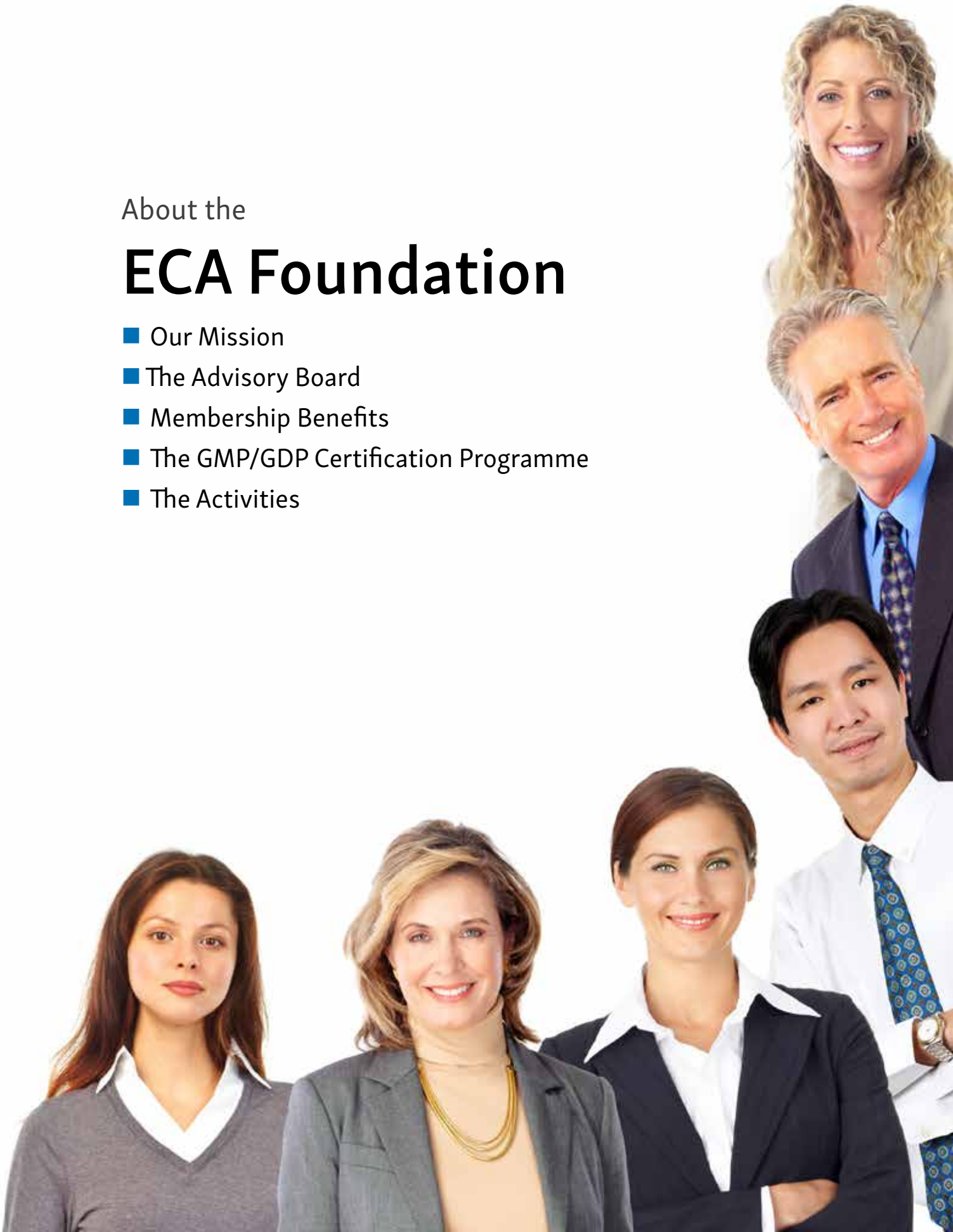


Foundation
*Fostering harmonisation
of GMP/GDP regulations*

About the

ECA Foundation

- Our Mission
- The Advisory Board
- Membership Benefits
- The GMP/GDP Certification Programme
- The Activities



About the ECA Foundation

The ECA was founded on the 1st of January 1999 as an independent not-for-profit organisation. It is chaired by a Scientific Advisory Board with 11 members of the pharmaceutical industry and regulatory authorities.

In 2010, the organisation was transferred to a Foundation.



With **close to 4,000 members**, ECA has become the leading European association with regard to pharmaceutical Quality Assurance and GMP compliance. The members from all over Europe and abroad represent almost 60 countries.

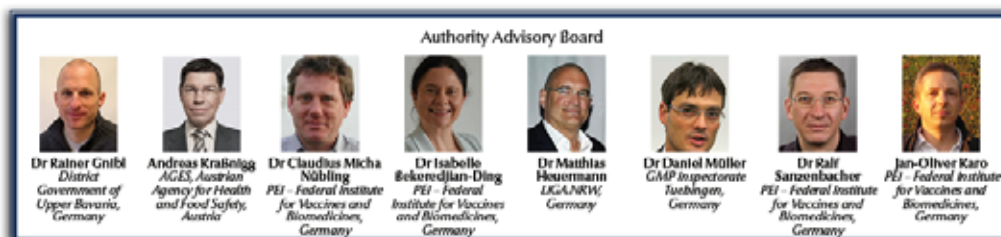
The Foundation is comprised of an educational organisation (ECA Academy) and various non-profit interest groups. The modern structure of the ECA Foundation allows to develop and include the activities of the interest groups and to have more flexibility to build new interest groups that support the needs of our members. To learn more about the ECA Foundation, please visit www.eca-foundation.eu.

Our Mission

„The ECA will provide support to the Pharmaceutical Industry and Regulators to promote the move towards a harmonised set of GMP and regulatory guidelines by providing information and interpretation of new or updated guidances“.

The Advisory Board

The ECA Advisory Board represents European regulatory authorities as well as the pharmaceutical and biopharmaceutical industry. By their voluntary work, the board members support ECA in fulfilling its mission to impart most relevant knowledge on the interpretation and implementation of GMP and regulatory requirements.



Red box - Part of the Foundation structure

Blue box - Not part of the Foundation (only advisory)

The ECA Academy

The ECA Foundation has been instrumental in developing a professional educational programme.

This programme, the training courses and conferences as well as the GMP Certification scheme are managed by the ECA Academy.

The ECA Academy is an educational organisation managed in co-operation with Concept Heidelberg, a professional conference organiser. Administrative tasks in this co-operation like the organisational handling of events and management of web services will be provided by Concept Heidelberg since the ECA Foundation does not employ own staff. This new organisational structure and the visualisation of the responsibilities provide the basis for a prosperous development of the organisation.

Membership Benefits

There are many reasons to join the European Compliance Academy. In the following, the 4 most important benefits are listed.

1. Discount

You can join any future ECA event with the reduced members' fee:

- For more than 60 conferences and education courses a discount of € 200,- will be granted.
- For GMP Webinars the discount is 25% off the regular fee.

In addition, publications and the ECA Good Practice Guides are available for a 35% discount.

2. Members' Area

Individual Members will have access to the members' area of the ECA Academy. The members' area includes e.g.:

- Free access to the ECA Guideline Manager – a database comprising more than 1.100 GMP guidelines. This online database is updated every month and can be sorted in two tree views, either by topics or by issuing authorities.
- Additional free ECA Academy Documents like Compliance Checklists, SOPs etc.

3. GMP Guideline Manager in ECA GMP WebApp:

With the ECA WebApp for your smartphone or tablet you have GMP information at hand. Anytime. Anywhere. Free of charge. And in addition to news, guidelines, courses and conferences and a comfortable search function available to everybody you as a member also have access to the password-protected complete GMP Guideline Manager database – including the two guideline tree views (sorted by topics or by issuing authority) also available in the Members' Area.

4. GMP Certification:

By completing the GMP Certification Programme participants receive an internationally acknowledged certificate.

How do you become a Member of ECA?

You automatically become a member for 2 years – free of charge – by participating in one of the ECA Academy courses or conferences marked with ECA (exception: Webinars).

Individual Membership (based on the calendar year) without attending an ECA event.

The annual membership fee is 190,- € plus VAT.

NEW: 3-year individual membership at the discounted rate of € 513,- (instead of € 570).

Group Rate

In addition to individual memberships, the ECA Academy also offers a discounted rate.

We do not offer company membership but you will receive a discount on the individual rate if a larger group of people becomes member.

Please contact us if you want to apply for this discounted rate at heimes@gmp-compliance.org. You and all your colleagues in the country the group rate was signed up for will automatically be able to take advantage of all ECA membership benefits.

Get involved in ECA's Interest/Working Groups

European QP Association

The European QP Association was founded in July 2006 with the goal to provide QPs in Europe with a platform allowing them to exchange experience, discuss the latest regulatory requirements, to identify and address difficulties and challenges and to support a harmonised European approach. Today, the Association counts more than 2.300 members from across Europe and beyond (from over to 40 countries).

www.qp-association.eu

European GDP Association

It is the goal of the Association to represent Responsible Persons for GDP, Logistic Managers and other individuals involved in a secure pharma supply chain. The Association provides its members guidance documents on GDP interpretation, a discussion forum and a GDP Supplier Database.

www.good-distribution-practice-group.org

Pharmaceutical Microbiology Working Group

Founded as RMM Group the group increasingly became the contact point for all microbiological topics, questions from members as well as from authorities. Therefore, the Group was renamed to Pharmaceutical Microbiology Working Group and extended its scope and activities – now providing advice on to all different subjects in pharmaceutical microbiology.

www.pharmaceutical-microbiology.org

Analytical Quality Control Group

The group aims at providing a networking platform for Analytical Chemists and Scientists and to facilitate an active discussion of the latest regulatory requirements as well as identifying and addressing technical issues and challenges.

www.analytical-quality-control-group.org

Validation Group

This group wants to establish a European-wide networking platform for facilitating active discussions of the latest regulatory requirements and to identify and address technical issues and challenges. Discussion/position papers and generic procedures are further supposed to provide an active support for a harmonised approach to common problems and issues.

www.validation-group.org

Visual Inspection Group

This group's goal is to take advantage of the long lasting experience and knowledge of its members and the learnings from previous conferences to contribute to a harmonisation and to generate a best-practice-paper. Much rather than a strict requirement document, this paper is intended to be a reference for controversial issues.

www.visual-inspection.org

Data Integrity & IT Compliance Group

The objective of the group is to support pharmaceutical industry to implement new IT technologies with regard to international GMP requirements.

www.it-compliance-group.org

ATMP Interest Group

Its objective is to provide a Europe-wide networking platform for persons involved in the development, manufacturing, quality management and marketing authorisation of Advanced Therapy Medicinal Products (ATMP) by facilitating effective and efficient communication between sciences, industry, competent authorities and the pharmacopoeias.

www.atmp-group.org

European GMP/GDP Certification Programme

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 takes the company's interests into account, i.e. in the further education the employees can select courses according to their individual professional demands, suit the course registration to the company's necessities.

By taking part in an education course or conference, the applicants become ECA members.

Certification Opportunities

The ECA Academy currently offers the following Certification Modules:

- 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
- Certified Data Integrity Manager

For more information please visit

www.gmp-certification.org