

The Software for Every GMP/QA Professional

All Important GMP Guidelines by













What is the GMP Guideline Manager Software?

The GMP Guideline Manager Software contains over 1,100 GMP guidelines, including FDA, EC and ICH. We have only compiled those guidelines that refer either to GMP topics or have an influence on GMP (e.g. Notice to Applicants). After you start the software, the table of contents appears. From here you can call up any of the guidelines. The GMP guidelines data base contains the complete texts. On your PC you can conduct quick research in the guidelines, a full-text search and even print out the texts.

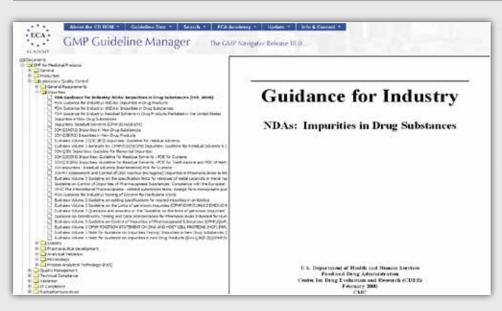
Web-based software

The GMP Guideline Manager is a web-based solution. This means no additional software is needed to run the GMP Guideline Manager. The application will be displayed by using a web browser like Internet Explorer or Mozilla. These browsers are already installed on each PC and laptop.

Table of content

The guidelines are displayed in a well-structured Guideline Tree. With the new software solution the pdf files are now integrated in the navigation tree.

Menu navigation



The simple menu navigation is easy to handle: just click on [+] to open a subordinate branch.

In this way, you can quickly find the desired guidelines, which are all available in PDF format.

Searching the GMP Guideline Manager



The software uses a search engine designed for web browsers. You can search not only for individual guidelines, but also for all guidelines referring to a particular topic.

An example: Where can I find requirements on 'Purified Water'? The GMP Guideline Manager only takes seconds to present you a list with all those guidelines containing the keyword.

You also may search only in a certain category, e.g. only in FDA documents.

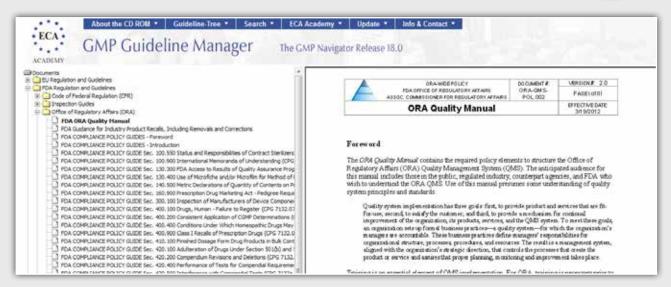
New Feature

Guideline Tree sorted by GMP Topics

In addition to the Guideline Tree sorted by issuing authorities, a second Guideline Tree is now part of the software. Users may use this Guideline Tree to find the applicable guideline, e.g. to "sterile manufacturing" or to "APIs".

So far, this helpful tool was available on the ECA Members Area only.





What should ECA Members do who have an old CD version?



As a registered user of the GMP Guideline Manager Software you are allowed to use the online version of the GMP Guideline Manager as well.

The online version contains the latest version with the updated Guidelines data base.

For the duration of your membership, you have free access to this online version! The online version can be accessed via the ECA Members Area.

Access the GMP Guideline Manager via your smartphone or tablet



You can access the databse also via the GMP WebApp.

ECA Members receive the login details for the Members Area at the ECA website.

The same login information can be used to access the GMP Guideline Manager database.

To open the app just enter <u>app.gmp-compliance.org</u> in the browser of your smartphone or tablet and the WebApp opens immediately.

Important:

This software cannot be purchased. **The software is a free gift for all members of the ECA Academy.**The European Compliance Academy (ECA) was founded on the 1st of January 1999. The ECA is an independent organisation chaired by a Scientific Advisory Board with 10 members of the pharmaceutical industry and regulatory authorities. With close to 4,000 members, ECA has become the leading European association with regard to pharmaceutical Quality Assurance and GMP compliance. Please read the information on the back of this brochure in order to learn more about how to become ECA Member.

How do you become an ECA Member?

In the past years it was only possible to become an ECA member by participating in one of ECA's conferences or courses. Since January 2007 membership is also possible without attending an ECA event.

Two kinds of membership are offered.

Individual Membership for just € 190,-*

Single-user version of the GMP Guideline Manager Software for individual ECA members With the individual membership you will be able to take advantage of all ECA membership benefits without necessarily attending a conference or a course.

- 1) **Discount:** Individual Members can join any future ECA event with the reduced members' fee:
- For more than 60 conferences and education courses a discount of EUR 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 with a 35% discount.

- 2) Members' Area: Individual Members will have access to the members' area of the European Compliance Academy. The members' area include among others free access to the Guideline Database of ECA. This Database with more than 400 GMP guidelines is the basis for the GMP Guideline Manager Software. The online database will be updated every month.
- **3) GMP Guideline Manager Software:** Members will receive the latest version of the GMP Guideline Manager Software:
- **4) GMP Certification:** By completing the GMP Certification Programme participants receive an internationally acknowledged certificate.

Group Rate*

Multi-user version of the GMP Guideline Manager Software for groups In addition to individual memberships, the ECA Academy also offers a discounted group rate.

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.

For more information please contact:

