

The SwAPP how2GCP eLearning Tool

Why is there a need for professional GCP-training?

Article 8 of the “Verordnung über die klinischen Versuche (VKlin)”¹, updated on 18 August 2004, now requires that any investigator wanting to perform a clinical trial demonstrate appropriate training and experience in Good Clinical Practice (GCP). Experience running clinical trials alone is no longer sufficient. The updated Art. 31 of the VKlin contains analogous requirements for members of ethical committees. The updated VKlin articles took effect on 1 September 2004.

Furthermore, all professionals (pharmaceutical companies and CROs) working in the field of clinical research must have appropriate education and training in GCP.

Advantages of the how2GCP eLearning tool

With the new provisions in effect, all clinical research professionals must be able to receive training in GCP quickly and efficiently. They are in need of an easy-to-use and easily accessible source of basic information for their education and GCP training. The internet is the perfect instrument, accessible any time and anywhere.

The Swiss professional association, SwAPP, is therefore offering its eLearning tool **how2GCP** as an attractive internet-based platform for modern GCP training.

As an internet-based learning program, how2GCP can be accessed by any standard internet browser with a personal user name and password and can be used individually, independent of time and place.

Regular updates (primarily to integrate new directives concerning Switzerland and the EU) as well as further developments of the tool are planned (e.g. practical case studies for advanced knowledge, modules for ethical committees, study nurses, additional languages, etc.).

Design of how2GCP

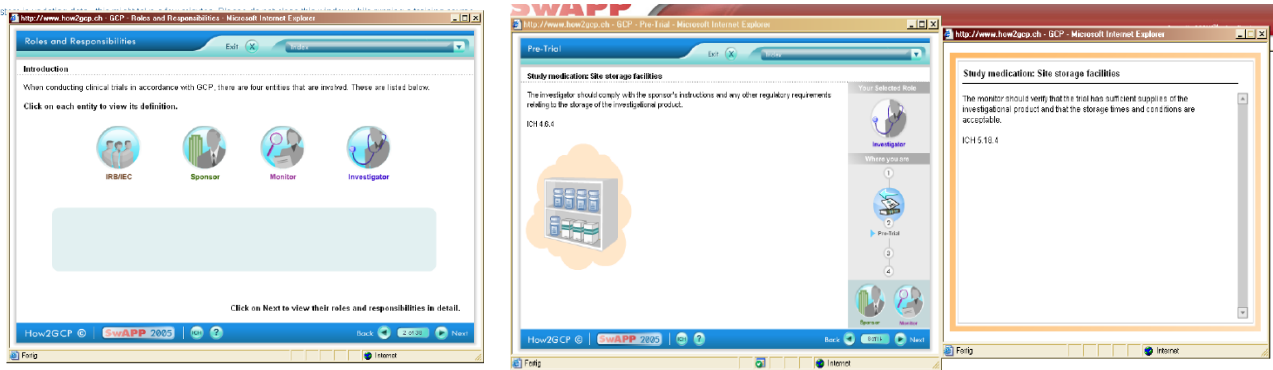
The GCP eLearning tool is a process-oriented training course in English with integrated texts of the VKlin in German and French. It is based on GCP principles, as defined in the ICH-Guidelines and VKlin.

¹ http://www.admin.ch/ch/d/sr/c812_214_2.html

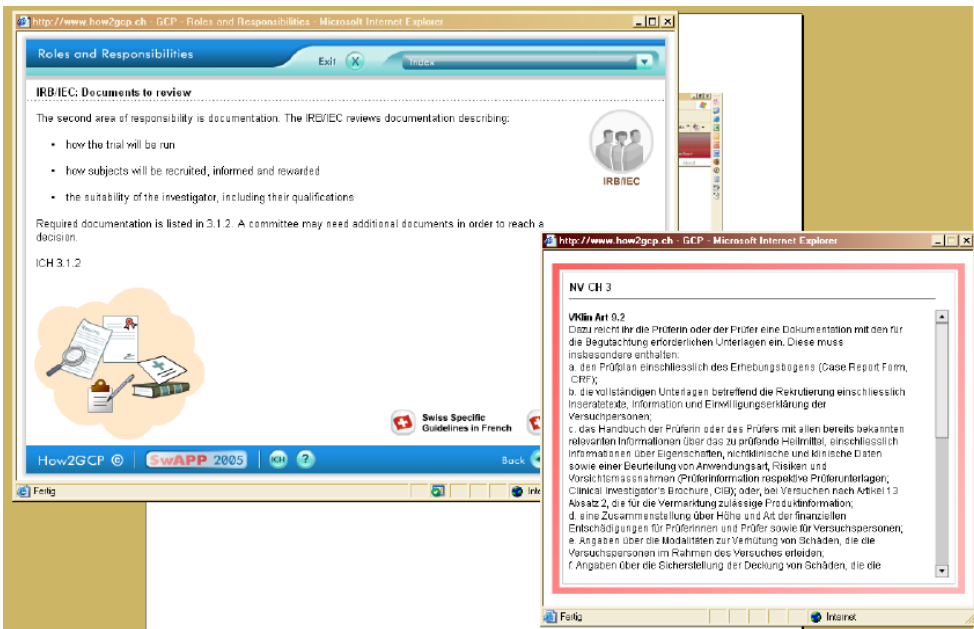
In the 6 modules:

- What is GCP
- Roles and Responsibilities
- Investigator Selection
- Pre Trial
- During Trial
- Post Trial

the relevant information, documentation, duties and responsibilities are presented for each phase of a clinical trial. It is possible for the user to switch between the different roles (ethical committee, sponsor, monitor, investigator) at any time in order to learn about the role of every partner.



The corresponding French or German text of the VKlin can be accessed as “pop-ups”.



An individual's progress through the program can be monitored by a game of dice.



How are the professional associations and authorities involved in the GCP eLearning tool?

The GCP eLearning tool is approved by the SwAPP Commission for Professional Development (CPD) and is honoured with 8 credits for pharmaceutical medicine.

How is completion of the how2GCP training verified?

To test the understanding of GCP, the tool offers a multiple choice test examination. If the examination is passed, the examinee automatically is awarded with a personalised certificate.

Costs

how2GCP is offered through a yearly subscription.

Fees depend on the number of user licences ordered:

Number of licences	Costs in CHF
1-5	200.-
6-10	400.-
11-20	600.-
more than 20	1000.-

The requested number of user licences will be released after receipt of payment. A subscription allows unlimited use of the tool (including for repetition and reference) for one year after the date of purchase.

Access to the multiple choice examination (including the certificate for successful completion of the examination) must be ordered separately from the yearly subscription at a cost of CHF 100.- for SwAPP members or CHF 150.- for non-members.

For further information about how2GCP or to place an order, please visit: www.swapp.ch or send an e-mail to: how2gcp@swapp.ch