

Further information about the Profess SOP-H quality system

What is the SOP-H system?

The SOP-H system is a user friendly quality system for investigators in a hospital who independently of any pharmaceutical sponsor, wish to initiate and conduct clinical trials. The SOP-H system ensures the investigator complies with all relevant applicable rules and regulations.

How was the SOP-H system formulated?

The SOP-H system consists of a number of standard operating procedures. The entire clinical research process is described in 11 procedures, i.e. the general SOPs: the Quality System, training and qualification, audit, fraud and misconduct. The primary research process is described in three phase SOPs: the preparation phase, the execution phase and the analysis and completion phase. These SOPs are hyperlinked to four other SOPs. These SOPs include the following processes: the study protocol and protocol amendments, monitoring, data management and statistical analysis.

What is the format used to design the SOP-H quality system?

The SOPs can be viewed in HTML format and can be printed in pdf format. The SOPs link to instructions which can be viewed in HTML. These instructions can also be printed in pdf format. A study cannot be conducted in compliance with the ICH GCP guideline without the use of checklists, forms and templates. The SOP-H system provides quick and easy links from all SOPs to instructions, checklists, forms and templates. The checklists, forms and templates are available in word format so that these can be edited and customised for a particular study..

How is the SOP-H system maintained?

Profess ensures that the SOP-H system is compliant with all applicable regulatory requirements. Profess will study all relevant applicable requirements and transcribe these into user friendly, bite sized, tasks and obligations, with a proper "Plain Common Sense" qualification. User comments will also be incorporated to continuously improve the system.

Costs of the SOP-H system?

The subscription for use of the SOP-H quality system is €5,400,-- annually for five (5) accounts. This includes unlimited access to the system and the opportunity for the purchaser to use the system for its' own research purposes. The system will be maintained on an ongoing basis by Profess. The SOP-H help desk is available to respond to any reactions, questions, remarks, or issues with the system. For unlimited access for all employees in the hospital Profess will be pleased to offer a customised budget. Please send a request for a proposal.

Whom should I contact?

For information regarding the system, its operation, an introduction to the system or for an ICH GCP course with the SOP-H system included please contact SOP-H@profess.nl.

How to apply?

If the subscription with your organisation has been arranged, you can register for the SOP-H quality system. When the terms and conditions have been agreed and the [registration form](#) has been completed , please send the registration form to Profess. Your user name and password will be sent to you within a couple of days.