

SPAQA was founded in 1989 to offer interested Quality Assurance (GLP QA) professionals a platform for the exchange of expertise and ideas. Since that time, SPAQA's scope has broadened to include members with interests in GCP, GMP and related areas (e.g. ISO). During our 20<sup>th</sup> anniversary in 2009, we looked backward to see how we had evolved, and at the same time looked forward to identify where we as a society wanted to go. We surveyed our members to determine their needs and their willingness to actively participate.

As a result of the survey taken, SPAQA initiated two "working groups" focused on GLP and Computerized System Validation (CSV) issues respectively, to increase the potential for networking among members and to provide time for one to one interactions amongst colleagues. Each of these two focus groups intends to meet 3-4 times per year. Discussion topics are submitted by the group's membership prior to the respective meeting. Discussions are lively, bringing together interested individuals from QA consultancies, Pharma, Agro, Chemical, and Contract Research Organizations (small as well as large multispecialty CROs) and academia. The informal nature of the group meetings fosters interactions at all levels and from all perspectives. SPAQA has also modified its web site ([www.spaga.ch](http://www.spaga.ch)) and now provides links and news to SPAQA members and non-members alike, as well as implementing a "Members only" area, where the discussion summaries of the GLP and CSV group meetings are provided.

The highlight of SPAQA's annual activities remains the Roundtable Discussion with the Swiss GLP Monitoring Authorities each Fall and an annual meeting with external speakers held each Spring.

This year's annual meeting which was held on 04 May 2010 clearly reflected the interests of our membership and was extremely well received. The program included three presentations spanning GLP, CSV and GCP themes as well as a presentation on Quality Metrics.

**Topics/Speakers at the 2010 Annual Meeting**

**On the road to GLP**

Dr. Silke Mark, CABMM Center for Applied Biotechnology and Molecular Medicine

**New AGIT Guidelines on Spreadsheet Validation and Change Management – Nightmare or Help?**

Dr. Silvio Albertini, F. Hoffmann-La Roche AG

**Mock GCP Inspections**

Rita Hattermer-Apostel, Verdandi AG

**Metrics for QAUs – Benefit or Pitfall**

Dr. Hermann Lehn, F. Hoffmann-La Roche AG

The Quality Metrics presentation was followed by breakout sessions with all attendees in an attempt to define metrics which could measure the quality/ performance of the Quality Assurance or Business processes, without being potentially misused. It was concluded that metrics can be generated which characterize a business or QA process. These should not be misused to measure the performance of an individual. The use of the metric and not the metric itself is critical.

The Roundtable discussion to be held in November 2010 with members of the GLP Monitoring Authorities will surely be the culmination of a successful year. The Roundtable discussion is based on questions submitted to the SPAQA board for submission to the GLP Monitoring Authorities. In previous years, the focus of these questions has been on general GLP themes including (Multisite, electronic archival, Peer Review, and Plan/Reporting issues). Attendance at the GLP Monitoring Authority Roundtable is open to all.

If you are interested in knowing more about SPAQA or wish to become a member, please contact us via our website ([www.spaqa.ch](http://www.spaqa.ch)) or per e-mail at [vorstand@spaqa.ch](mailto:vorstand@spaqa.ch)



### **SPAQA Board 2010**

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