

SQA 27th Annual Meeting Abstract Submission Instructions

Important Information – Submission Deadline 30 September 2010

- If you are submitting more than one abstract, you can use the same login for each abstract.
- You can alter your abstracts at any time up to the deadline.
- Abstract text is required for all submissions.
- Submissions may be amended at any time before the deadline (30 September 2010). All **completed** submissions will be automatically submitted for review on the day of the deadline.
- **TIP** - SQA urges you to prepare your abstract before submitting, via a word document, which you can cut and paste into the fields for final submission.

Abstract Guidelines

Abstracts will be accepted for the following presentation types:

- **Poster**;
- 30 minute **Podium** presentation (25 minute presentation with 5 minutes of Q&A and transition);
- 90 minute **Session** (entire session devoted to a single topic with one or more presenters);
- 90 minute **Panel Discussion** (entire session devoted to a single topic, discussion with 4-5 experts and a moderator);
- 60 or 90 minute **Roundtable Session** (entire session devoted to a single topic with several presenters and breakout discussions in small groups).

Required Information

Prior to submitting an abstract, please make sure that you have the following information available:

- Contact information for all presenting authors, experts, or moderators;
- Biographies for all presenting authors, experts, or moderators (under 150 words each);
- Abstract text in paragraph format (under 500 words);
- Content level (Basic, Intermediate, Advanced):
 - **Basic** – *general material, appeals to a broad audience,*
 - **Intermediate** – *more specialized but with some broad appeal,*
 - **Advanced** – *specialized material with higher level analysis;*
- Abstract keywords.

Registration

Annual Meeting registration will be available in November 2010. All presenting authors, experts, or moderators of abstracts accepted for presentation will be required to register for the Annual Meeting and pay the appropriate fees, in accordance with the published fee schedule.

Regulatory Speakers

The following instructions should be followed if your abstract includes a regulatory agency representative as a presenter.

- If the abstract submitter requests that SQA pay the travel expenses of the regulatory speaker, then the abstract must clearly indicate this request, and the inclusion of the regulator must be approved in advance by the Program Committee and the established regulatory invitation process must be followed – see SOP GA-02-01.xx.
- If the regulator does not require fee waiver or travel reimbursement, then the abstract submitter should indicate on the abstract that the speaker does not require fee waiver or reimbursement.
- Invited regulatory speakers for regulatory updates sessions or symposia may have their fees waived and travel reimbursed, but only if the process is followed in accordance with SOP GA-02-01.xx

Hot Topics

The SQA Specialty Sections have developed a list of suggested “current issues” and “hot topics” for Annual Meeting presentations. Abstract authors are encouraged to consider these topics when developing an abstract submission.

Hot Topics for Presentation	
Animal Health	Current QA Practices (Risk Management and Auditing Techniques)
	Quality of FDA Submissions (Adverse Events, guidelines used by regulators to refuse to file, tips to improve documents)
	Challenges with Biologics
	Learning from 483s
Beyond Compliance	Ethics and Conducting an Audit
	Corporate Compliance Quality: Breaking away from GxPs
	How training and Job Functions go together: Effective Qualifications
	GMP and Controlled Substances: What are the Requirements
	How to handle outside influences at a GLP or GCP CRO?
Bioanalytical	Global harmonization of bioanalytical method validation guidance
	Representatives from global regulatory authorities, including the FDA
	Company protocols for Incurred Sample Reanalysis (ISR)
Biotechnology	Investigational process for small and large molecules
	Protein Characterization (EPA/FDA) – defining and auditing protein characterization
	Types of technology on Biotech – facilities, science (e.g., biomarkers)
	Biotech and Regulations: The new, the old, what is needed
Clinical	The FDA proposal on reporting Fraud - how will the industry comply?
	Outsourcing Quality (completely outsourcing your internal QA department) - what's at risk?
	Outsourcing QA and QC, Outsourcing Quality that could be considered - Quality oversight of outsourced work
	Part 11 and clinical trial sites
	The new FDA investigator inspection program (and transparency)
	Regulatory agencies and sharing of information (FDA-TGA-EMA)
	Electronic Data Capture: validation and configuration and CQA's involvement
	Quality Agreements for electronic data capture software vendors and CROs
	Good Clinical Laboratory Practices (GCLP)
	Performance Metrics for managing vendors
	Assessing Investigator Responsibilities in light of the new Guidance (Oct 2009)
	Studies using IMP from Pharma/Biotech: What are the responsibilities of the Sponsor in these situations
	Ethical challenges in conducting international clinical trials - in particular when resource-poor countries are involved
	Conducting risk-based inspections by regulatory authorities
	FDA's increase in auditing IRBs and how will this affect if or when sponsors audit IRBs
	Conducting studies and auditing in Australia following TGA (therapeutic Goods Administration) clinical trial handbook
Data integrity and Risk Management	

Computer Validation	Use of Single Sign-on, Where it is justified, how to validate and other implications/concerns in the regulated environment <ul style="list-style-type: none"> Example: How long do I need to keep User ID data from my Active Directory / LDAP systems
	Cloud Computing <ul style="list-style-type: none"> Is it safe? Will FDA reject my data? What to look for in Validation/change control
	A regulatory update on the Part 11 Survey
	Archiving of electronic records
	Expectations of the EPA for Computers in GLP
	Cloud Computing, Compliance and Security a Panel Discussion
	Virtualization of servers - regulatory expectations for control, configuration management, IQ, data integrity and security, validation challenges
	Agile Computer Systems Development - challenges in regulated environment
	When do I use ITIL's Incident Management and Problem Management vs. QA's Deviation (Waiver) and Corrective Action (CAPA) processes?
	Supplier Audits – what should I do to ensure the selection and contracting processes set-up my company for success and compliance
Validation world has expanded beyond GxPs	
GLP	Coming soon
GMP	Coming soon
Medical Devices	The status of CDRH, an update on 2010 CDRH initiatives, and the regulatory path for 510(k) medical devices
	FDA oversight of foreign clinical device trials including the recent HHS OIG report
	Considerations for the use of software or computer-based equipment as the test article in pre-clinical studies
Scientific Archiving	Coming soon
University	Mixed GLP and non-GLP environments in the University <ul style="list-style-type: none"> Conducting research and enforcing compliance in a mixed environment University Animal Care Facilities GLP and IACUC overlap
	Computer validation, electronic records and Part 11 compliance in University and Academic Health Center settings
	Novel drug development in the University <ul style="list-style-type: none"> Performing a GLP study as a hybrid (use non-GLP labs for the dose analysis because GLP-compliant labs cannot analyze the test material in a validated state). Example: gene therapies for cancer therapy. Failure of Sponsor to provide (or understand importance of providing) test article characterization documentation for GLP testing of novel drugs Lack of guidance from the FDA regarding new scientific advances at the University
	Managing the University QAU <ul style="list-style-type: none"> Can University-wide QAU fulfill responsibilities of all GXP regulations and how would it be structured? In-house QAU vs. Consultant Communication between University Contract Office and QAU Benefit of QAU to University
	Coursework and training in GxP, quality assurance and good research practices in academic institutions
Regulatory agencies and inspections at the University <ul style="list-style-type: none"> Current findings at universities and other academic institutions University response to inspection (pre-, in process, post-) Are regulators familiar with University culture? 	

Miscellaneous	GAMP 5
	Methods of performing risk based assessments
	Discussions about the interface of ISO and GCP/GLP, and its application to clinical research
	Bioanalytical assays
	Use of electronic notebooks
	Incurred sample reproducibility
	Current 483s, warning letters
	483s related specifically to bioanalytical testing
	Areas of applicability for GLP in clinical studies
	Changes in FDA since Dr. Hamburg became commissioner
	Use of central labs in clinical studies/problems encountered/solutions
	FDA efforts toward "transparency"

Abstract Submission Process

Abstract Submission

- The first time you use the 27th Annual Meeting abstract submission website, you must register to use the system. Any SQA User ID and password that you already have will not be sufficient – you must create a new user account.
- When you have prepared your abstract, log in to the submission system with your e-mail address and password. The link to the submission area is accessible via <http://www.sqa.org/am2011>.
- You will be taken to a screen from which the submission process starts. **Please read the instructions carefully.** If you want to submit a new abstract you should click the link that says "Click here to submit a new abstract."
- Submitting an abstract is a multi-step process. Each step asks several questions. Some questions are marked "required" and you will not be able to complete your submission until these questions have been answered.
- Do not include the names of authors in the title or text of your abstract. The title should be succinct while clearly indicating the nature of the abstract submission. Capitalize the first letter of each word and do not add a period at the end.
- Please note that some scientific symbols may not appear correctly in the abstract book. You can avoid this problem by writing the name of the symbol in full, for example "beta" instead of β .
- If you have to stop part way through the process, your submission will be held in temporary storage until you return later and complete all the required questions. When you log in again, you can click on your incomplete abstract and resume the submission process.
- You will be asked to confirm that the presenting authors will register to attend the Annual Meeting and will pay the appropriate registration fees. All speakers must register for the Annual Meeting. Please visit the SQA website at <http://www.sqa.org/am2011> to review the registration fees.
- Once you have completed your submission, click the "Finish" button. If you have answered all the required questions, your abstract will be assigned a reference number and you will receive an e-mail confirmation. If you have not answered all the mandatory questions, you will be alerted and your abstract held in temporary storage until you return and complete all the questions.

Amending a Submission (*You may make changes to your submission(s) at any time up to the deadline.*)

- Log in to the system. You will see your abstracts listed. Click on the abstract that you wish to change.
- Amending an abstract is the same as the original submission process except that the online form will be completed automatically with your previous answers. You do not have to change an answer unless it is incorrect.
- When you reach the final step and press "Finish," you will be sent an e-mail confirmation.

Withdrawing a Submission

If you wish to withdraw your submission, please contact SQA Headquarters at sqa@sqa.org with the title and reference number of your abstract.