An Update from the Society of Quality Assurance
for the Mid-Atlantic Region Society of Quality Assurance
Presented by
Tammy Barkalow, RQAP-GLP
2017 Vice President
Society of Quality Assurance (SQA)
Mission Statement:
Promote and advance the principles and knowledge of quality assurance essential to human, animal and environmental health.

Vision Statement:
A world with safe and effective biologics, chemicals, drugs and medical devices for humans, animals and the environment.
www.sqa.org will have a new look just a few weeks.

Members-only access to
- Regulatory Resources
- Specialty Section Networking and Discussion
- Career and Mentoring Opportunities
- Quality Matters e-newsletter, and more!
SQA Regulatory Resources

• SQA Communications with Regulatory Authorities
• Regulatory Databases
• GXP Inspectional Experiences
• Repository of Global Regulations
• Specialty Area Resources
• Regulatory Speakers at Annual Meetings, Quality Colleges, Webinars, and Symposia
<table>
<thead>
<tr>
<th>Date</th>
<th>Communication</th>
<th>Addressee</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>12 September 2017</td>
<td>SQA comments on the Draft Guidance on Good In Vitro Method Practices (GIVIMP) for the Development and Implementation of In Vitro Methods for Regulatory Use in Human Safety Assessment</td>
<td>Organisation for Economic Co-Special RRT operation and Development</td>
<td>Clinical Specialty Section (CSS) RRT</td>
</tr>
<tr>
<td>22 August 2017</td>
<td>SQA comments on Draft Guideline for the Notification of Serious Breaches of Regulation (EU) No 536/2014 or the Clinical Trial Protocol (EMA/430909/2016)</td>
<td>European Medicines Agency</td>
<td>Clinical Specialty Section (CSS) RRT</td>
</tr>
<tr>
<td>20 July 2017</td>
<td>SQA comments on Draft OECD GLP Advisory Document No. 19 on the Management, Characterisation and Use of Test Items</td>
<td>Organisation for Economic Co-Special RRT operation and Development</td>
<td>Special RRT</td>
</tr>
<tr>
<td>26 June 2017</td>
<td>SQA comments on EMA/15975/2016: Guideline of GCP compliance in relation to trial master file (paper and/or electronic) for content, management, archiving, audit and inspection of clinical trials</td>
<td>European Medicines Agency</td>
<td>Clinical Specialty Section (CSS) RRT</td>
</tr>
<tr>
<td>28 February 2017</td>
<td>SQA comments on guideline on strategies to identify and mitigate risks for first-in-human and early clinical trials with investigational medicinal products</td>
<td>European Medicines Agency</td>
<td>Special RRT</td>
</tr>
<tr>
<td>19 January 2017</td>
<td>SQA comments on the NPRM GLP published in August 2016</td>
<td>Dr. Toelle and Ms. Maloney</td>
<td>Special RRT</td>
</tr>
</tbody>
</table>
Regulatory Databases

FDA 483 Database
The FDA 483 Database is provided to SQA members by the SQA Learning Foundation. 2014, 2015 and 2016. (1 October 2012 - 18 February 2016). Additional FDA 483 data will be added.

Select the Find button to see all results.

FDA 483 Search
<table>
<thead>
<tr>
<th>Field</th>
<th>Input Field</th>
</tr>
</thead>
<tbody>
<tr>
<td>Firm Name</td>
<td></td>
</tr>
<tr>
<td>CFR Reference</td>
<td></td>
</tr>
<tr>
<td>Inspection Date</td>
<td></td>
</tr>
<tr>
<td>Between</td>
<td></td>
</tr>
<tr>
<td>Keyword</td>
<td></td>
</tr>
<tr>
<td>Find</td>
<td></td>
</tr>
</tbody>
</table>

Laboratory Inspection Database
The EPA/FDA Laboratory Inspection Database is provided to SQA members by the SQA Learning Foundation. Inspections from 36 October 1999 through 29 August 2015. Additional data will be added as it is obtained.

Select the Find button to see all results.

Laboratory Inspection Search
<table>
<thead>
<tr>
<th>Field</th>
<th>Input Field</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laboratory</td>
<td></td>
</tr>
<tr>
<td>City</td>
<td></td>
</tr>
<tr>
<td>State</td>
<td></td>
</tr>
<tr>
<td>Country</td>
<td></td>
</tr>
<tr>
<td>Inspection</td>
<td></td>
</tr>
<tr>
<td>Date Range</td>
<td></td>
</tr>
<tr>
<td>Agency</td>
<td></td>
</tr>
<tr>
<td>Find</td>
<td></td>
</tr>
</tbody>
</table>
Professional Development through SQA

- Quality College Courses
- Special Symposia
- Online Courses
- Annual Meeting Presentations
- Webinars
- Mentoring Program
- Registered Quality Assurance Professional (RQAP-GCP & GLP) programs

www.sqa.org
Previous Educational Topics Provided by SQA

- Selected Topics in BioAnalytical Auditing
- Advanced Topics in Computing Compliance
- GCP Hot Topics: Audit Management
- Managing GLP Multisite Studies in Accordance with OECD Monograph No. 13
- Creeping GMPs
- QA Consulting 101

- Good Practices: Understanding the GxP Regulations Using a Quality System Approach
- Effective, Value-Added Auditing for the 21st Century
- Fraud and Misconduct in PV and GMP
- SEND: Implementation and Validation
- Study Director Training
- CAPA Across the GxPs
- Public Speaking Workout
SQA Online Learning

- On-demand — Access any time, anywhere you have an internet connection
- Self-paced — Work through the modules at your own pace
- Interactive — Course includes interspersed review questions, and a quiz at the end of each module
- Printable certificates of completion are available
- RQAP re-registration units are available for individual courses

Visit www.sqa.org/learn for details!
Online courses coming in 2017...

21 CFR Part 11: Electronic Records; Electronic Signatures
Short course

Study Director and Principal Investigator Training
Seven modules

Metadata
Data that describe other data
- Author
- Date Modified
- Date Created
- File Size

Metadata can be created manually or by automated information processing

Source: http://whatis.techtarget.com/definition/metadata

Desirable Skills of a Study Director
See the big picture
Allocate and effectively use resources
Be innovative when resources are short
Be perceptive to strengths and limitations
Use strengths and limitations accordingly
Make and execute critical judgment calls

www.sqa.org
Online short courses in development...

- Good Documentation Practices
- Auditing Soft Skills
- Sponsor/CRO Relations
- GCP: Writing Audit Reports
- Preparing for Agency Inspections: GLP
- Preparing for Agency Inspections: GCP
- Preparing for Agency Inspections: MHRA/EMA
- ... and more!
Webinars held in 2017

- OECD 17: Application of GLP Principles to Computerised Systems
- Quality Risk Management (QRM) - Introduction to the Application of QRM in Clinical Research
- Remote/Desktop GCP Audits
- Current Challenges for Anti-Drug Antibody Assays in Regulated Bioanalysis for Immunogenicity
- Honeybee Health: The latest buzz on colony decline (October 17)
- Tactical Questioning (November 2)
Webinar Library

• Many include complete webinar audio/slide recordings
• Others slides only
Chapter Webinar Series

- Slated for 2018
- Each North American Chapter will be asked to host one webinar
- Regional Chapter Presidents Committee working on details
Quality Metrics for the QA Professional was the topic of this year’s Symposium, which was held in Woburn, Massachusetts.
34th SQA Annual Meeting & Quality College

8-13 April 2018
Anaheim Marriott, Anaheim, California, USA
The Wonderful World of Quality

Abstracts due 10 October 2017!
www.sqa.org/sqa2018
SQA Annual Meeting

The SQA Annual Meeting includes training and concurrent sessions dedicated to promoting and advancing the principles and knowledge of quality assurance essential to human, animal and environmental health worldwide.

SQA presents a program of interest to QA professionals, management, study personnel and regulatory authorities around the world. Sessions typically focus on regulatory-based topics in clinical (GCP) and preclinical (GLP) research and manufacturing (GMP) arenas. Other areas of interest represented include animal health, bioanalysis, biotechnology, computer validation, medical devices, pharmacovigilance, scientific archiving, university issues and much more.

Session recordings available for purchase
Global QA Conference

• Edinburgh, Scotland, 1-3 November 2017
  hosted by the Research Quality Association (RQA)
  https://www.therqa.com/learning/5th-global-qa-conference/

• Japan 2020 – hosted by the Japan Society of Quality Assurance

• United States 2023 – Washington, DC area – hosted by SQA
Mentoring Program

Society of Quality Assurance members are eligible to participate in the Mentoring Program!

**Mentees**
Interact with successful experts, receive personalized feedback and encouragement, and acquire new technical knowledge and skills.

**Mentors**
Obtain new technical information, expand their professional networks, and gain recognition as subject matter experts.

**Peer Partners**
Network with other experienced Quality Assurance professionals through a one-on-one parallel exchange of information.

Over 300 successful matches have been made since the program began in 2009!
RQAP Program

Registered Quality Assurance Professional (RQAP)

- Laboratory and Field RQAP-GLP
- Clinical RQAP-GCP

RQAP Credential

The Society of Quality Assurance is proud to offer the professional credential Registered Quality Assurance Professional (RQAP) for professionals working in Good Laboratory Practices as well as for professionals working in Good Clinical Practices. Registration is a recognized standard of experience and knowledge throughout the QA Industry, in the US and around the world.

What the credential demonstrates

- Proof of your knowledge of the regulations/guidelines and how they are applied
- Commitment to a high quality standard in the QA industry
- Personal professional growth and achievement

How it Works

1. Professionals must pass an examination in either Good Laboratory Practices or Good Clinical Practices to receive the RQAP credential.
2. Registered professionals must re-register every three years by submitting documentation of ongoing professional activities. These activities include, but are not limited to:
   - Attending the SQA Annual Meeting and/or Quality College
   - Attending events of SQA Regional Chapters
   - Attending events of relevant professional organizations, e.g., JSQA, RQA, RAPS, DIA, ACS, ACRP, NAIC, AALAS, etc. (See our MUO Organizations and Liaison Organizations.)
   - Completing courses in the SQA Online Learning Center
   - Attending SQA webinars or webcasts offered by relevant professional organizations.

Society of Quality Assurance

Home to the world's best QA professionals

www.sqa.org

www.sqa-lf.org
Publications

• New e-newsletter published at least quarterly
• Regulatory hot topics
• Technical articles
Quality Matters

Member Newsletter of the Society of Quality Assurance

Back to Quality Matters Home

Regulatory Hot Topics

Provided by the SQA Board of Publications, 27 July - 18 Sept 2017

To provide information on regulatory updates (especially international issues) for inclusion in Quality Matters, send an email to sqa@sqa.org.

Quick Links

US ENVIRONMENTAL PROTECTION AGENCY

US FOOD AND DRUG ADMINISTRATION
   Animal and Veterinary
   Biologics
   Clinical
   Drugs
   Medical Devices

INTERNATIONAL UPDATES

www.sqa.org
Specialty Sections

The Specialty Sections provide members with a forum for discussion and information sharing in their specific areas of the research Quality Assurance field and also contribute to Society education and publications in their specialty areas.

Animal Health

Beyond Compliance

Bioanalytical/Biotechnology

Clinical

Computer Validation

GLP (with EPA subcommittee)

GMP

Medical Device

Pharmacovigilance

QA Consultants

Scientific Archiving

University
Questions?