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QA Quality Matters

A Member Publication of the Society of Quality Assurance

INSIDE

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Taking it to the Next Level!

Scott Cook
President, 2013

What an exciting year! We have been extremely active in so many areas of SQA that it is hard to know where to begin. Let's get off the starting line with a review of the year beginning in Indianapolis and ending with our upcoming 4th Global QA Conference/ 30th SQA Annual Meeting in Las Vegas.

Our 29th Annual Meeting in Indianapolis, Indiana was the highlight of the year. We had an excellent turnout, a great facility, program and a keynote speaker that identified four core commitments to having a successful organization and I definitely see those qualities in SQA.

Our September Quality College and Special Symposia in Raleigh, North Carolina, on "Qualifying Vendors and Subcontractors" (co-sponsored by the SQA Regulatory Forum Council and the North Carolina Chapter SQA) and new technologies: "Where Are They Going To Show Up Next?" (co-sponsored by the SQA Computer Validation Initiative Committee and the SQA Medical Device Specialty Section) was a successful combination. I look forward to seeing more of these co-sponsored events in the future.

We have made great strides this year in a number of areas of SQA Mentoring, Quality College, regulatory communications with the EPA and FDA, liaisons with other societies, scholarship/awards, formation of a SQA Learning Foundation, RQAP and accreditation improvements, proactive assistance with EPA and GAO investigations, 483 Repository possibilities, CVIC digital signature survey, Rapid Response Team (RRT) involvement with BASS, MDSS/GLPSS and initiatives with the OECD guidance on Peer Review. We have just submitted two RRT initiatives on Draft Guidance for Industry and Staff titled "Applicability of Good Laboratory Practice in Premarket Device Submissions" and "Bioanalytical Method Validation."

These are great examples of your society engaging in our future regulatory settings. We are continuing to develop the new website, LMS, Basic GCP and Basic GLP online courses. Launch is targeted for the 4th Global QA Conference / 30th SQA Annual Meeting in April.

With the direction and leadership of the Specialty Section Chairs and the Program Committee, the final schedule for oral presentations at the 4th Global QA conference/ 30th SQA Annual Meeting is almost complete, and notifications have been sent to authors. Also, don't miss the announcement of the special "show night" that will replace our special event at the 4th Global QA Conference/ 30th SQA Annual Meeting in Las Vegas. You will be able

continued...

to go to a show Wednesday night with fellow SQAers. You'll have five shows to choose from.

It is with great pleasure and honor that I introduce you to our new SQA President, leader and colleague Greg Furrow. Greg worked for the University of Maryland and the USDA before joining Eli Lilly and Company as an analytical chemist. While at Lilly, he held positions in Analytical Development Research, Parenteral Cephalosporin Manufacturing Administration, Quality Control and Analytical Laboratory Management, Human Resources and Quality Assurance Management. He was at Lilly for 21 years before joining Charles River where he was Sr. Director of Regulatory Affairs and Compliance for 5 years. In 2011, Greg joined the WIL Research Company where he is Vice President of Quality and Regulatory Compliance. Greg has degrees in Chemistry and Analytical Chemistry from the University of Maryland and is currently Vice President of SQA, SQA Regulatory Communications Coordinator and SQA's EPA representative on the OECD GLP discussion group. I know Greg will lead us to the next level and do it without missing a "beat"….Go Deviations!!!

As I reflect on our accomplishments in 2013, what I am most proud of is the participation and involvement from everyone in our society. What I wanted to see was action from our membership, and the review of the year shows that you exceeded my expectations. I want to thank and applaud the effort this year by the members who stepped up and took on leadership roles. This was critical to our success in 2013. It has built a strong foundation for 2014. As our regulatory environment continues to evolve, we are positioning the society as one of the most powerful resources and places for young professionals in regulatory compliance.

Mark your calendar and plan to join us as we are "taking it to the next level" at the 4th Global QA Conference / 30th SQA Annual Meeting 2014!!!

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www.instem.com

Seventh Wave Laboratories
www.7thwavelabs.com

West Coast Quality Training Institute/ Pacific Rim Consulting
www.pacrimqa.com

Join this list of SQA supporters in 2014!

Annual Meeting supporters help underwrite some of the meeting expenses in exchange for recognition in the Annual Meeting program book, on signage at the meeting, in SQA Newsletters and on the Annual Meeting website. Diamond, Titanium, Platinum, Gold, Silver and Bronze Sponsor contribution levels are available. The minimum contribution for sponsors is $500.00.

A Note from SQA Headquarters

As 2013 comes to a close, we'd like to take a moment to thank the wonderful SQA members that make this organization great. We love working with you throughout the year and seeing the hard work you put into SQA programs to make them a success. We accomplished so much in 2013 and we are bursting with excitement for what is to come (see below!). The 4th Global QA Conference and 30th SQA Annual Meeting is a milestone conference, and we just can't wait to celebrate with you all in Las Vegas! Until then..

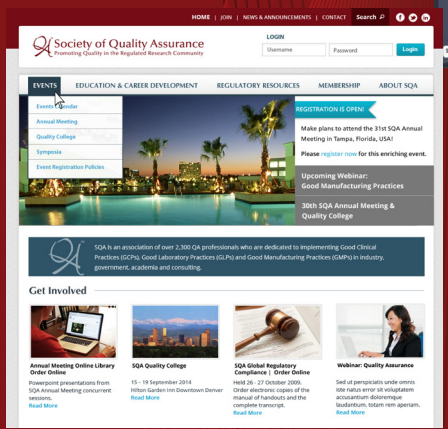
Happy Holidays

and "Cheers" to an exciting new year!

New in 2014

SQA is launching a new online learning program!

Take our Basic GCP and GLP two-day training courses from your office or home on your own time.



SQA will also debut a new look for its website this year.

Members benefit from reduced rates for online training and many other professional development opportunities.

www.sqa.org

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Regulatory Hot Topics! Hot Links!

REGULATORY REVIEW

US ENVIRONMENTAL PROTECTION AGENCY

EPA Announces New Standards for Antimicrobial Efficacy Testing
http://www.epa.gov/oppfead1/cb/csb_page/updates/2013/ae-testing.html

US FOOD AND DRUG ADMINISTRATION

DRAFT GUIDANCE -Guidance for Industry Bioequivalence Studies with Pharmacokinetic Endpoints for Drugs Submitted Under an ANDA
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM377465.pdf

DRAFT GUIDANCE -Guidance for Industry ANDA Submissions —Refuse-to-Receive Standards
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM370352.pdf

DRAFT GUIDANCE -Interim Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM377050.pdf

DRAFT GUIDANCE -Procedural Registration for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM377051.pdf

DRAFT GUIDANCE -Procedural Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM377052.pdf

EUROPEAN MEDICINES AGENCY

European Medicines Agency and FDA announce launch of generic medicines application inspections initiative
Collaborative effort builds upon 2009 Good Clinical Practices Initiative. The European Medicines Agency (EMA) and the United States Food and Drug Administration (FDA) today announced the launch of a joint initiative to share information on inspections of bioequivalence studies submitted to the EMA, the FDA and/or to the regulatory authorities in some EU Member States in support of marketing-authorisation applications for generic medicines. The joint initiative also introduces a mechanism to conduct joint inspections of facilities where these bioequivalence studies are conducted.
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2013/12/news_detail_001996.jsp&mid=WC0b01ac058004d5c1

Regulatory Hot Topics! Hot Links! continued

Statements of non-compliance with GMP now publicly available in Eudra GMDP
The European Medicines Agency (EMA) has launched a new version of the Eudra GMDP database which includes, among other changes, the publication of statements of non-compliance with good-manufacturing-practice (GMP).
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2013/12/news_detail_001994.jsp&mid=WC0b01ac058004d5c1

VICH GL42: Pharmacovigilance: data elements for submission of adverse event reports (AERs) UPDATED
http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/10/WC500005060.pdf

VICH GL30 on pharmacovigilance of veterinary medicinal products: controlled list of terms UPDATED
http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/10/WC500005066.pdf

VICH GL35: Pharmacovigilance: electronic standards for transfer of data UPDATED
http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2013/03/WC500140353.pdf

Draft VICH GL52 on Bioequivalence: blood level bioequivalence study
http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2013/12/WC500158372.pdf

Draft Recommendation on pharmacovigilance surveillance and signal detection of veterinary medicinal products
http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2013/12/WC500158371.pdf

Presubmission guidance: questions 21 to 30 UPDATED
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/q_and_a/q_and_a_detail_000020.jsp&mid=WC0b01ac0580022713

Quality by design UPDATED
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000162.jsp&mid=WC0b01ac058076ed73

Committee News

4th GQAC: Program Committee Update

JoAnn Boyd and Diane Clements
Members, Program Committee

The Program Committee is making the final plans for the 4th Global QA Conference and 30th SQA Annual Meeting. We'd like to remind you that now is the time to register early and save over $100 on full conference registraiton rates! Early rates end 14 March 2014, so be sure to make your travel plans soon!

The conference will be held at the Cosmopolitan of Las Vegas and a special SQA room rate is secured for conference attendees. Please visit **www.4thGQAC.org** for reservation and travel details.

The Program Committee members have been expediting the planning and are completing the program and abstract selections for the meeting. With 6 concurrent tracks, oral presentations, panel discussions, round-table sessions, and posters will promote valuable opportunities for information exchange. The final day will be mostly devoted to a joint International U.S. Regulatory Outlook and a Q & A session.

We would like to thank everyone who has submitted an abstract, and those Specialty Section members who have offered to review them. Final acceptance and placement will be based on scoring and "hot topic" status. All abstract authors have been notified. The program will be available in January.

The committee is reviewing potential tours and shows for our group while in Vegas. Stay tuned to the conference website. Details will be announced soon!

New Years Eve on the Las Vegas Strip

The Quality College includes courses on Sunday, Monday and Friday during the conference.

Also, watch for upcoming emails regarding volunteers. Volunteers are needed for packing the attendee bags, manning the registration desk, serving as session chairs, and badge checking at points during the meeting. Please consider volunteering some of your time and talent - we need it!

The committee promises another exciting conference that will prove educational and professionally enlightening. We can't wait to see you in Vegas!

Visit www.4thGQAC.org for updates!

Meet the Historical Committee!

Society of Quality Assurance Historical Committee

The SQA Historical Committee started as an effort from two SQA members, **Barry Benson** and **Patricia O'Brien Pomerleau, RQAP-GLP**, who wanted to be sure that the progress of the society was documented and our publications and photos preserved over the years. Obviously, our methods have evolved as the world went digital, but our mission remains the same! The Historical Committee continues to preserve SQA's legacy, and we'd like you to join us! We need photographers and members to review the historical records for archival. If interested, please contact sqa@sqa.org for details!

SQA Photo Contest

One of our favorite activities each year is offering a photo contest in conjunction with the SQA Annual Meeting. This is something the committee had done in the past and decided to reinstate in 2012 and have continued since.

Submit your favorite shot from this year, and our photog expert judges will examine all submissions and award great prizes like this digital photo frame!

How to Enter

Submit an entry form and your electronic photo files to our SQA HQ liaison, Erin Irtenkauf at erin.irtenkauf@sqa.org.

The following categories will be used for judging and awarding prizes.

Nature & Landscapes
Elements of Design
Travel and Place
Flowers
Sports/Action

The contest is open to all SQA members, regardless of their photographic skill level. It's a fun way to share part of yourself with your QA colleagues.

Visit the Historical Committee page for all the details!

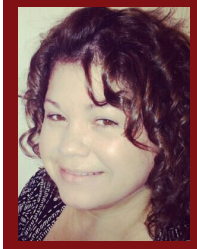
Meet the 2014 Historical Committee

2014 Committee Chair
Ernest S. Pile
Sr. GCP Auditor
Teva Pharmaceuticals

2014 Past-Chair
John Shafer
Quality and Compliance
Zoetis

Moira Bandoli, RQAP-GLP
GLP Compliance Auditor
mjb consulting, llc

JoAnn Boyd
QA Manager
Southwest Research Institute



Sherry Garrett
QA Auditor
Zoetis

Founding Member
Patricia O'Brien Pomerleau MS, RQAP-GLP
Consultant

Other members, not pictured are Hugh Hauser (Board Liasion), Alenda Branch, Anthony Brewer, Wanda Riggs, and V. Amalan Stanley, RQAP-GLP.

MRDC SQA Member Spotlight

The Membership Retention and Development Committee (MRDC) will showcase the diversity of our membership by highlighting an SQA member in each issue of Quality Matters.

Q & A with SQA Member, Carol Lee...

How long have you been a member of SQA?
A long, long time; since 1991!

What brought you to SQA?
My career took me from a marine scientist to managing aquatic toxicology studies to agrichemical studies, where I was a QA professional working on GLP studies 100%. SQA became an invaluable resource in my GLP training.

Tell us about your QA profession/involvement:
I have served on several committees and electoral positions over the years. Currently, I am a member of the GLPSS and the RFC committees, and am the EPA liaison for the SQA. Recently we have formed the EPA GLP subcommittee, which I agreed to chair.

What is a recent or favorite SQA activity?
My main focus will be working with the newly formed EPA GLP subcommittee. Our main goal is to provide an avenue that enables SQA members who have a professional interest in this area to delve into EPA and international regulatory matters in more depth and report activities back to the GLP Specialty Section. Our first teleconference was this past October, and we have already identified several new initiatives, including:

- Hosting a Webinar with Frances Liem, Office of Enforcement and Compliance Assurance, February 2014
- Presenting a Poster at the 2014 Annual Meeting introducing the newly formed subcommittee
- Developing a web-based training program on Auditing Field Studies
- Liaise with and develop synergies with other organizations interested in EPA GLPs

What has SQA done for you?
You are never too old or too experienced to learn something new. Training, via classes, webinars, or the annual meetings, has been most important to me.

What is your favorite quote?
"The best laid plans of mice and men often go astray." J. Steinbeck, taken from R. Burns, To a Mouse.

Specialty Section News

How Time Has Flown

Cathy Stevens-Hernandez
Clinical Specialty Section Chair

I can't believe that the year is nearly over. It seems that while so many things were accomplished in the Clinical Specialty Section this year that there are so many more that need to be done. That is why I am pleased that even though I am stepping down as CSS Chair at the end of the year, CSS will be in the capable hands of Jenny O'Brien for 2014.

In 2013 we added new members, re-instated monthly teleconferences, and wrote news articles. We added to the CSS Library and discussed on the listserv many important aspects of clinical research. We wrote GCP test questions and abstracts for the 2014 Global SQA meeting. We created slides and explored GCP and PV topics in webinars and teleconferences with CSS members. Here's an example of some of the topics we have explored recently.

Month	Discussion Topic	Discussion Leader
September	PV Modules: What are They? Why are they important for the USA?	Vaska Tone
October	FDA Guidance for Industry: Electronic Source Data in Clinical Investigations	Lisa Olson
November	E-source: Open Discussion	Lisa Olson
December	FDA's new Refuse to Accept Policy for 510(k)s	Glenda Guest

I hope that in the future CSS technical experts will become more and more excited about sharing their personal knowledge with others. We have many GLP experts who are eager to learn cross-GXP concepts. If you are a GCP expert, I hope that you will consider volunteering your time. Get involved. Pay it forward. Become a member of CSS and share your knowledge in teleconferences and newsletter articles, abstracts and listserv ideas with others. Then, as Robert Frost would say, once you have taken that path it will make all of the difference.

A big thank you to all who have volunteered their time in 2013 to make CSS a better... no, one of the best specialty sections! We became a tighter-knit group and one that is well founded to carry on into the future.

Beyond Compliance Specialty Section Update

JoAnn Boyd
Past Chair, BCSS

Cheryl McCarthy CQA, CBA
Chair, BCSS

The Beyond Compliance Specialty Section (BCSS) continues to be a strong presence in the Society Quality Assurance Annual Meetings by providing Hot Topic presentations and successful training through the Quality College. Committee members continue to update a 3-year planning document that encourages and supports active membership in BCSS. The programs within the document provide the combined knowledge of BCSS quality professionals in sharing their expertise.

The BCSS committee members provide quality tools for improving processes to the quality professional such as process mapping, six-sigma tools, root cause analysis, CAPA programs, pareto charts, Round Table Discussions, and many others. Be sure to attend the BCSS meeting at the **4th Global QA Conference & 30th SQA Annual Meeting**, April 6-11 2014 if you are interested in being a part of this mentoring and educational experience.

Meet specialty section members and enjoy enlightening events provided by BCSS at the confernece. A number of BCSS members will be giving presentations that will prove very informative and beneficial.

The Beyond Compliance Specialty Section of the SQA website provides the current BCSS poster, current activities, the Salary Survey, Hot Topics for BCSS, and a number of presentations, papers, newsletter articles, and activities provided by the BCSS members.

Monthly teleconferences are the first Wednesday of each month at 3:00 PM ET. If you are interested in joining the Beyond Compliance Specialty Section, please email Cheryl McCarthy, Chair at cmccarthy@eclinicalsol.com.

Studying Abroad, Not Just for College Students!

Sandy Hancock, MS, RQAP-GLP
Member, University Specialty Section

While visiting colleges with my daughter during her senior high school year, I have noticed that many universities highlight their programs for students to study abroad. As preparations are underway for the 4th Global QA Conference and the 30th SQA Annual Meeting, I am excited to share that members of the University Specialty Section (USS) have engaged in their own version of study abroad.

In 2012, **Dr. Carmen Navarro** from the University of Barcelona visited two universities in the US that have established quality assurance units. Dr. Navarro was hosted by USS member, **Marilyn Marshall, RQAP-GLP** at the University of Arizona and hosted by USS member, **Rebecca Davies, PhD**, at the University of Minnesota. During her visits, Dr. Navarro witnessed quality assurance systems in action as evidenced by the University of Arizona in-house GLP laboratory qualification program developed by Ms. Marshall and the Quality Central Program directed by Dr. Davies at the University of Minnesota College of Veterinary Medicine. Dr. Navarro reciprocated the international invitation and, during 2013, both Ms. Marshall and Dr. Davies visited Spain for a first-hand look at the robust quality assurance program implemented to assure the integrity and accuracy of data produced by core facilities and research groups at the University of Barcelona.

In December 2013, USS member **Frances Richmond, BNSc, MSc, PhD**, hosted a visit for **John-Moses Uwanduoma Maduabuchi, BMLS, BMMS, MSc**, at the University of Southern California International Center for Regulatory Science. Dr. Maduabuchi visited the US on behalf of the Society of Quality Assurance in Nigeria and gathered information to support the new Regulatory Science programs currently under development at the University of Nigeria Nsukka. According to Dr. Richmond, this type of exchange "gives us the chance to share experiences and to identify many common concerns, even when our home environments seem superficially rather different."

These SQA study abroad activities have provided several of our USS members with the opportunity to exchange strategies for meeting the challenges that arise when incorporating quality standards into academic research. Additionally this allows participants to also gather resources to strengthen the quality initiatives and programs at their individual institutions. A final benefit is the networking that occurs as we interact with quality professionals from around the world!

If you are interested in hearing more about these stories, visit with our USS members at the 4th Global QA Conference and the 30th SQA Annual Meeting in Las Vegas. Or join the USS and attend our monthly teleconferences! The USS invites any SQA member who is interested in quality in research at academic institutions to join our specialty section. Our membership reaches across all boundaries to include those from industry, academia, the US and beyond! If you are interested in further information about the USS, contact **Dr. Rebecca Davies** (Co-Chair), **Anna-Maria Escherich** (Co-Chair), **Vicki Crutchfield, RQAP-GLP** (Vice-Chair) or **Karen Toulouse, RQAP-GCP** (Secretary).

New GLPSS Subcommittee formed: EPA GLP Subcommittee

Carol Lee
Member, Good Laboratory Practices Specialty Section

The GLP Specialty Section recently formed an EPA Subcommittee to better address specific topics related to the Agrochemical industry and other industries regulated by the EPA. The primary goal is to provide an avenue that enables SQA members who have a professional interest in this area to delve into EPA and international regulatory matters in more depth and report activities back to the GLP Specialty Section.

The subcommittee is over 50 members and growing! The first teleconference was held October, 2013. The EPA GLP Subcommittee members have identified and are working towards implementing several new initiatives, including:

- Host an SQA Webinar with **Frances Liem**, Office of Enforcement and Compliance Assurance, February 2014
- Present a Poster at the 2014 Annual Meeting introducing the newly formed Subcommittee
- Design and hold several webinars on subjects focusing on EPA-regulated testing. The goal is to hold two or more webinars per year. Topics will include an overview of the EPA GLP regulated field testing environment (targeting May 2014) with future webinars on topics such as how to audit specific types of field based testing (Magnitude of the Residue, Environmental fate, Radiolabeled Metabolism/Confined Rotational, Worker Exposure, Aquatic/Field Dissipation, etc.). Topics such as monitoring GMO studies, auditing analytical chemistry/metabolism data of EPA studies, and others are also being vetted for inclusion into future webinars.
- Develop a web-based training program on Auditing Field Studies
- Liaise with and develop synergies with other organizations interested in EPA GLPs

Teleconferences are held on the third Tuesday of each month at 11 AM ET. The subcommittee is currently seeking interested members to build a strong and active group. If you are interested in joining this new subcommittee, please contact **Carol Lee** at carol.lee@jrfamerica.com or send your request to SQA Headquarters at sqa@sqa.org.

Society of Toxicologic Pathology 33rd Annual Symposium

June 22–26, 2014
Washington, DC

TRANSLATIONAL PATHOLOGY: Relevance of Toxicologic Pathology to Human Health

To register for the meeting and learn more about the program, continuing education courses and special events, visit www.toxpath.org.

Toxicologic pathologists work in diverse settings studying changes elicited by pharmacological, chemical, and environmental agents, and factors that modify these responses. This work involves the integration of pathology data into hazard identification, risk assessment, and risk communication frameworks that guide safety decisions for potentially toxic substances. A central part of this process is the translation of pathologic effects in animal models to address specific issues in public health.

This symposium will focus on translational science and the relevance of toxicologic pathology to human health. Topics will include the predictive value of nonclinical models and how animal model and human endpoints inform each other. Progress in the development of new nonclinical animal models and other types of models will be discussed, highlighting areas where models are highly predictive of human endpoints and areas where alternative models are needed. Emerging technologies which have the potential to improve translational capabilities will also be presented, with an emphasis on advancements that will impact regulatory decision making in coming years. As the field of epigenetics is rapidly advancing, the role and utility of epigenetic endpoints in toxicologic pathology and their relevance to human health will be addressed. Environmental toxicologic pathology plays a critical role in understanding health impacts of environmental exposures; therefore, how pathology outcomes inform human health assessments and regulatory decisions will be discussed. Finally, as the incidence of comorbidities in the human population increases, there is a greater need to develop translational models that provide useful information on human populations with comorbidities; the challenges of developing such relevant animal models will be addressed.

SQA Quality College Courses

Please join the SQA Education Committee and Regulatory Forum in Las Vegas, Sunday-Monday, 6-7 April 2014 and Friday, 11 April 2014, for Quality College courses held in conjunction with the 4th Global QA Conference. Visit www.4thGQAC.org for details.

1. Basic Training: Good Laboratory Practice
2. Good Clinical Practice: The Basics
3. Basic Concepts in Computer Validation
4. Developing a GLP-Compliant Program in a University Setting
5. Managing GLP Multisite Studies in Accordance with OECD Monograph No. 13
6. Animal Health: The Basics and Beyond
7. Pharmacovigilance Audits
8. QA Consulting 101
9. SQA Leadership Development
10. Archiving 201: Beyond a GLP-Compliant Archiving Function
11. Electronic Data Capture and Animal Health
12. The FDA Is Coming to Your Veterinary Clinical Site: Don't Panic, Prepare!
13. Problem Definition Through CAPA Effectiveness: Across GxPs
14. New Perspectives in QA - Tools, Techniques and Strategies for Enhancing Effectiveness and Enjoyment
15. Current Topics in Good Laboratory Practice
16. Good Clinical Practice: Beyond the Basics
17. Advanced Topics Related to Medical Device Studies
18. Hosting Client Audits in the GxP Environment
19. Good Practices: Understanding the GxP Regulations Using a Quality System Approach
20. QA Professional Fundamentals 101

SQA Welcomes New Members

SQA welcomes the following members who have joined the Society from 5 September 2013 through 2 December 2013:

New Affiliate Members

Alexandra Konstantinova	OCT Rus
Amy Lara	Pacific Pharmaceutical Services
Beth Malloy	Genentech Inc
Bill Hackett	Stellar Industries
Bryony Borneo	The EMMES Corporation
Christi Bollinger	Xenometrics LLC
Christopher Webster	Novartis Pharma AG
Christy Milner	Samumed
Clarice Bumagat	BioMarin Pharmaceutical Inc
Dennis Ionata, RPh	Theradex
Diane McAlinn	Custom Medical Specialties/Custom Assemblies Inc
Doris Davis	Alethia Clinical Research
Douglas Avery II, MBA	The Clorox Company
Frances Williamson	Ventana Medical Systems
Guergana Gueorguieva	Genentech
Heather Mitchell Groves, MIS	Quintiles
Jennifer Sorgen	Genentech Inc - PDQA
Jodi Mccomb	QACV Consulting
Jody Goodman Blumberg	Palm Beach CRO
John Harris	Astellas
Julie Rousseau	inVentiv Health Clinique
Karl Tradewell	Sharpstream Life Sciences
Keith Huie	Alexza Pharmaceuticals Inc
Kimberley Mack	ARCADIS - US
Kimberly Gaston	Monsanto Company
Linda Johnson	Waterborne Environmental inc
Lisa Dillon	Bristol-Myers Squibb
Lisa Dodson	Synchrony Labs
Lisa MJ Jones	RD Jones & Associates
Meaghan Mitchell	Critical Path Services
Michelle Lee	Genentech Inc
Nguyen Tran	Instem
Nicole Ordway	Bristol-Myers Squibb
Nora Rietmann	Daussing and Associates
Rochelle Tan	Pacific BioLabs
Sandra Sueoka Chen	InClin Inc
Sandy Cascone	CRO
Sarah Helms	INC Research
Savithree Chetty-Tulsee, CCRA	SCT Consulting
Scott Chadwick	Pacific Pharmaceutical Services
Sherry Sigelman	PAREXEL International
Talitha McMurtry, RQAP-GLP	GLP QA LLC
Terry Schwanz	Computype
Tierra Mayo	AIBio Tech
Tyson Mew	Ofni Systems
W Thomas Koch	Novartis
Wendy Ng, RQAP-GLP	BRI Biopharmaceutical Research
Yu W En Ou-Yang	National Taiwan University Hospital (NTUH)

New Active Members

Jacqueline Potter	Pfizer Inc
Lynn Ow Chek Ing, RQAP-GLP	Gleneagles CRC Pte Ltd
Miguel Zamora, MS, MIB	Novartis Pharmaceuticals
Monica Logan	BioAgilytix
Sandra Mills Williams, RQAP-GLP	RTI International

New Outreach Members

Vaibhav Choudhary	Fresenius Kabi Oncology Ltd - INDIA
Md Islam	Shafi Consultancy Limited - BANGLADESH
Webby M.Si	Mandiangin Freshwater Aquaculture Dvlpt Ctr (MFADC) - INDONESIA
Vikas Kumar	Fresenius Kabi Oncology Ltd - INDIA
Chi Napoleon Forpah, MSc	Watershed Task Group - CAMEROON
Manish Kumar	Ranbaxy Laboratories Ltd - INDIA
Ritesh Kumar	Dr. Reddy's Laboratories Ltd - INDIA
Adebisi Ayobami Nurudeen	University College Hospital Ibadan - NIGERIA

Reclassification from Affiliate to Active Members

Barbara Munch	GlaxoSmithKline
Danielle Ricard	Research Institute of the McGill University Health Center
Evelyn Coleman	Stiefel, a GSK Company
Kathryn Larimer, RQAP-GLP	Charles River Laboratories

SQA Calendar of Events

6 -11 April 2014

4th Global QA Conference
30th SQA Annual Meeting
Las Vegas, Nevada, USA

12 -17 April 2015

31st SQA Annual Meeting
Tampa Marriott Waterside
Tampa, Florida, USA

3-8 April 2016

32nd SQA Annual Meeting
Gaylord Texan Resort
Grapevine, TX, USA

Contact sqa@sqa.org for details.