American Society for Quality (www.asq.org) – Washington D.C. and Maryland Metro, Section 509 (www.asq509.org)

Biomed/Biotech Special Interest Group Meeting

"Good Clinical Practice (GCP) Concepts for Quality Clinical Trials"

Presented by

Jan H. Pierre, MPH

Principal Consulting
Quintiles Consulting

and

"Quality Assurance in Disaster Recovery"

Presented by

Cynthia Smith, RQAP-GLP

Senior Quality Assurance Auditor
Bridge Laboratories, Inc.

October 8, 2009 (Thursday) Evening

6:00 PM – Networking and Pizza and soft drink with a door prize

6:15 - 9:10 PM – Program

9:10 – 9:15 PM – Door-prize drawing and networking

Open and free to the public

Location:

Kelly's Deli Conference Center, 7519 Standish Place, Rockville, MD 20855

Driving directions:

From **I-270** (N or S bound): Take Exit 9A and exit from the first right exit.
Turn left (east) onto Shady Grove Dr.
Turn right (south) onto Rockville Pike (**Route 355**).
Turn left (east) onto East Gude Dr.
Turn left (north) immediately onto Crabb's Branch Dr.
Turn left (west) immediately onto Standish Place.
(The first building on your right side is 7519 Standish Place; open parking)

The conference room is on the first floor with its entrance opposite to the left side of building main entrance.

For headcount purpose, please register by *Thursday noon, October 8, 2009.*

Registration Website: http://www.asq509.org/ht/d/DoSurvey/i/35817

For registration problems or further information contact **Dr. George Chang**, Co-Chair of Biomed/Biotech SIG, at gchang2008@yahoo.com or call **240-793-8425**.

Presentation Summaries:

Good Clinical Practice (GCP) Concept for Quality Clinical Trials - This presentation will provide you with a basic overview of today's clinical trial landscape and the application of GCP. We will examine quality concepts in clinical research, specifically, what does FDA look for when examining the quality and integrity of clinical research studies. Further, could you detect or possibly prevent fraud from happening to you. In addition, you will walk away appreciating the work that biomedical researchers do and the importance of clinical trials.

Quality Assurance in Disaster Recovery - Disasters are happening more frequently and Recovery is taking on a different perspective. This presentation will provide a general introduction to the role of Quality Assurance in Disaster Recovery preparedness. This presentation will address some of the basic requirements when preparing for a disaster as well as identifying areas of concern in a GLP regulated environment. Are you prepared?

Speakers' Bios:

Jan Holladay Pierre, MPH, currently serves as Principal Consultant with Quintiles Consultants**.** Ms. Pierre serves as a project resource and the team leader for various bioresearch monitoring (BIMO) projects. Ms. Pierre has more than twelve years of experience working in the clinical research arena, with a unique combination of expertise in inspections, regulatory compliance, auditing, quality assurance, and training. She was an FDA Investigator with over six years of experience auditing/inspecting sponsors, IRBs, clinical investigators, manufacturers, and non-clinical laboratories. Ms. Pierre was also a member of the Foreign Inspection Cadre while at FDA. She has experience as a Site Compliance Director overseeing clinical trial operations; a CRO QA Director responsible for developing SOPs and conducting internal and external audits; and a Regulatory Compliance Director responsible for ensuring clinical trials meet regulatory compliance. She also served as faculty with RxTi, a clinical research training organization. Ms. Pierre holds an M.P.H. in International Health Policy.

Cynthia L. Smith, RQAP-GLP (**Cynthia.Smith@bioreliance.com**) is a Sr. Quality Assurance Auditor for Bridge Laboratories, Gaithersburg, MD. She has over 20 years experience working in the field of GLPs. Prior to joining Bridge Laboratories, she had almost 10 years in Quality Assurance at Covance Laboratories, Vienna, VA, and has held various positions between the two which included:

- GLP Quality Assurance
- Training Specialist
- Computer Validation Auditor
- Toxicology Technician

Cynthia has been active in both the National Capital Area Regional Society of Quality Assurance (NCARSQA) and the Society of Quality Assurance (SQA) throughout her career in Quality Assurance, and currently holds a position on the Board of Directors for NCARSQA. She has attended and conducted numerous training programs on a variety of topics including GxPs, Computer Validation & Electronic Signatures, and Multi-Site studies. Cynthia holds a Bachelor of Science degree in Animal Science from the University of Maryland.