

MARSQA MONITOR

Serving the Mid-Atlantic Region Society of Quality Assurance

Volume 8, Issue 2

June 2003

President's Message

Frank Bosley

Greetings fellow members!

It looks like spring is finally going to get underway, just in time for the summer equinox! Go figure. Seriously, despite the protracted winter we have all had to endure, the MARSQA community has kept itself very busy and the Program Committee has put together a great schedule for 2003. We have already run a very well received GLP Basics workshop as well as the April Meeting with over 100 members in attendance! At summer's end, we have several more workshops with a commitment from Dr. Viswanathan (FDA) to speak at our Analytical Chemistry workshop, as well as the CVC offering an Advanced Computer Validation workshop! Be sure to check out the website for updates on the agendas for these workshops.

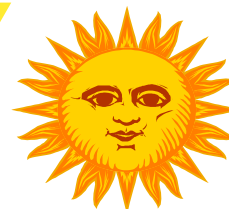
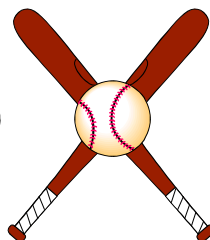
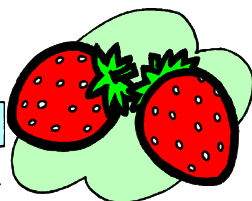
In addition to the workshop activities, we are teaming up with the North Capital Chapter (NCARSQA) as co-sponsors of the SQA Annual Meeting to be held in the Washington, D.C. area this October. Our chapters are providing the entertainment at the opening reception, so be sure to mark your calendars and come down for the party and support your chapter! More details on the meeting will be added to the website as the agenda becomes finalized.

Our organization is very strong financially, as evidenced by the decision to offer our June Meeting at no cost to our membership. This Board takes the fiduciary duties it has been entrusted with very seriously and is constantly reviewing ways of generating a return to our membership. If there is any particular service you would like to see offered (workshop, meeting theme, etc.), please do not hesitate to contact someone on the Program Committee, or any other Board member. We are also currently researching different auditing firms. We want to have an independent financial audit of our books to make certain that our assets and liabilities are all properly qualified and accounted for.

As always, the only way that we can ensure our continued success is to have an engaged and involved membership. Whether you run for an office, want to serve as a committee chair, or help out as a registrar at a membership meeting, every bit of time you can commit makes this a better organization overall.

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MARSQA MISSION STATEMENT

It is the mission of MARSQA to

- Continually strive to advance the research quality assurance professions by providing the resources, programs, and training necessary for the professional development and recognition of its membership.
- Serve as a forum for the open discussion of the theoretical, practical, and ethical applications of the quality assurance profession.
- Foster a partnership between the quality assurance profession and the regulatory agencies that results in the attainment of mutually beneficial compliance.
- Support and advance the goals and mission of the Society of Quality Assurance.

Corporate Sponsors

MARSQA would like to thank our corporate sponsors for their generous support to our continuing mission:

Fort Dodge Animal Health

Become a Corporate Sponsor. Make a donation or sponsor a meeting and keep the mission alive. As a thank you, your company will be listed here in the MARSQA Monitor and on the MARSQA website. Please contact any member of the MARSQA Board of Directors for information.

MARSQA Board of Directors – 2003

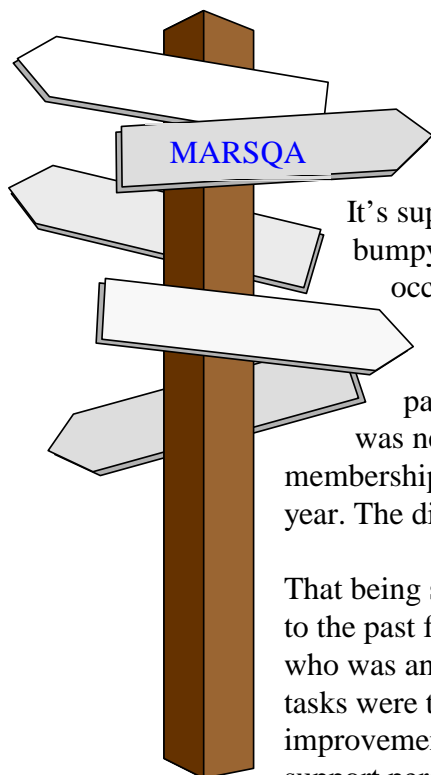
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Membership Committee Update

By: Jane Nelson



It's supposed to get easier, right? Membership renewal for 2003 has been a little bumpy to say the least! Rather than make excuses for the multiple scenarios that occurred during this membership drive, it's better to note where improvements can be made, implement them and move on. On the positive end, I was able to interact with more people than I would normally have the opportunity to in the past. While it's taking some time to complete the printed directory process, it was necessary to carry out some painstaking steps to ensure we served the membership fairly. I want to thank all of you for your patience and understanding this year. The directories should be appearing shortly!

That being said, it is necessary to understand what hindered the process this year relative to the past few years. One issue was the loss of our small business management company who was an integral partner in renewal/directory process. In lieu of this company, these tasks were taken up by MARSQA volunteers. A positive result was that process improvements were identified where MARSQA can reduce both the time and cost of support personnel. MARSQA has identified a new company, and the migration is currently in progress.

The biggest revelation was that we, as an organization, are not utilizing the website to its fullest potential. By sending out invoices requesting information that required manual input into the system was extremely costly in the end. Joanne Jackson personally input all people who paid by check that did not register online. That was a BIG job and I thank her for that contribution. All manual inputs had to be verified, as any QA auditor would point out, and were. Any payment discrepancies had to be reconciled which also proved to be quite time consuming. Next year it will be a requirement that all renewals, regardless of payment choice must be entered online.

Please note: Please review and submit any changes to your personal information on the invoice or on the Members-Only section of the website. All members will be included on the Online Membership Directory.

STUDENTS TAKE NOTE!!! There is a reduced membership rate of \$25 for full-time students who furnish proof of their full time status and a copy of their student ID.

WHAT'S NEW IN 2003... The Members-Only section of the MARSQA website has arrived! Members please take advantage of this website. Members have access to the Online Membership Directory, the latest edition of the MARSQA Monitor and the ability to update personal information. If you are a member and have not received a user name and password, please contact the webmaster on the MARSQA homepage. Coming soon... regulatory information updates, Committee updates, notes and presentations. Stay tuned....

Program Committee Update

By: Jane Pasquito

The April 9, 2003 membership meeting was another success! Over 100 people attended the meeting at the Cock and Bull in Lahaska, PA. Cathy Kryzanasuskas, Director on the SQA Board, started the meeting off with an SQA update. Presentations were given by Kevin Enad of Taylor Technology, Inc., “*Electronic Archiving Operations*”, Stacey Blackmer of GlaxoSmithKline, “*New Draft FDA Guidance on Part 11: Scope and Application*”, and Ken VanLuvanee rounded out the day with his presentation on “*21 CFR Part 11. Let’s Talk Basics*”. You can view the presentations on www.marsqa.org in the [Upcoming Events](#)

The Program committee is busy putting the final touches on the June 4, 2003 membership meeting, which will be held at the Ramada Inn, Somerset, NJ. We have three great speakers lined up. Roseann B. Termini, B.S., Ed.M., J.D., “*HEALTH LAW: Federal Regulations of Drugs, Biologics, Medical Devices, Foods and Dietary Supplements*”, Alan G. Minsk, Partner and Leader, Food and Drug Practice Team, Arnall Golden Gregory, LLP (Atlanta, GA) “*Preparation For and Response to Regulatory Audits: Avoiding Common Pitfalls*”, and Helen Fedoriw, RPh, Director, Regulatory Operations, Wyeth Consumer Healthcare “*Overview of HIPAA and Its Impact on Clinical Research*”. Additional information can be found on www.marsqa.org.

Please feel free to let us know if you have any suggestions for upcoming membership meetings. We would appreciate any input from the membership on potential speakers or topics that would be of interest to the membership. You may contact any member of the program committee with suggestions; Jane Nelson, Cathy Kryzanasuskas, Denise Wilson, Wanda Franklin Hunter, Patrick Dalton, Chirine Fiouzy, Sonya Gray, Amy Pawlak, Cynthia Kelsch and John Cihiy.

April Meeting Speaker Summaries

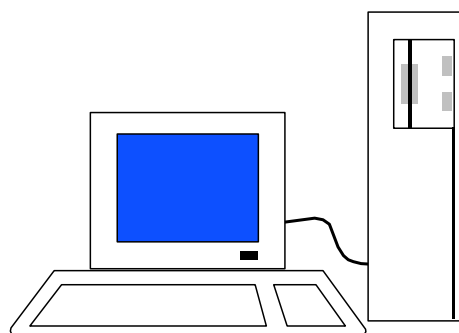
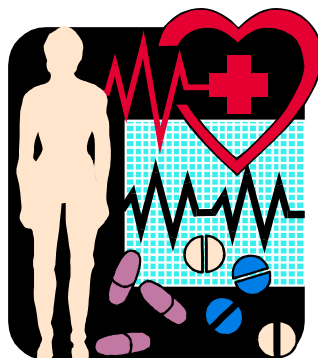
By: Jane Pasquito, Amy Pawlak, Sonya Gray

To view copies of all of the presentations from the April meeting, visit the MARSQA website at www.marsqa.org.

Ken VanLuvanee

21 CFR Part 11; OK, Let’s Talk Basics

Ken VanLuvanee, President, Apyx, Inc. was one of three speakers at the April 9, 2003 membership meeting. Apyx Inc. is a company that provides services such as Document Management, Regulatory Publishing and System Validation. Mr. VanLuvanee provided those in attendance with some insight on the requirements set forth in 21 CFR Part 11, Electronic Signatures and Electronic Records and presented the material in a unique “user friendly” manner. He presented definitions as written in the regulation and re-defined the definition in a few simple words. As a member of the audience watching Mr. VanLuvanee, I had the feeling that this regulation is not that hard to follow after all. He described how this regulation has changed or will change certain aspects of our lives as individuals in the pharmaceutical industry, as well as how the new Draft Guidance for Industry on Part 11 (February 2003) might provide some relief. www.marsqa.org. The Draft Guidance can be obtained from <http://www.fda.gov/cder/guidance/5505dft.PDF>. Information on Apyx, Inc. can be found at www.apyxinc.com.



Kevin Enad
“Electronic Archiving Operations”

Kevin Enad, Network Manager of Taylor Technology, Inc. (TTI) started off the April 9th membership meeting. He gave an overview of the issues surrounding the archiving of electronic data from a CRO’s perspective and how TTI has set up their archive procedures. TTI is a bioanalytical CRO that generates analytical data for pharmaceutical industry clients. Some of the concerns an Archivist has regarding electronic data include the ability to capture any metadata associated with a file, support for multiple versions of a file, archiving all related files at the same time, the durability of the media the archives are stored on, hybrid systems, separation of client data, archiving databases that are constantly changing and the electronic records of the archive system itself.

TTI utilizes four types of archive procedures that are performed manually by a member of the IT staff: snapshot archiving, study archiving, software archiving and data archiving. The snapshot archiving procedure is performed on laboratory robotics and database files and takes all files from a system and records them onto a CDROM. This procedure does not separate the data in any way and relies on the existing file naming conventions and directories to distinguish one file from another. The study archiving procedure is used to archive all electronic files associated with a completed study including the reports (drafts & final), emails, supporting Excel spreadsheets, etc. These files are burned to a CD that is assigned to a specific client. Software archiving is performed on in-house developed software and scripts when they are finalized, validated and installed. Most software is burned to its own disk, whereas small scripts are combined onto one disk. The data archiving procedure is used to archive all of the data generated on the mass spectrometers. Once the laboratory staff has imported the data into the LIMS system, the data on the mass spectrometers is eligible for archive. All eligible data for a client are copied to their own WORM disk. Logs are kept of each archive session for retrieval.

Although there are some benefits to these types of manual archiving, a lot of manpower is needed to perform these procedures as well as to retrieve the archived files when needed. In a pilot program TTI validated the use of the Nugenesis Archive system to archive the data from 5 mass spectrometers in an automated fashion. The Nugenesis system consists of a Windows NT server with a CDROM jukebox and an Oracle database, which tracks the files that have been archived. The Nugenesis system archives files based on pre-determined rules at timed intervals and will capture user-specified metadata for the files being archived. Data can be retrieved via a web browser that allows for searching based on the file names or acquired metadata. Once data are archived to the system, the system is able to make multiple copies of the data as well as erase the data from the source system.

The Nugenesis pilot program has shown that automated archiving works for the data collected by the mass spectrometers and is an efficient replacement for TTI’s current procedures. In 2003, TTI will be expanding the role of Nugenesis to archive all of the mass spectrometer data and will explore how Nugenesis can replace the snapshot and study archiving procedures.

Stacey Blackmer
“New Draft FDA Guidance on Part 11: Scope and Application”

In 1991, pharmaceutical manufacturers wanted paperless record systems for GMP so they asked FDA to allow electronic signatures; thus, Part 11 was issued in 1997 as regulation. Although the FDA issued Part 11 based on industry requests, companies (food, cosmetic and pharmaceutical) pushed back on Part 11 implementation. Draft guidance documents were issued for comment beginning in August 2001. Comments received noted that the requirements of 21 CFR 210 and 211 did not carry the same weight for all regulated processes in the GMP environment. In addition, investigators were inconsistent in their interpretation and 483 issuance. Finally, the GMPs were out of date.

In August 2002, FDA announced an initiative to enhance GMPs that would 1) focus attention on high-risk areas, 2) ensure FDA does not impede innovation, and 3) maintain FDA consistency. In October 2002, the FDA announced that a policy statement would be issued in February 2003 on how this GMP enhancement initiative would affect Part 11. The guidance (which may not be implemented as currently written) was issued as a “Draft for Comment” on February 25, 2003. The FDA withdrew the previous draft Part 11 Guidances and Compliance Policy Guide but did not withdraw the Guidance Computerized Systems Used in Clinical Trials. The FDA acknowledged in this new draft guidance on Part 11 the concerns raised by Industry that 1) there is inappropriate interpretation of Part 11 by some FDA staff, 2) there is an unexpected significant increase in the cost of compliance and, 3) compliance restricts use of electronic technology and discourages innovation without providing significant public health benefit.

The intent of the new draft FDA guidance is to narrow interpretation of scope and exercise discretion over enforcement of Part 11 in certain areas (such as validation, audit trails, copies of records, retention of records and legacy systems) but will enforce compliance through the GxPs and will enforce the rest of Part 11. The proposed scope would make fewer records subject to Part 11 and several changes are proposed to implementation, definitions, signature manifestations, signature/record linking, general requirements, electronic signature components and controls and controls for identification codes/passwords.

You might ask, what’s next? The answer: maintain compliance with corporate policies, modify policies as necessary as new regulations are issued, stay current with industry initiatives, and keep talking amongst ourselves. Until the guidance is finalized, it’s business as usual.

Education Committee Update

By: Joanne Jackson

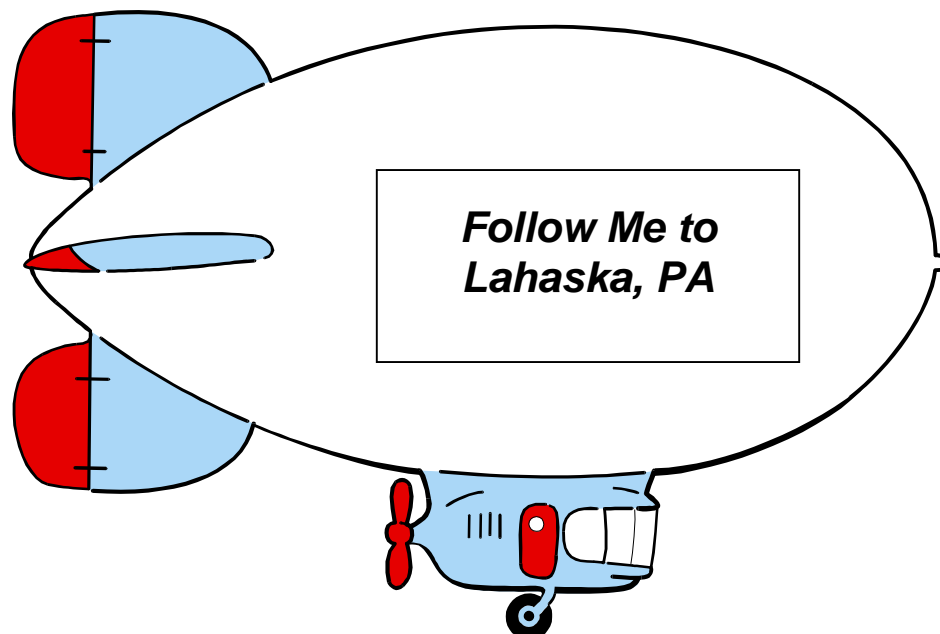
Once again, MARSQA is offering a number of workshops to its membership. The first of two GLP Basics workshops was offered May 8 & 9. While the number in attendance was slightly less than usual, the group was quite diverse and very interactive making the workshop a valuable experience for both the attendees and the presenters. MARSQA takes pride in offering quality training workshops at very reasonable prices. Please take advantage of the workshops that are scheduled for the remainder of the year.

2003 Workshop Calendar

Principles of Computer Validation
Analytical Chemistry for QA Professionals
Advanced Computer Validation
GLP Fundamentals

June 18 and 17, 2003
September 17 and 18, 2003
September 25 and 26, 2003
November 12 and 13, 2003

If you have any questions or if you are interested in becoming a presenter/facilitator at one of MARSQA's workshops, please contact: Joanne R. Jackson (908) 218-6660 or Lynda Olsen (908) 298-4478



MARSQA Computer Validation Committee

Summary of 20 February 2003

Held at ICON Clinical Research in North Wales, PA

Please join us for the Basic CVC Workshop, Principles of Computer Validation to be held June 16 and 17, 2003 in Lahaska, PA. Course Highlights include:

- ◆ Software Development Lifecycle Overview
- ◆ Planning/Conducting/Documenting the validation process
- ◆ Testing Phases and Associated outputs
- ◆ Overview of FDA 21 CFR Part 11 and HIPAA
- ◆ Warning Letters and 483 citations for computer validation
- ◆ Opportunity to develop validation documents for Lab Instruments and GCP Application systems

This Workshop has been filled every year so register today to reserve a spot!

Please join us for the much anticipated follow-up to the popular Basic CVC Workshop to be held September 25 and 26, 2003 in Lahaska, PA. The course will concentrate on two main topics:

- ◆ Vendor audits from preparation to reporting and follow-up
- ◆ The increasingly challenging area of Security

Please Note: Registration for both the Basic and Advanced courses will be available on the MARSQA website.

A. Technical Discussion

1. New FDA Draft Guidance for Industry (Part 11, Electronic Records; Electronic Signatures – Scope and Application, February 2003) was distributed and some implications were discussed. It was suggested that a document be generated by the CVC and distributed to the MARSQA community letting them know that we (the CVC) are aware of the guidance and will be following it and will give periodic updates as new information is available.
2. Retrospective Validation: Can this be used as a validation approach for new systems
3. Expected documentation for validation testing: pass/fail log, signed/dated print outs, error reports, other testing documentation
4. Software vs. Hardware, when to validate separately or together
5. The amount of validation necessary for software integral (built into) laboratory instrumentation
6. The “Risk-Based” approach to Part 11 compliance: Is this legitimized by the new Part 11 guidance? What are other companies doing?
7. Electronic signature/record links in hybrid systems
8. What is required in a SDS for: custom built computer systems, Commercial off the shelf (COTS), COTS with some customization, and configurable COTS?
9. HIPPA vs. Part 11 – a presentation was distributed on this topic.
10. What measures should be taken to ensure security and data integrity for standard medical equipment provided by the sponsor for a phase III trial?

The next CVC meeting will be held at Taylor Technology in Princeton on May 8, 2003.

For more information on the Computer Validation Committee (CVC) contact the MARSQA website at www.marsqa.org

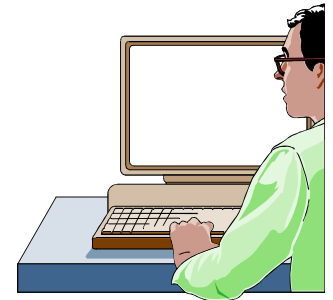
Webmaster's Corner

By: Frank Bosley

Just a quick update on some added features that are currently in development. A set of bulletin boards is currently undergoing beta testing. The plan is to offer several different community bulletin boards within the Members-Only section that are split up by discipline (GLP, GCP, cGMP) or by topic (Disaster Recovery, Part 11 Remediation, Inspection Readiness Hints). The initial beta board will be a General Regulatory Info board and hopefully we will gather enough information on how we want to split up the different boards. If you have ideas on how this topology should look, please drop a note to support@marsqa.org.

Our Career Center has really started to pick up. We got off to a relatively slow start in the beginning of the year, due in no small part to the lagging economy, but in the past month, more than ten additional job openings have been posted. If you, or someone you know, are looking for exciting opportunities within the quality assurance environment, be sure to visit our Career Center at <http://www.marsqa.org/career1.htm>.

As always, comments/criticisms/suggestions about the site are always welcome!



Treasurer's Report

By: Janet L. Emeigh

MARSQA continues to be financially strong. Our membership has been steadily increasing. By the end of last year, MARSQA recorded it's highest membership level of 358! As of the beginning of May of this year, we already have 285 registered members. The training courses also have provided a strong stream of revenue and the Career section on the website generates a year round source of income and provides the revenue to pay for the maintenance of the website.

As a result, we were able to offer the June meeting as a free meeting for MARSQA members and the Board of Directors is looking for other ways to give back to the MARSQA community. We of course have to be careful not to be reckless as it was not that long ago that MARSQA had to raise dues and membership meeting registration fees in order stay in the black. With sound fiscal management, we hope to continue to provide high quality programs and services to the membership without having to raise dues and fees for many years to come.

That said, below is a summary of the financial status as of June 2, 2003:

Account	Balance	Interest (YTD)
Commerce Bank	\$31,930.81	\$28.73
Willow Grove (Checking)	\$7,424.55	N/A
Willow Grove (Savings)	\$216.84	\$0.87
Citadel (2 CD's and Money Market)	\$56,960.71	\$477.39
Total Liabilities and Equities	\$96,532.91	\$506.99

ATTENTION ADVERTISERS:

The Mid-Atlantic Region Society of Quality Assurance is pleased to announce that advertisements will be available both in the Monitor, as well as on our website, www.marsqa.org. The fee structure has been discounted to better serve the advertisers, including consultants and corporate sponsor companies.

The fee structure will be as follows for the entire year (3 newsletters, website):

- Full page ad: members: \$75, non-members: \$150
- ½ page ad: members: \$50, non-members: \$100
- ¼ page ad: members: \$25, non-members: \$50

The fee structure for placing an advertisement on the website only will be \$25 per ad per year. You will have the ability to change you advertisement as necessary throughout the year for both the newsletter and the website. All fees for these new advertising plans will be billed at the beginning of the year.

The fee structure will remain unchanged for placing an advertisement in a single issue of the Monitor only:

- ½ page ad: members: \$25, non-members: \$50
- ¼ page ad: members: \$15, non-members: \$25
- 2" x 3 ½" ad: members: free, non-members: \$15

If you are interested in more information or would like to place an advertisement in the next issue of the newsletter or on the website or both, please contact Ms. Debra Sedor at 215-628-5474 or by e-mail at: dsedor@prius.jnj.com.

ADVERTISEMENTS

The following are for paid advertisements. The appearance of these ads in the MARSQA newsletter does not constitute an endorsement or a recommendation by MARSQA.

***Executive Search for the
Healthcare Industry***

HADLEY
Associates

Thomas M. Hadley, President

**147 Columbia Turnpike • Florham Park, NJ 07932
Tel. 973.377-9177 • Fax 973.377-9223**

**THE DEADLINE FOR SUBMISSION
OF ARTICLES AND
ADVERTISEMENTS FOR
PUBLICATION IN THE SEPTEMBER
2003 NEWSLETTER IS
August 1, 2003.**

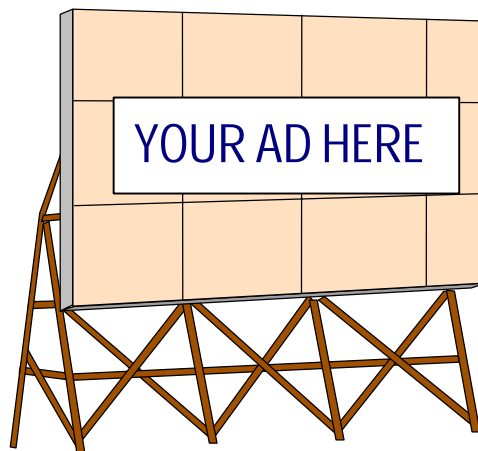
Quality Assurance Auditor

Taylor Technology, Inc., a premier contract laboratory providing mass spectrometric bioanalytical services to the Pharmaceutical Industry, has a position currently available for a Quality Assurance Auditor. This is an excellent opportunity to work within a high-performance QA Team using state-of-the-art technology, and to gain GLP/QA experience working with a range of pharmaceutical industry clients in a non-animal environment.

Preferred candidates will have a scientific background and at least 2 years of auditing experience (preferably GLP). The position will involve auditing all aspects of the company's operations including analytical studies, facilities and computer systems (including application development and testing).

Taylor Technology, Inc. offers a competitive benefits program with health, dental, vision and disability insurance, as well as 401K and profit-sharing programs. We are committed to training and employee development. Qualified candidates should send resume and salary requirements to:

Taylor Technology, Inc.
107 College Road East
Princeton, NJ 08540
FAX: 609-951-0080
Email: seekjob@taytech.com



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Computer System Validation Specialists

2003 Seminar Schedule

❖ Achieving & Maintaining 21 CFR Part 11 Compliance ❖

June 03 Princeton, NJ

Sep 22 Chicago, IL

Dec 02 Somerset, NJ

❖ Computer System Validation in FDA-Regulated Industries ❖

June 04-05 Princeton, NJ

Sep 23-24 Chicago, IL

Dec 03-04 Somerset, NJ

❖ Auditing Computer System Providers ❖

June 06 Princeton, NJ

Sep 25 Chicago, IL

Dec 05 Somerset, NJ

For additional information, contact us at:

Tel: 215.354.1720 Fax: 215.354.1725 E-mail: info@validassoc.com Web: www.validassoc.com



Schedule of Courses – June 2003

Bensalem, PA

Introduction to Process and Equipment Validation – June 4, 2003

- What major components go into the development of IQ/OQ/PQ protocols
- How to identify and document the critical elements of a validation summary report

“More than a Checklist”: Quality Auditor Training, 2-Day Seminar June 5, 6 2003

- How to develop a versatile strategy that is applicable to any type of audit
- How to implement effective auditing techniques during practical role playing exercises
- Auditing is an art, not merely the recitation of questions printed a generic checklist

Somerset, NJ

Computer System Validation, 4-Day Seminar June 16 – 19, 2003

- June 16, 2003 - How to apply a Risk Based Approach to Computer Systems Validation; How to develop a structured System Life-Cycle model for CSV
- June 17, 2003 - How to Write a Validation Plan; How to Write a System Requirements Specification; Design and Perform a Risk Analysis
- June 18, 2003 - How to Write a System Design Specification; How to Write an IQ/OQ/PQ
- June 19, 2003 - How to Execute Validation Test Protocols, Error Reporting; How to Write a Validation Summary Report; How to Write a System Retirement Plan and How to Create a System Management Plan

Certified 21 CFR Part 11 Manager, 4 Day Seminar June 24 – 27, 2003

- June 24, 2003 - Introduction to 21 CFR Part 11
- June 25, 2003 - Compliance and Remediation Strategies for 21 CFR Part 11
- June 26, 2003 - Validation of Computer Systems for 21 CFR Part 11
- June 27, 2003 - IT Infrastructure Issues and 21 CFR Part 11

For more information contact:

**Stelex University, Two Greenwood Square, Suite 310, 3331 Street Road, Bensalem, PA 19020
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