

MARSQA MONITOR

**MARSQA
MONITOR**
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MARSQA Membership Meeting Recap

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MARSQA Board of Directors and committee chairs (from left): Denise Botto, Raneen Henry, Kiet Luong, Megan Lawhead, Stacy Wilson, Tina Myers, Nancy Gravino, and Penny Jegede



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October 2015 MARSQA Meeting Recap: Computer System Validation Forum and GLP Forum

Two forums were held prior to the October membership meeting and were open to all meeting attendees. One forum focused on Computer System Validation and the other forum focused on Good Laboratory Practices.



GLP Forum participants discussed “Hot Topics” such as archiving of materials at the close of the study and the master schedule with respect to terminated studies.

October 2015 MARSQA Meeting Recap: Presentations



Above:

Santosh Tharkude, Sr. Compliance Specialist presented on: Digital Signatures in Regulatory Environment.

Santosh provided a great introduction on what digital signatures are, why they are popular, how they work in a regulated controlled environment, how to identify a fabricated digital signature, and how to create an official verifiable, digital signature with the right tools.

Below Right:

Dave Evans, Regulatory Compliance and Governance: Challenges of Cloud Service Providers.
 Dave discussed cloud service versus the regulated industry, which regulations would cover their use (21 CFR part 11 and part 820, EU GMP Annex 11) and whether data could be compromised. He also outlined the inspection readiness of cloud providers and their ability to match up to today's regulatory hurdles.



MARSQA Disclaimer:

Please note, during membership meetings, photography during the meeting may occur. If you do not wish your photograph to be included in upcoming MARSQA newsletters, please e-mail newsletter@marsqa.org

Food Safety: The FDA and You

Yesterday, I went to the grocery store and picked up a gallon of milk from the refrigerated case. I thought to myself, “How do I know this milk was stored in a sanitary environment and stored properly during transportation?” Each year, 48 million people (1/6 people) suffer from a foodborne illness; over 100,000 people are hospitalized and thousands die ([FDA, 2015](#)). In January of 2011, the FDA Food Safety Modernization Act (FSMA) was signed into law by the President. The goal of FSMA is to “shifting the focus of federal regulators from responding to contamination to preventing it ([FDA, 2015](#)).”

The five key elements of the FSMA are preventative controls, inspection and compliance, imported food safety, response, and enhanced partnerships between food safety agencies. Sanitary transportation of human and animal food is one area of focus in the FSMA.



In 2007, the Motor Carrier Division of the Michigan State Police reported 22 cases of illegal and unsafe food transport on Michigan highways during 2006 (Ref. 10). The report included numerous findings including raw poultry hanging from the roof inside the cargo area of a truck, with juices dripping onto open boxes of produce below. The food was being transported in an unrefrigerated truck with an internal temperature greater than 70°F ([FDA, 2010](#)).



Food safety and veterinary medicine agencies are working together to implement the Sanitary Food Transportation Act of 2005 (see “[Advance notice of proposed rulemaking](#)”) which provides directive on sanitary transportation practices ([FDA, 2015](#)).

Food Safety: The FDA and You

Modernization has also affected food safety with respect to Good Manufacturing Practices. Beginning in late 2002, a modernization working group was tasked with examining the GMPs to “determine whether the regulation was in need of modernization. Also, the group was specifically tasked to focus on risk-based preventive controls, i.e. those that would have the greatest impact on assuring food safety (FDA, 2014).” The working group concluded that due to changes both in food industry and food science supported review and revision of the GMPs. Areas for modernization included appropriate training and knowledge, food allergen plans for establishments with 8+ food allergens, environmental pathogen control program for processors of ready-to-eat foods, development and maintenance of sanitization procedures, require critical records be available to the FDA investigators. The committee seeks to obtain additional information specific to temperature relationships and food safety (FDA, 2014).

Check out the
FDA website for
more info!

Article References: [University of Penn, 2011](#) and [FDA](#)

The screenshot shows the FDA website's 'Food' section. At the top, the FDA logo and 'U.S. Food and Drug Administration' are displayed, along with the tagline 'Protecting and Promoting Your Health'. A search bar is visible on the right. Below the navigation menu, the 'Food' section is highlighted. A large banner for the 'Education Resource Library' features three images: 'Food Safety' (hands washing produce), 'Nutrition' (a hand holding a can of food), and 'Cosmetics' (a person applying lipstick). Below the banner, the text reads 'CFSAN's Education Resource Library' and 'The Library offers educational materials related to food safety, nutrition and cosmetics.' To the right, a 'Popular Topics' sidebar lists several items, including 'Proposed Changes to the Nutrition Facts Label', 'Draft Guidance for Industry: A Labeling Guide for Restaurants and Retail Establishments Selling Away-From-Home Foods - Part II', 'FSMA: Final Rule for Preventive Controls for Human Food', 'FDA Food Safety Modernization Act (FSMA)', and 'See More Popular Topics'.

Shifting Approaches to Auditing Software Vendors:

by Chris Wubbolt, QACV Consulting

The industry's current focus on data integrity is not surprising considering that several regulations, including the GLP regulation, originated out of data integrity and fraud issues. With the prevalence of computerized systems and automated systems used to collect regulatory data, what is surprising is that many QA professionals have not yet significantly changed their approaches to how they review data and audit systems and processes.



One example of this is how software vendors are audited.

When I first started auditing software vendors over 20 years ago, the vendors would bring out binders of SOPs and software development documentation (usually based on a waterfall system development life cycle (SDLC) methodology) to present during the audit. Software vendors sold systems and applications to sponsors and CROs that were installed at sponsor or CRO site. The sponsor or CRO was solely responsible for the validation of the application and security and integrity of the data. Software vendors now host applications through software-as-a-service (SaaS) and share responsibilities with their customers for validation as well as data integrity. Today, we rarely discuss software escrow accounts with vendors to protect software. Instead, we now focus on controls for protecting our GxP data. Security, disaster recovery, backup and restore, replication, etc. These are all aspects that take on a greater priority when we audit software vendors. Simply checking off a question on an audit checklist that the vendor has a disaster recovery plan isn't good enough.

The auditor needs to fully assess the adequacy of the vendors data integrity controls. Data integrity controls and processes become even more complicated as vendors typically contract with one or more third party co-location data centers that maintain servers and other infrastructure components for the vendor.

- What agreements does the SaaS vendor have with the data center to support data integrity controls?
- What agreements do you, as a customer, have with the SaaS vendor, to support your disaster recovery and business continuity programs?

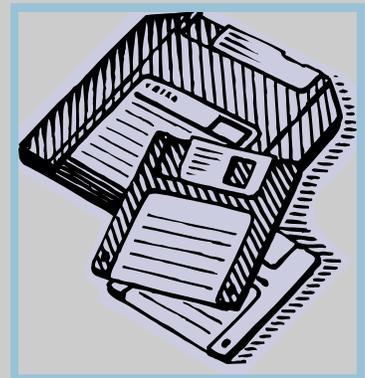
Shifting Approaches to Auditing Software Vendors (continued)

Another difference in how software vendors operate today is the use of Agile software development methodologies. Agile is definitely not waterfall. When I audit a software vendor that uses a waterfall SDLC methodology, I know exactly what to expect. When I audit a software vendor that uses an Agile SDLC process, I never know what to expect. Software vendors all have different approaches to how they use the Agile process.

Vendors also use a multitude of software development and testing tools, such as Altassian and Microsoft Visual Studio suites, on how they manage their Agile process and the “artifacts” that the Agile process produces. A vendor can’t easily develop software using an Agile process without the use of these tools. The “artifacts” that are generated and maintained by these tools have replaced the binders that we would review when we audited a software vendor 20 years ago. These artifacts are now used to demonstrate that the vendor is in compliance with their internal SOPs and processes on how they develop software. For SaaS vendors, these artifacts will also likely be used to support a sponsor or CROs validation of their GxP system.

When auditing a software vendor, fully understanding how these tools are used and how they are controlled or qualified is critical to understand how they may impact the validation status of your GxP systems. Someone asked me once if validation requirements have changed over the past 20 years or so. I thought about this question and answered, no, the requirements really haven’t changed (too much).

However, the technologies and the methodologies that are now used have changed. We still need controls, but the controls that we apply now are different. As QA professionals, we need to focus our auditing approaches to reflect these changes in tools and processes in order to fully assess and audit vendors and how they may impact our validated applications and GxP data.



MARSQA Computer Validation Committee

On Wednesday, September 30, the CVC hosted Computer Validation Training in Lahaska PA on Updates on Recent Regulatory Guidance. This training provided an overview and discussion of guidance documents from the FDA and other regulatory agencies that have recently been published. The documents reviewed included the FDA e-Source Guidance, MHRA Data Integrity Guidance, E-Informed Consent Guidance, Mobile



Apps and Patient Reported Outcome Guidance, and OECD GLP CSV Draft Guidance #16. It was great to be able to get together as a group to discuss these, ask questions and gain a further understanding of the guidance documents. This was the first time the CVC offered this type of training and we would like to continue this on a regular basis.

On **November 18-19**, the CVC will be hosting Advanced Computer Validation Training. Although we have provided this training in the past, we have totally revised the agenda with new, exciting topics. These include, Deployment Process for SaaS in a Managed Hosted Environment, Validation Considerations for e-Informed Consent Systems, SOC II Reports - What Are They, and Qualification of Technology Hosting Providers for Regulatory Compliance. We will also be holding Breakout Sessions on discussing Current Warning Letters and FDA-483s and a Round Table discussion with topics from the attendees. Sound good??!!



You can register now at the MARSQA website and of course walk ins are always welcome. Hope to see you there!



Upcoming Events

MARSQA
Fall Membership
Q42015 Meeting

Tuesday, December 8th

11:00am-3:30pm

C*ck and Bull Restaurant
Peddler's Village, Lahaska, PA

1Q2016 MARSQA
Meeting:
March 2016

See www.marsqa.org for meeting details and registration information

- **Data Integrity**, Presented by Lorrie Schuessler, *Manager, Computer Systems Quality Assurance, GlaxoSmithKline*
- **From Inception to Prescription: Preclinical Drug Development**, Presented by Dr. Alan Hoberman, *Executive Director, Global Developmental, Reproductive and Juvenile Toxicology, Charles River Laboratories, Inc.*

MARSQA Computer
Validation Training

November 18-19, 2015

C*ck and Bull Restaurant
Peddler's Village, Lahaska, PA

See www.marsqa.org for meeting details and registration information

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| Member Status | 7 - 13 November |
| MARSQA Member | \$250 |
| Nonmember | \$275 |

To contact the entire MARSQA board please e-mail: board@marsqa.org

For individual Board Member e-mail addresses, please see: <http://www.marsqa.org/board.shtml>

Bright Idea Corner

Submit topics for presentations, volunteer to present on your area of expertise or suggest ideas for the next newsletter!

Contact us at: newsletter@marsqa.org