

MARSQA MONITOR

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FDA Issues Draft Guidance on Nanotechnology

Nanotechnology?

So what's the *BIG* deal?

According to the FDA they see it as a very important area for regulatory involvement: "The U.S. Food and Drug Administration (FDA) regulates a wide range of products, including foods, cosmetics, drugs, devices, veterinary products, and tobacco products some of which may utilize nanotechnology or contain nanomaterials. Nanotechnology allows scientists to create, explore, and manipulate materials measured in nanometers (billionths of a meter). Such materials can have chemical, physical, and biological properties that differ from those of their larger counterparts."

In fact the regulatory interest is so strong that in 2006 a Nanotechnology Task Force was formed and in 2007 they determined that industry guidance documents would be needed. A Task Force Report was issued in July 2007 and the general finding found was "...that nanoscale materials present regulatory challenges similar to those posed by products using other emerging technologies...challenges may be magnified both because nanotechnology can be used in, or to make, any FDA-regulated product, and because, at this scale, properties of a material relevant to the safety and (as applicable) effectiveness of FDA-regulated products might change repeatedly as size enters into or varies within the nanoscale range.

The emerging and uncertain nature of the science and potential for rapid development of applications for FDA-regulated products highlights the need for timely development of a transparent, consistent, and predictable regulatory pathway." Soon we will see the application of nanotechnology in medicine.

Read more about this interesting emerging science at: <http://www.fda.gov/ScienceResearch/SpecialTopics/Nanotechnology/default.htm>

Three new FDA guidance's and a fourth in draft are now available:

1. [Final Guidance for Industry: Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology](#)
2. [Final Guidance for Industry: Safety of Nanomaterials in Cosmetic Products](#)
3. [Assessing the Effects of Significant Manufacturing Process Changes, Including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, Including Food Ingredients that Are Color Additives](#)
4. [Use of Nanomaterials in Food for Animals - Draft Guidance for Industry](#)

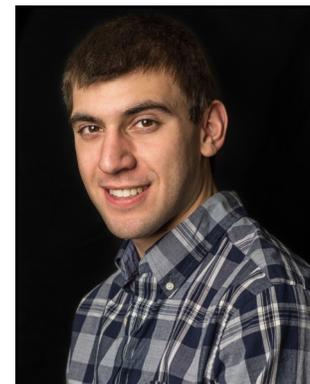
March 2015 MARSQA Membership Meeting:

A College Student's Perspective

Inviting college students to membership meetings is a 2015 MARSQA executive board initiative. Daniel Davis, provided insight on his experience attending the most recent membership meeting.

Question 1: What did you learn from attending the MARSQA meeting? What did you enjoy about the meeting?

I enjoyed the presentations by Christian Steber from the Parenteral Drug Association regarding drug development and on cloud technology by Bill Drummond. I enjoyed meeting new and friendly people. Meeting people from the FDA, Charles River Laboratories, GSK, BMS, and many other companies was an enjoyable experience. I plan to attend the meeting on June 25th and network.



Daniel Davis
East Stroudsburg

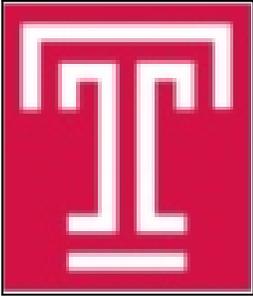
Question 2: What is your perspective on MARSQA and the industry?

I think that presentation is extremely important to distributing information. I was extremely impressed by how well organized the event was. Each speaker and member was excited to be a part of this meeting, and I was happy to join them. I had the privilege to attend the board meeting prior to the event. It was well put together and everyone got along well, which created a welcoming environment. Along with that the atmosphere was very professional, but there was room to have a great time.

The experience was well worth my time, and I am very eager to join the meeting again. Overall I think MARSQA is an exceptional organization and it is a great approach to distribute new information to others in the community. This is an industry that will continue to strive and move forward as more information is shared in an effort to come up with answers to questions that have been pursued for decades.

Question 3: What are your future aspirations?

I have a huge interest in the science, Biochemistry - proteins, DNA and cell cultures, as well as working in a laboratory performing assays for any research. My goal to accomplish in the Biochemistry realm is still uncertain currently but hopefully once I start getting more experience I will figure out a goal then. I hope to earn a career in Biochemistry, while also being a part of something I sincerely enjoy.



“Many students were very interested in joining and this is in line with the MARSQA President’s goal of increasing membership, specifically in the student population..”

- Ranee Henry on students’ response to MARSQA at the Temple University Career Night



MARSQA Members Speak at Temple University Career Night

Written by: Ranee Henry, President MARSQA

On Thursday, April 30, 2015, MARSQA was invited to be a guest speaker at the Regulatory Affairs and Quality Assurance graduate program’s Career Night at the Temple University School of Pharmacy in Fort Washington, PA. The event was invitation only for current Temple University RA and QA students and Alumni to socialize and network with prospective employers.

MARSQA members Ranee Henry, Kiet Luong and Richard Serafin explained the benefits of joining a Professional Affiliation like MARSQA and the advantages it can bring to a student’s career. The following individuals also presented on the following topics:

- **Karen Campbell**, Investigations Branch Director, Philadelphia District, U.S. FDA
- **Tamara Ely**, Senior Policy Advisor at CDER, Office of Compliance, Office of Manufacturing and Product Quality, "Positions at CDER."
- **Steven Beck**, Senior Recruiter, Clinical Operations/Clinical Data Management/Regulatory Affairs, inVentiv Health Clinical, "Resumes are a formality. Networking is a necessity!"
- **Priya Bhutani**, Founder & CEO, RegDesk, Inc., "Global Healthcare Compliance Needs a Reboot."
- **Dale Cook**, RAPS, Philadelphia Co-Chair, "The Role and Importance of Professional Societies in the 21st Century: Tips to make the Most of Your Investment."

"Mid-Atlantic Regional Society of Quality Assurance Experience: Benefits of Joining."

Ranee Henry (President of MARSQA),

Kiet Luong (Vice President of MARSQA)

Richard Serafin (MARSQA Member)

The importance of networking and professional social media as well attending MARSQA Membership Meetings, was stressed to ensure a smooth transition into a new field, or promoting yourself. It really is still about “who you know.” Networking with people all across our business (i.e. LinkedIn) is just as important as your education and skill set.

FDA Proposes Additional Rule for Tobacco Regulation

“Electronic cigarettes, also known as e-cigarettes, are battery-operated products designed to deliver nicotine, flavor and other chemicals. They turn chemicals, including highly addictive nicotine, into an aerosol that is inhaled by the user (FDA).” But, are these products regulated? What are the potential risks? Are there benefits? These questions remain to be answered.

While cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco are regulated by FDA Center for Tobacco Products, the FDA Center for Drug Evaluation and Research (CDER) only regulates e-cigarettes that are marketed for therapeutic purposes.

The FDA has issued a proposed rule that would extend the agency’s tobacco authority to include specified newly defined tobacco products such as electronic cigarettes, cigars, pipe tobacco, certain dissolvables that are not “smokeless tobacco,” gels, and waterpipe tobacco. Additional information regarding the proposed rule can be found on the [FDA’s Extending Authorities to Additional Tobacco Products webpage](#). The public is encouraged to submit comments on e-cigarettes to the FDA through July 2, 2015.

Some of the reported adverse effects of e-cigarettes reported from the public include: pneumonia, congestive heart failure, disorientation, seizure, hypotension, and other health problems. It is noted that under the Food, Drug and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act, information regarding voluntary information and concerns can be accepted for tobacco products not yet regulated.

Therefore, whether e-cigarettes directly caused these reported adverse events is unknown.

The FDA has held multiple workshops for scientific and medical experts as well as the public to discuss e-cigarettes to gain better inform the FDA about e-cigarettes to use this information presently rather than after the finalization of the rule. See [here](#) for all events related to tobacco issues.

Click [here](#) for additional information regarding Tobacco Regulation.

Search the FDA website for a wealth of information regarding tobacco products and e-cigarettes.

<http://www.fda.gov/newsevents/publichealthfocus/ucm172906.htm>

***“The eye sees
only what the
mind is
prepared to
comprehend”
Henri-Louis
Bergson***



Lisa Zaborowski, MARSQA SQA Scholarship Winner

I was given an extraordinary opportunity to attend the annual SQA meeting this year in Tampa. It was a very educational experience. There were so many opportunities available, that it was difficult to decide what to attend. The opening ceremony and remarks, all the courses, presentations and panel discussions that I did attend were excellent and educational. On Monday, I was able to attend a Quality College titled: New Perspectives in QA: Tools, Techniques & Strategies for Enhancing Effectiveness and Enjoyment; which was very interactive and provided me with the opportunity to meet many new QA professionals from different regulatory fields and share experiences. It was a great way for me to start the week as it helped me feel more comfortable.

One area in which I wished to expand my knowledge was in the area of Biologics and Bioanalytical method validation and I was thrilled there were two days and multiple presentations in which expertise in these areas was discussed. I took the opportunity to attend all these presentations.

I tried to experience some variety and attended the final round of The GLP World Cup as well as the Q&A for this, which was fun but very informative.

My favorite was two different panel discussions. One was titled "Teaching New Dogs Old Tricks" which provided auditors insight into auditing skills and tools from experienced auditors. And the other intriguing panel was "QA and Testing Facility Management: A team for compliance success or a compliance mess" which provided great interaction and communication skills for QA, TFM as well as between Sponsors.

SQA also provide great networking opportunities outside of the meeting, with a dinner cruise on the Yacht Star Ship on Monday evening and a trip to the Tampa Zoo with giraffe feeding and dinner. It was especially nice to meet and interact with other CRL auditors from other sites as well as QA professionals from other companies.

A special thank you to MARSQA for the scholarship that provided me with the opportunity to attend as well as my company's management at Charles River Laboratories.



Tony Borisow, MARSQA SQA Scholarship Winner

Having recently been downsized as a result of large Pharma mergers and acquisitions, winning the MARSQA SQA Award for 2015 in Tampa could not have come at a better time! Of course the educational aspect of the meeting was invaluable, but this year it was the rekindling of old relationships and the blossoming of newer ones or those that were previously more distant that really made the meeting special and extremely beneficial for me.

In the month since the meeting, I've been extremely fortunate to have had several new and interesting job opportunities introduced to me. Three of these opportunities were a direct result of the leads and good words provided by MARSQA members in attendance at the meeting in Tampa, and a fourth was from a MARSQA member who was not in attendance.

I am truly blessed to have had the opportunity to have served this organization, and for the amazing members who reach out a helping hand when it's needed. And that includes all of the behind-the-scenes work that the Board and Committee members do to make opportunities like this possible!

Lastly, I would like to give a special thanks to Lelia Scott. Not only for her great presentation on protecting regulated data from vulnerabilities, but also for helping me track down the cab in which I left my cell phone following drop-off to go home at Tampa Airport, and not leaving for her gate until the cab and phone were returned!

MARSQA ties – enough said!



MARSQA Member Spotlight: Richard Serafin, Manager, QA - GLP Bioanalytical

Where do you work and what is your specialty?

I work at Morphotek, a biopharmaceutical company developing monoclonal antibodies for cancer therapy.

What was your pathway to the regulatory world?

While I was in graduate school, I worked part-time in a hospital toxicology and clinical chemistry lab. I thought I'd always work in a hospital environment. However, a few years later I accepted a position as the supervisor of the Biopharmaceutical Analysis Lab at the Medical College of Virginia. This was my first experience working at a CRO and regulated bioanalytical method validation and sample analysis. I quickly discovered it was quite different from a hospital laboratory.



Dick Serafin

What would you consider one great achievement thus far in your career?

I recently completed my Masters of Science degree in Quality Assurance and Regulatory Affairs from Temple University School of Pharmacy.

What is the legacy that you would like to leave behind?

I've been blessed with a wonderful wife and four great children. The example I'd like to leave them is that I was a good husband and father to my family. I hope to instill in them these same qualities with their families.

MARSQA Sponsor Spotlight:

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Quality System and SOP Development

Technical Writing

Supplemental Quality Staffing

For more information, visit our website

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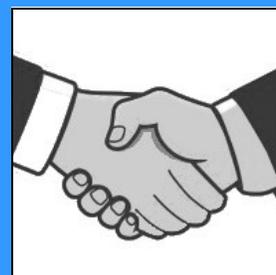
Email: contact@qacvconsulting.com

Become a MARSQA Sponsor!

Is your company interested in becoming a MARSQA sponsor? To become a sponsor you can host a MARSQA meeting, provide catering, or support to MARSQA.

Benefits include: Advertise in the MARSQA newsletter, acknowledgement on the MARSQA website and member meetings, free job postings, and free registrations are MARSQA member meetings or training events. Sponsorship Levels include: Platinum, Gold, Silver, Bronze, and In Kind

For more information, contact a MARSQA Board Member or review the Sponsorship Policy on the MARSQA website (<http://marsqa.org/>).



Upcoming Events

<p><u>MARSQA Summer Membership Meeting</u></p> <p>June 25, 2015 11:00am-4:00pm</p> <p>C*ck and Bull Restaurant Peddler's Village, Lahaska, PA</p>	<p>Presenters:</p> <ul style="list-style-type: none">• <u>Biologics Super Highway - An Auditor's On-Ramp</u> Presented by Deborah Parker, B.A Compliance Specialist, GQRC-ANA Bristol-Myers Squibb• <u>Keynote: Navigating through Waters without Getting Wet</u> Presented by Mike Hourigan <p>See www.marsqa.org for meeting details and registration information</p>
<p><u>Clinical Quality Assurance Discussion Group</u></p> <p>"CQA Discussion Group"</p> <p>September 15, 2015 11:30am-4:00pm</p> <p>C*ck and Bull Restaurant Peddler's Village, Lahaska, PA</p>	<p>Anticipated discussion topics are as follows :</p> <ul style="list-style-type: none">• <u>Regulatory Inspection of Sponsor / CRO on Trial Master File</u> Presented by <i>Mike Rashti</i>, BIMO Auditor & Trainer, LLC• <u>Data trending List</u>• <u>Automated Data Trending Audit Tools</u> Presented by external speaker• <u>Follow-up presentation from Transclerate</u> <p>See the CQA Discussion Group LinkedIn page https://www.linkedin.com/groups/Clinical-Quality-Assurance-Discussion-Group-5180873/about</p>

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