NEW ENGLAND PDA NEWSLETTER

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Connecting People, Science and Regulation

In This Issue:

January Dinner Meeting
Wednesday January 14
Event Topic: Visual Inspection

Speakers:

John Shabushnig
Pfizer Inc., Senior Manager
Quality Systems and Technical Support
Leader PDA Visual Inspection Interest Group
Chair Global PDA
Survey of Industry Visual Inspection Practices
(as presented at Berlin conference)

Mike de la Montaigne
President, Eisai Machinery USA Inc.
will present
"Latest Trends in Inspecting Parenteral Products"

Dinner Meeting Times:

5:30p.m. to 9:00p.m.
Registration / Networking: 5:30p.m. to 6:30p.m.
Dinner Meeting: 6:30p.m. to 9:00p.m.
Contact: Jerry Boudreault
Boudreault@ddres.com

Are you interested in submitting an article for a future NEPDA Newsletter? Then download and submit the "Article Submission Policy" at the Chapter Resources link at our website: http://pdachapters.org/newengland and submit it to melissa@mjqualitysolutions.com

QA Before you Outsource:
Evaluating the Quality Oversight at CMOs

By Jonathan M. Morse, RAC
Principal Consultant
Complya Consulting Group, LLC
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Contract Manufacturing Organization (CMO) qualification and quality oversight are major elements to consider when selecting your outsourcing partner. How your CMO ensures that adequate controls are in place and how it handles major quality issues are critical factors to scrutinize before entering into a contract agreement. This article will provide an examination of the level of oversight and different quality assurance approaches provided by CMOs and Sponsors, including CMOs in emerging countries.

Communication & Trust

During CMO selection, it is critical to ensure that good communication is established between the sponsor and CMO Quality organizations. Establishing strong Quality-Quality communication up front is key to ensuring smooth communication later. Both parties should foster a 'partnership-style' relationship. As companies sometimes discover too late, communication and trust are intertwined.

Sponsor behavior and tone can encourage or discourage candid communication from the CMO. For example, one sponsor makes it a habit to always thank their CMO for sharing bad news before addressing the news. Another sponsor ordered coffee and donuts for all of the operators at their CMO, while another sent Godiva chocolates to their CMO counterparts, in recognition of their noteworthy efforts during particularly busy times.

Similarly, the CMO plays a key role in fostering good communication (and trust) with the sponsor. Frequent and preemptive communication to the sponsor is critical, especially when encountering deviations. Some CMOs provide real-time web-based updates for clients to follow the status of batch processing. Being responsive and addressing client feedback and observations made during audits and visits are fundamental to being a good partner.

Cultural Issues and Overseas CMOs

When working with an international CMO, cultural differences play a key role in understanding and communication. For example, sponsors should be particularly sensitive about when and how to discuss audit observations with CMOs in cultures where 'saving face' is highly valued. In other instances, language barriers may make the distinction between 'major' and 'minor'

deviations unclear. As in any case, it is critical that expectations are understood in both directions between sponsors and CMOs.

Being aware of local customs, including how to properly exchange business cards or how to make appropriate "small talk" during mealtimes, can go a long way in building bridges with a CMO. One sponsor recently sent Diwali (a major Hindu holiday) greetings to their Indian CMO, while another used an on-line translation website to send greetings to a CMO in Seoul on a major national holiday there. These small gestures can make a difference to operators who work through their own national holidays to accommodate our production schedules.

Quality Agreements

US-based companies are increasingly adopting the European requirement for Quality Agreements as vehicles to capture sponsor-CMO expectations.
Quality Agreement key sections include:

- Audits and/or Inspections
- Regulatory Authority Inspections
- Certificates of Analysis and Certificate of Manufacture
- Product Dating and Coding
- Stability Testing
- Retain Samples
- Change Control
- Equipment Validation, Calibration, and Preventive Maintenance
- Process Validation and Qualification
- Training and Qualifications
- Supplier Quality Assurance for Purchased Materials
- Labeling
- Batch Record
- Exception Reports
- Reworking and Re-inspection
- Product Testing and Lot Release
- Product Storage and Transportation
- Record Retention
- Product Complaints
- Returned Goods
- Product Recall

The Quality Agreement should be broad and comprehensive while providing enough detail on each topic to avoid any confusion. For example, decisions about the use of quarantined API in a batch, or control and movement of quarantined final product should be captured in advance of batch processing.

Batch Disposition

The ultimate responsibility for batch disposition lies with the sponsor, and the sponsor should determine in advance the criteria they will use to make this determination. While CMO batch release certainly plays an important role, sponsors frequently elect to perform full batch record review prior to establishing their own batch disposition. Some companies write their SOPs to allow for reduced batch record review of commercial product after consistent quality has been demonstrated on a statistically representative number of consecutive batches. Assembling a Lot File, including executed batch records, certificates of analysis/conformance, resolved deviations or OOS results, and documentation of finished quantity, provides the sponsor with clear and complete justification for their product disposition.

Conclusions

The sponsor-CMO relationship is built on communication and trust, and to be successful at it requires input and effort from both parties. Reaching agreement in advance on how to handle anticipated decision points is important to preempt finger-pointing. Prioritizing the partnership-style relationship from planning through execution creates an environment where mutual success is the most likely outcome.

Women in Science are *Inspiring Minds*!

By Enith Morillo, M.S., Supervisor Quality Control
Tedor Pharma Inc

Over a decade ago, a group of distinguished women affiliated with and supported by the Museum of Science - Boston, joined forces to create a one-of-a-kind forum to foster innovation and inspire girls and women in their pursuit of careers in engineering and science. These women, trailblazers in their own right, have continuously empowered females by hosting bi-annual luncheons in support of their mission, inviting guest speakers representing the elite of academia, the healthcare sector, and industry. Amongst past speakers we find distinguished leaders such as Vicki Sato, Ph.D., former President of Vertex Pharmaceuticals, Angela Belcher, Ph.D., cofounder of Cambrios Technologies Inc., and Susan Lindquist, Ph.D., former Director of the Whitehead Institute for Biomedical Research. Last year, during their 10th anniversary, guest speakers from MIT and Harvard University captivated the audience with topics ranging from bio-scaffolding to natural selection in the human genome.

With the support of longtime advocate of gender equity, Dr. Ioannis Miaoulis, President and Director of the Museum, and stemming from the Women in Science (WIS) forum, came 'Inspiring Minds: Meet Women in Science'. Held every May at the Museum, this exceptional program brings together women in science and technology to share their experiences and expertise through lectures, demonstrations, and Q&A sessions aimed at reaching out and inspiring. In 2008, professionals representing Amgen, Genzyme, Vertex Pharmaceuticals, Schlumberger, MIT and BU, to name a few, captivated their audiences with exciting demonstrations and talks about microbiology, patent law, medicine, and even archaeology.

It is initiatives such as WIS and Inspiring Minds that offer PDA members an excellent platform to support females in science and engineering, and to help lessen the gender gap in the biotech and pharmaceutical industry. Whether by attending their events or volunteering some of their time and expertise, PDA professionals can significantly contribute to tapping into unfathomed potential, and help WIS and Inspiring Minds reach farther and further into our communities.

NEPDA PRESIDENT'S MESSAGE:

By *Louis Zaczkiewicz, CQE-ASQ*
Senior Engineer
Hyaluron Contract Manufacturing

It has been my honor to be the President of your chapter for the past two years. When I started, I have to admit that I felt apprehensive. After all, I was following in the footsteps of Bob Pazzano, Mark Staples and Myron Dittmer. How was I going to improve on what they had already done (like the infamous "PDA Chapter of the Year" award issued during Mark's tenure)? Now that it's almost over, it's time to look back and take stock of how it all worked.

I've been part of a great Board of Director team including President-Elect Jerry Boudreault, Treasurer Rusty Morrison, Secretaries Melissa Smith and Richard Paiva, and Members-at-Lodge Myron Dittmer and Bruce Rotker. Additionally this Chapter was supported with an active group of Business / Planning Committee members. Over the past 2 years we've held 10 educational meetings on PDA technical reports, 12 business/planning meetings, published 8 newsletters, judged and given awards at the Massachusetts High School Science fair, started the PDA's first student chapter, began electronic registrations for our meetings, increased meeting attendance, had our first educational program outside of Massachusetts, developed our Chapter website, approved 3 new policies and expanded our chapter's support for our members.

Because of an active group of meeting sponsors, we've added free appetizers and the first drink for each of our meetings. Moreover we've been able to reduce meeting attendance fees and even been able to offer a $10 fee to students and unemployed members.

Next year will be our Chapter's 20th anniversary. At our November meeting we elected a new team under the leadership of Jerry Boudreault to take us through the next 2 years. Each nominee to the Board of Directors has been active in our chapter's Business / Planning meetings for at least 1 year as recommended by Global PDA. Your new Chapter Officers will take over on January 1, 2009 and are as follows:

President:	Jerry Boudreault
President-Elect:	Rusty Morrison
Secretary:	Sarvang Mishra
Treasurer:	Maryellen Brown
Members-at-Large:	Melissa Smith and Louis Zaczkiewicz

We can all expect great things from this new team.

We are all part of a wonderful organization. The PDA has been expanding membership benefits by adding a new journal called *IPQ*, in addition to the regular publications of the *PDA Letter*, *PDA Journal of Pharmaceutical Science and Technology* and published Technical Reports. Global PDA has also recognized that our little world up here in New England has many pharmaceutical companies, and has put together a 2-day conference on Clinical Trials Management. Depending on the success of this conference, it could become an annual event.

So what am I going to do with my free time? As you may know, I've been nominated to serve on the PDA Board of Directors. As only four of the nine candidates will serve, I am by no means assured of one of those positions. If elected I will do my best to help maximize membership benefits. If not, I'm sure other service opportunities will fill the time.

Thank you again for allowing me to lead this prestigious organization.

Louis

News from the PDA Student Chapter at Middlesex Community College

For those of you who attended the September NEPDA meeting, you will remember the excellent poster session on stem cells put together by students from our student chapter. Dr. Jessie Klein, one of the faculty advisors of the student chapter, has let us know that this 5-session course is being held at their Lowell campus from 5 to 10 pm on January 6, 8, 12, 13 and 15. The course is BIN 562 40 "Human Embryonic Stem Cell Culture" and the instructor is Dr. Mariluci Bladon. This course is designed to provide “hands-on” techniques for the growth and analysis of Human Embryonic Stem Cells (hESC). Participants will learn basic terminology, follow SOPs for the preparation of nutrient media and culture of hESC and mouse feeder layer cells, freeze cells and analyze karyotypes. Markers will be used to distinguish between the undifferentiated state and committed state Human Embryonic Stem Cells. The prerequisites are a Certificate in Biotechnology, Associate in Biotechnology preferred, or permission of instructor. The cost is $650.
To learn more about this course, call Lisa Tuzzolo at 978-656-3109 or e-mail tuzzolol@middlesex.mass.edu

To register for BIN 562 40, call 800-818-3434

The New England Chapter of the PDA is pleased to announce the availability of business-card size advertising opportunities in our newsletter; at a cost of $100 per newsletter (other conditions apply — please see full details in our "Newsletter Sponsorship Policy", hyperlink provided below). Since its inception in 1988, our chapter has seen a significant growth in membership and participation. Our newsletter has the following reach:

- **Our direct e-mail distribution reaches over 1,800 contacts throughout New England.**
- **Our membership includes people from manufacturing, research, QA, QC, engineering, contract manufacturers, consultants, regulatory, etc.**
- **The newsletter is promoted at New England PDA's bi-monthly dinner meetings, often with company tours, which regularly attract 100-150 attendees.**
- **The newsletter is posted to our chapter's website at Global PDA (www.pda.org), an organization that has over 10,000 members.**

We offer vendors, consultants, operating companies and other organizations the opportunity to promote themselves and also support the NE PDA Chapter by purchasing advertising in our newsletter:

1. ***Download and fill out the "Newsletter Sponsorship Policy" form located at the Chapter Resources link of the NEPDA website: http://pdachapters.org/newengland***
2. ***Email artwork along with a scanned copy of your completed form prior to the deadline to melissa@mjqualitysolutions.com***
3. ***Submit the completed form with check payable to PDA New England Chapter and send it to:***

   Maryellen Brown
   41 Berkeley Rd
   Framingham MA 01701

Deadline	Publication Date
January 15, 2009	February 2009
April 15, 2009	May 2009
July 15, 2009	August 2009
October 15, 2009	November 2009

Questions:

About the newsletters and articles, advertising artwork? E-mail Melissa at melissa@mjqualitysolutions.com
About advertising opportunities? E-mail Maryellen Brown at mbrown@inscogroup.com