PDA Southeast Chapter

SOUTHEAST CHAPTER
www.pdase.org

Letter From the President

March, 2004

This is my last letter as President of the Southeast Chapter of the PDA as my two-year term has come to an end. Officer elections were held in December and Lisa Eklund has been elected as the new President. She will serve as President for the 2004 – 2005 term along with Lucia Clontz as Vice-President, Tony Pavell as Treasurer and Anita Garrett as Secretary. Congratulations to all the newly elected officers! I am leaving the Chapter in very good hands.

> Please get involved so this chapter will continue to grow and provide educational and networking opportunities into the future.

When I took office two years ago I had several objectives in mind for my term. I hoped to provide the membership with programs of interest and to increase membership participation in the chapter. I also wanted to improve the chapter website. It is difficult for me to judge the accomplishments, however, attendance at the meetings was good, we have a few new faces involved in running the chapter, and we have a greatly improved website. I am happy to report the Chapter has survived the last two years and indeed continues to thrive.

I want to thank all the Companies who have sponsored the Chapter during the last two years. Your support has been incredible and much appreciated. I hope you have found the association to be worthwhile and will continue to support the Chapter in the future. I also must thank all the volunteers who have provided support by chairing committees or participating on those committees as members. Their names have been in each newsletter. To all of you, thank you so much for contributing your time and effort to make the Southeast PDA chapter one of the best PDA Chapters.

Finally, I have greatly enjoyed my association with this organization. It has helped me grow personally and professionally. I will continue to serve as the Past President so you are not rid of me yet. As always, I want to encourage everyone to participate in any way they can in this organization, as

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the rewards are great. Please get involved so this chapter will continue to grow and provide educational and networking opportunities into the future.

Mary

PDA Southeast Chapter Election Results

Elections for officers of the Southeast Chapter of the PDA were held in December 2003 for the 2004 – 2005 term. The offices up for election included President, Vice President, Secretary and Treasurer. Ballots were mailed to Southeast Chapter members mid November with the request to return the ballots by mid December. Congratulations to newly elected officers Lisa Eklund (President), Lucia Clontz (Vice-President), Tony Pavell (Treasurer), and Anita Garrett (Secretary). A special thank you to all those who ran for office. Outgoing officers are Mary Carver (President), Lisa Eklund (Vice-President), and Kim Hughes (Secretary). Tony Pavell was reelected for a second term as treasurer.

CAPA: Effective Management of Deviations

By Jodi L. Miller, Sr. QA Specialist, Purdue Pharmaceuticals L.P.

The topic at the recent PDA Southeast

Chapter conference was the CAPA system, presented by Carol Brandt, Director of Life Sciences with Clarkston Consulting. Ms. Brandt's presentation entailed CAPA: Effective Management of Deviations. CAPA stands for Corrective Action, Preventive Action, and has been implemented into quality systems in the industry as a management control tool for identifying existing problems and potential problems, encountered while investigating deviations.

Corrective Action, as presented, is an action taken to eliminate the causes of an existing non-conformity, defect or other undesirable situation in order to prevent recurrence. Preventive Action is an action taken to eliminate the cause of a potential non-conformity, defect, or other undesirable situation in order to prevent occurrence. [ISO 8402]

The objective for a CAPA system is a procedure that appropriately identifies sources of quality problems, receives quality information data that is complete, accurate and timely, and applies the appropriate statistical methods, detecting recurring quality problems. In addition, the CAPA system procedure should verify that once appropriate actions have been taken, the corrective and preventive actions are effective and properly documented prior to implementation.

The system should be manageable and used as a reporting tool for effective tracking and trending of deviations. The goals of a good deviation management system are to incorporate a CAPA program that tracks the impact, effect or success in completion of corrective/ preventive actions, reported in consistent formats within one system, and allows for appropriate QA oversight.

The solution is to create a system with one method of reporting and evaluation, one method of response, ensuring appropriate action has been taken, and the issue is closed. The system should also have one central database with effective tracking and trending.

CAPA isn't going away, so the sooner one implements a Quality System providing data that is complete, accurate, timely, and effective, the better off pharmaceutical companies will be.

In response to the tragic accident that occurred at West Pharmaceuticals, the PDA Southeast Chapter Donated $1060 to help those effected by the accident. In response, West Pharmaceutical Services sent the following letter of thanks.

WEST Pharmaceutical SERVICES

GLOBAL HEADQUARTERS
101 Gordon Drive • Lionville, PA 19341
TEL 610-594-3075 • FAX 610-594-3010
don.morel@westpharma.com

DR. DONALD E. MOREL, JR.
Chairman, President and Chief Executive Officer

August 2003

PDA SE Chapter
8900 Capital Blvd.
Raleigh, NC 27616-3117

ATTN: Anthony Pavell, Treasurer

Dear Friends of West,

On behalf of the worldwide West family, I would like to thank you for your generous donation to our Kinston Relief Fund benefiting the victims of the accident at our facility in North Carolina on January 29.

Because of the compassionate and caring response from friends and concerned groups around the world, West has been able to assist our employees throughout this difficult period.

Please accept this small gift as our token of appreciation for your support.

With warm regards,

Donald E. Morel, Jr., Ph.D.
Chairman, President and Chief Executive Officer

Enclosure

Global Partners with
Daikyo Seiko Ltd.
The West Company Mexico S.A. de C.V.

Impurities Found in GMP Raw Materials For Use in The Pharmaceutical and Biotech Industry

Presented by Ronnie Brooks, QA for Mallinckrodt Baker, Inc.
Written by Christine Cramer, Kelly Scientific Resources

Ronnie talked about meeting specifications for a USP grade excipient from a manufacturer's point of view and He itemized many impurities most commonly seen ("black specks") including:

Process related –

Oxides - especially in hydroscopic inorganic salts
Charred particles often accompany drying process
Metal shards
Dirt particle may appear in naturally mined earth products.

Packaging related –

Paper or wood fibers
Adventitious materials.

Some of these impurities may be acceptable and some may not. Some of these impurities should only be seen by the API manufacturer; such as metal shards should be found with in line detectors and an investigation performed when discovered. Metal shards and dirt are not usually listed as acceptable process impurities in the final product. The responsible API manufacturer must have determined the practices to be followed for product disposition when such impurities are discovered during the process.

Packaging design has to be considered not only for the supplier's packaging operation but also to permit the removal of the material without contamination by the customer. Transportation methods should be considered in conjunction with packaging to provide a usable container upon delivery to the customer.

Adventitious materials are those things that you should NOT expect to find in the product, i.e. glass, metal shards, bug. When these contaminants are found the customer should immediately register a complaint as something is demonstrably wrong with the process.

What should a customer do when upon sampling "normal" process impurities are found? Follow the USP standards and notes, identify and quantify the findings. Know the permitted limits. If the monograph limits are higher than what your process can tolerate, then the customer may need to find ways to clean the USP material during their process, eliminating the impurities down stream. Alternatively, the customer may need to make their own specifications and find a manufacturer willing to make that special product. What aspects of production may be affected for the API manufacturer by tightening the impurities

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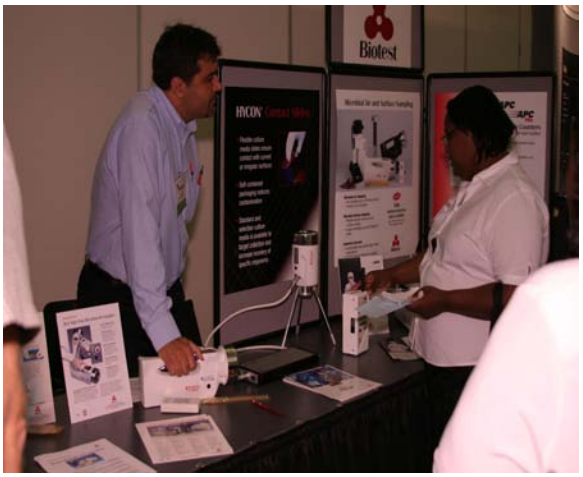
specifications for the material that has just become a custom order? Price, time, quality, stability, process, containers….

The word from this API manufacturer seems to be that the customer should know that raw materials can and will contain impurities. Ronnie didn't come out and say it in so many words, but the message came across clearly that a user should write their sampling and test methods in such a way that normal impurities within USP limits are recognized and dealt with as routine and not catastrophic events. He did say that release of product must depend on the results of full testing. If the "black specks" in question are adventitious or unknown and not a process impurity, then the lot must be rejected. Submit a complaint to the supplier; and include the offending particles for analysis. Limit your potential rejection problems by carefully managing your supplier relationships. Before approving a supplier you should be welcome to audit the manufacturer's process and review raw material test results. Especially, you should know what you need and specify those needs. If the customer's process was developed and validated using USP grade material, then the raw materials used should only need to meet those criteria during the life of its production.

It is not surprising that an API manufacturer would want to remind us all that perfect is not what the specifications require. But the message is legitimate, and a business needs to recognize and define what is "good enough" for their process and follow the operating procedures supporting those definitions. Thank you Ronnie for sharing your experience with us and reminding us that we need to remain aware that a product that has been manufactured under GMP conditions and meets USP specifications may nevertheless show up with specks, and still prove to be usable.

PDA Southeast Chapter
Sends Most Chapter Information
Electronically.

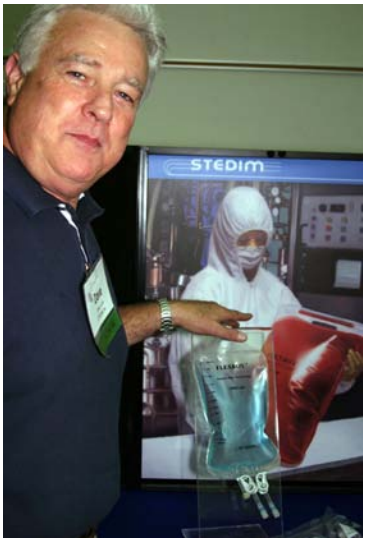
If you have a new email address, please send this information to PDASE at proflink@bellsouth.net

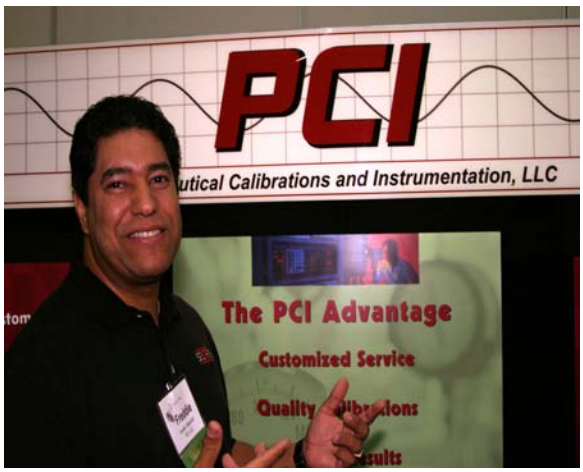


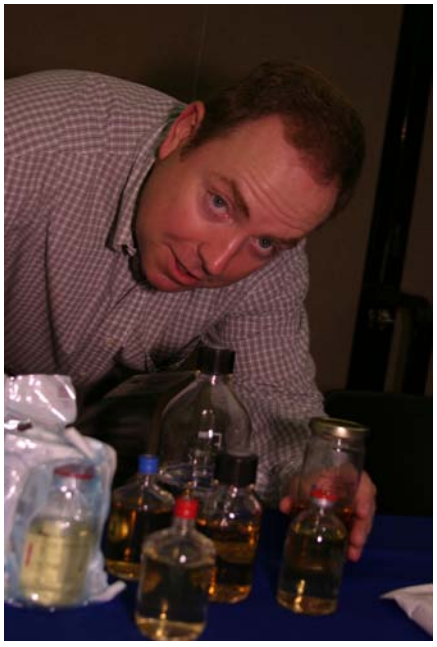
PDA SE Fall Meeting, 2003

PDA Southeast Chapter 2003 Fall Meeting and Exhibitor Show held on September 23, 2003, was a successful event with 35 venders exhibiting. The meeting attracted 137attendees representing more than 30 companies. The event was held at a new venue – the McKimmon Conference and Training Center, Raleigh, NC. The conference center provided spacious areas for both the meeting presentations and the exhibitions.

Two speakers were featured at this event. Carol Brandt, Director of Life Sciences for Clarkston Consulting presented on the topic "CAPA-Effective Management of Deviations". Ronnie Brooks from Quality Assurance at Mallinckrodt Baker, Inc. discussed "Impurities Found in GMP Raw Materials for use in the Pharmaceutical and Biotech Industry".







Photos courtesy of Carla Stevens, PCI

Part 11 Joint Dinner Meeting

Written by Lisa Eklund, QA/QC Manager, Fresenius Kabi

On 1/13/04, the PDA Southeast Chapter and the NC Pharmaceutical Discussion Group held a joint dinner meeting. The title of the meeting was "Software Solutions to Meet Part 11 Requirements in Pharmaceutical Manufacturing." The keynote speaker was John McKenney, President and co-founder of SEC Associates. After his presentation, there was a panel discussion by a software vendor, a consultant, and an industry representative. Joe Miles from SAP represented the vendor. Frank Anders was a consultant from Lloyd's Register Serentec. Tony Pavell, Validation Manager from Cardinal Health, also participated as a pharmaceutical company representative.

John McKenney discussed the changes in the part 11 requirements. The FDA withdrew the guidance policies for validation, glossary of terms, time stamps, maintenance and copies of e-records, and the compliance guide. These changes were made because the initial scope was too broad, the economic analysis was flawed, and smaller companies were only using paper systems. Therefore, the desired effect was not achieved. Now there are fewer records involved in the scope. The key aspects of a system are limited access, operational system checks, authority checks, device checks, staff qualifications, and accountability policies. The FDA will continue to enforce the predicate rules.

Mr. McKenney presented a brief flow diagram for part 11 assessment. First you should determine any predicate rule requirements. Then you should narrow the scope and identify e-records that require part 11 controls, then you assess the risk and evaluate the level of controls appropriate to the risk, and finally you should implement part 11 controls.

Mr. McKenney wanted to emphasize that there are also implied records. These are not explicitly required by predicate rules, but they are expected to prove compliance with predicate

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Golf Social

(NOT for the serious golfer!)

Friday, June 4, 2004
Hedingham Golf Club
Start time tbd

Watch for registration information to follow

Free Webinars Sponsored By: NOVERANT

Free Webinar Series Sponsored By Noverant:

The Principles of Good Training Practices for FDA-Regulated Companies

Medical Devices

Date and Time: March 24, 2004 2:00 EST

Speakers: Robert Rhoads
VP of Manufacturing and Human Resources
Precision Medical Products, Inc.
Developing a Successful Training Program for Medical Device Manufacturers

David Clissold
Senior Associate
Hyman, Phelps & McNamara, P.C.
Understanding How FDA's Regulatory Guidance For Electronic Records And Electronic Signatures Applies To Your Business Practices

Attendance: Visit www.noverant.com to register!

Pharmaceuticals

Date and Time: March 25, 2004 2:00 EST

Presentations: Peter Amanatides
Director, QA Support
DSM Pharmaceuticals, Inc.
The Critical Elements of a Successful and Compliant Training Solution

David Clissold
Senior Associate
Hyman, Phelps & McNamara, P.C.
Understanding How FDA's Regulatory Guidance For Electronic Records And Electronic Signatures Applies To Your Business Practices

Attendance: Visit www.noverant.com to register!

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rules. One example is training records.

After the keynote presentation, the panel participated in discussions as an open forum. There were many questions posed by the audience. The answers were given according to the individual's perspective. Therefore, you could get help from an industry representative, a software representative, and a consultant. Additionally, Mr. McKenney participated in the discussions. Questions were asked about database/ spreadsheet validation, HPLC validation status of software vendors, international regulations, and emerging technology validation. Wireless network systems, camera phones, etc., represent some of the new wave of technology which will require procedural controls.

Pictured above are members of the 2003 PDA Southeast Chapter Executive Committee: (standing L-R)Tony Pavell, Cindy Smith, Mary Carver, Teresa Frisone (sitting L-R) Lisa Eklund, Pam Webb and Susan Moore.

Mark Your Calendars for the PDA Southeast Chapter Spring Meeting

Tuesday, April 20, 2004

at the

NC Biotechnology Center

If you have newsletter questions/comments, please contact:

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Watch the PDA Southeast Chapter web site, www.pdase.org for information on upcoming events.