PDA Southeast Chapter

SOUTHEAST CHAPTER
www.pdase.org

Letter From the President

August, 2003

Hello to all the PDA Southeast Chapter members across North Carolina, South Carolina, Georgia, Florida, Virginia, and Tennessee. I am happy to report that the Chapter is alive and well and continuing to work toward our mission. In part, our mission is to foster and advance the art and science of pharmaceuticals, medical devices, and biotechnology along with encouraging education and training of personnel. To this end, we are sponsoring the 2003 Fall Meeting and Exhibits Show.

PDA SE Fall Meeting and Exhibits Show, September 23, 2003 at the McKimmon Conference and Training Center

The event will be held on September 23, 2003 at McKimmon Conference and Training Center in Raleigh, North Carolina. Quality related topics (CAPA Program, Incoming Quality Assurance) will be presented. There will be opportunities to network and ask questions of the presenters and colleagues attending the meeting. The meeting is also an ideal opportunity for those who are not able to attend large vendor shows at association annual meetings to meet and talk with exhibitors to learn about new technologies or ways to improve processes. If you are interested in knowing which exhibitors previously participated, see the November 2002 newsletter posted on the website (pdase.org). Refer to the registration form enclosed in this newsletter for additional information. We hope to see you at the show!

The Fall Meeting and Exhibits Show will be the last planned event for the Chapter in 2003. However, we have already made plans to hold a joint meeting with the North Carolina Pharmaceutical Discussion Group in January to talk about Part 11 Compliance. Mark your calendars for January 13, 2004. The event will be a

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dinner meeting held at the Embassy Suites in Cary, North Carolina. Additional information will be available on the PDA Southeast Chapter website at pdase.org or contact Lisa Eklund at 919-553-3831, ext. 1901 or Terri Polson at 919-483-5790.

Finally, the Chapter will be holding elections for officers in the next few months. Elected offices include the President, Vice President, Treasurer, and Secretary. In order to hold an elected office, you must be a member of the PDA. If you are interested in participating as an officer or as a committee chair or member please let me know. You do not have to be a member of the national organization to be a member of the Chapter or to participate on a committee. The Chapter can always use volunteers. See you in September.

Mary

2003 Golf Event

Written by Terri Polson, Special Events Chair

The Annual Southeast Chapter Golf Social was held June 6 at Hedingham Golf Course in Raleigh. It was a perfect day to be outdoors, meeting and networking with other Chapter members, chasing the little white ball around to qualify for some amazing prizes and give-aways, and enjoying a catered bar-b-que and fried chicken dinner. Prizes were awarded to the following teams/individuals:

Best Effort
David Brande, Contamination Control Technology
Erin Raney, Prudential Clean Rooms
Tony Pavell, Cardinal Health
Samir Patel, Sequence

Lowest Score
Todd Pruden, Steris
David Jordan, Honeywell
Mary Carver, Eisai
Steve Ferguson, Steris

Longest Drive, women	Terri Polson, Mary Carver
Longest Drive, men	Keith Gibbs, Todd Pruden
Closest to Pin, women	Betsy Jonas
Closest to Pin, men	Tony Cripe, Steve Podolski
Closest to Pin, men or women	Jeremy Fairchild
Straightest Drive, women	Elizabeth Knott
Straightest Drive, men	John Adams
Longest putt, women	Mary Carver
Longest putt, men	Kevin Ehlert
Shortest drive, women	Erin Raney
Shortest drive, men	Frank Golden

A very special 'thank you' to the sponsors for this years tournament, without whom this event would not be possible:

Accugenix
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Fisher Scientific
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MKCS,Inc
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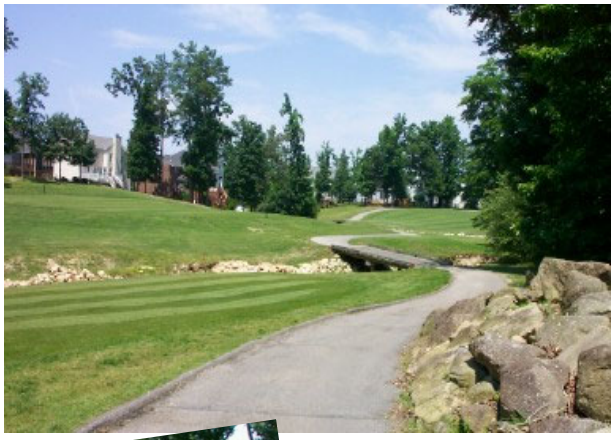
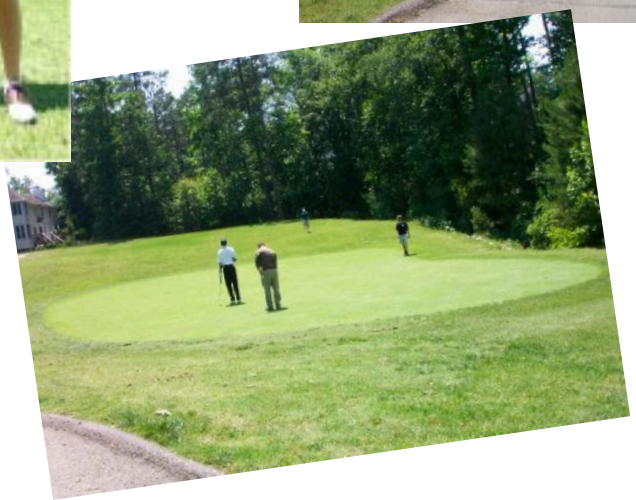
Golf 2003





PDA-SE Chapter Teams Up with NCPDG for Joint Meeting and Dinner

The local Chapter of PDA and the NC Pharmaceutical Discussion Group are planning a joint dinner and meeting, Tuesday, January 13, 2004. Details are as follows:

"Software Solutions to Meet Part 11 Requirements in Pharmaceutical Manufacturing"

Tuesday, January 13, 2004

Embassy Suites, off Harrison Ave, Cary, NC

Keynote Speaker
John McKinney - President and co-founder of SEC Associates, Inc. and former member of the PDA Task Group on 21 CFR Part 11

Format
Presentation by John McKinney on recent Part 11 changes and the use of software to address Part 11 requirements
Panel discussion which will include a Part 11 software vendor, a pharmaceutical consultant on Part 11, and a pharmaceutical company representative; audience participation is encouraged

Panelists
Greg Catgart, PTC (vendor)
John Davis, Serentec (consultant)
Tony Pavell, Cardinal Health (industry)

Cocktails & Reception	6:00-6:30pm
Dinner	6:30-7:30pm
Program	7:30-9:00pm

NOTE: Attendance is limited to the first 75 registrants so mark this date on your calendar and look for registration information in October.

Developing SOPs for Pharmaceutical Environments

Written by Gregory Davenport, Pharmaceutical Validation Consultant with Lloyd's Register Serentec

INTRODUCTION

Having worked in regulated environments from anti-tank systems operations to validation of pharmaceutical systems, I know well the importance of SOPs (Standard Operating Procedures) related to pharmaceutical manufacturing. SOPs define methods for task performance, standardized task performance, forms the basis for task training, provides an information tool to support users, and fulfill FDA regulatory (cGMP) requirement.

SOPs are essential to the activities in a manufacturing facility or pilot plant, and are required for all critical operations in the pharmaceutical manufacturing process. The requirement for written standard operating procedures in our industry is found in 21CFR 211, including the following:

Subpart F-Production and Process Controls § 211.100
"Written procedures; deviations. a) There shall be written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess. Such procedures shall include all requirements in this subpart. These written procedures, including any changes, shall be drafted, reviewed, and approved by the appropriate organizational units and reviewed and approved by the quality control unit. b) Written production and process control procedures shall be followed in the execution of the various production and process control functions and shall be documented at the time of performance. Any deviation from the written procedures shall be recorded and justified."

Yet many of us have experienced multiple problems involved with SOPs and their application. They change frequently, are not always followed, take too long to review and approve, are inconsistent and vary from department to department, are rarely written for end users, are not detailed enough or are too detailed, don't define how a job is really done, and . . . the list can continue. Procedures are more than simply functional documents that define the what and how of a task. Procedures are the results of a process that includes generation, review, approval, implementation, distribution, maintenance, and control. Many of the procedural problems I listed above have their roots in activities that are inadequate or improperly controlled.

Planning how SOPs look and how they are to be written is an important preliminary task for SOP documentation. This plan will direct what your company's procedures will look like and how they are to be written. "Templates" cover more than just the appearance of the procedure; they need to include a site wide agreement of standard content. Once these issues are resolved and agreed on, the generating, reviewing, and approving of a procedure will go much faster. Additionally, the resulting SOPs will be easier to use in training and will contribute to better, more consistent performance.

There are three main types of pharmaceutical SOPs:

1. Administrative tasks (rules or rule-based, such as who has permission to enter a particular secure physical or virtual area)
2. Cognitive tasks (a decision-making activity, for instance, reviewing Calibration Records)

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3. Motor tasks (task specific activities, such as setting up a Bioreactor for operation)

These tasks usually have some overlap.

In this article I intend to address SOP development in five stages: 1) Preliminary tasks, 2) Determining SOP scope, 3) Deciding SOP Detail, 4) Generating a Procedure, and 5) Review and Approval.

1. Preliminary Tasks

Before writing SOPs, consider what procedures are needed, what procedures have already been written, the type and amount of training intended for users, user experiences and characteristics, and that SOPs ensure the quality of their staff - i.e., staff is knowledgeable about obligations, regulations and responsibilities, and how the SOPs will be used in "real scenarios."

A two-tiered system for procedure documentation is recommended. First create procedural guidelines that provide a brief overview of task requirement completion. Second create a SOP(s) with detailed performance criteria to execute identified tasks. Guidelines provide general overviews of task instruction and can be easily amended, reviewed, and approved in one functional area, and then point to existing SOPs for various site operations. Whereas an SOP can require an extended delivery period due to revision of task specific details written in the SOP, and the multiple department reviews and approvals required.

Because the amount of applications can be prolific when determining which SOPs are needed, creation of a SOP on SOPs is suggested. This may sound odd, but direction should be provided for SOPs: when to review them, levels of responsibility, approval procedure, and retention period. Another concern is how internal evaluation and audits of SOPs will be conducted and what response will occur from findings.

Use an ascending order when writing SOPs:

- Develop a guideline and test it to ensure it meets relevant requirements and regulations.
- Once the guideline is finalized, write the SOP
- Identify the main steps
- Add details and specifics
- Do checks and reviews
- Formalize the SOP by having someone sign off on the document

An SOP can have more than one guideline, for instance an SOP on calibration of liquid flow measurement systems may have directions for system set up and operation, and attached to that document, a separate guideline for out of tolerance findings.

When the SOPs are finalized, employees need training in reference to what the procedures are, what action is expected of them, and when the SOPs will be in effect. SOPs will not be effective if personnel do not know how to use them. After SOP implementation, departmental reviews should be scheduled to ensure personnel are following them correctly, and identify whether or not an SOP requires updating.

Version control is important to explain why a change occurred the way it did. The most effective way to do this is keep file copies of SOPs with the date stamp for approved use. When the FDA comes in for an inspection, they may ask for SOPs on operations for a product three years ago, more than likely SOPs have changed in this time.

2. Determining SOP scope

Determining where an SOP is needed can be identified by creating flow charts in operational areas identifying processes involved and tasks within processes. These tasks become an initial list of procedure titles. The SOPs written will define how tasks are to be performed. If procedures already exist, they can be mapped to the identified tasks. Comparing flow charts or titles between function areas can identify where common procedures, which aids in standardization.

When uncertain if an SOP is required, consider these questions: a) Is the task or activity important? b) Is more than one person involved? c) Does the task or process affect the safety, identity, strength, purity, or quality of the product? d) Does the task need to be done consistently? If the answer is "yes" to any of those questions, procedures should be written.

Determining the breadth of an SOP needed depends on whether a procedure describes a process with many tasks (performed by various people in multiple departments) or whether the procedure defines one task and the steps needed to accomplish that particular task. On occasion specific types of task functional documents may be called *work instructions* to provide details on how one person accomplishes his or her job. Some facilities in industry may distinguish between SOPs and *work instructions*. Whatever the functional document is called, it must be well constructed to support actual performance defined.

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Definition of a general hierarchy of procedures that follow from corporate policy is acceptable. As the procedures get more localized, they will focus more on how a department or area operates. For example, large multinational company may have the following policies and procedures that go from general to more specific:

- Corporate Quality Policy: Sterility Assurance (Level 1)
- Corporate Procedure: Use of Media Fills in Aseptic Drug Product Filling (Level 2)
- Site Procedure: CIP and SIP Validation for Aseptic Products Processing (Level 3).

Industry practices and preferences may differ, but a good practice is to have procedures covering the related tasks that one person (or one team) does at a particular time. For example, a SOP for production bioreactors functionality can define specific tasks in a manufacturing environment. The related tasks could include set-up, operation, disassembly, cleaning, troubleshooting, calibration, and preventative maintenance.

An individual SOP for each task can be written, or one procedure drafted covering all tasks. Grouping tasks to be completed by one team or individual during "normal" operations (for example, set-up, operation, disassembly, and cleaning) is a viable path. The remaining tasks (troubleshooting, calibration, and preventative maintenance) can be written as separate SOPs. A right or wrong way does not exist for this aspect of procedure development. In my experience, smaller, shorter procedures are easier to develop and maintain, but you end up with more of them. I have discovered that users find several two to six-page procedures less intimidating than one 50-page procedural document.

Identify who will use the procedure. *Primary users* are those who perform the tasks defined; *secondary audiences* are those who need to know something about the procedure but do not directly use it. Who are your primary users? Are they experienced? Is your work force stable in its turnover and hiring? What is the reading level of work personnel? How will staff actually use the documents? Will workers have the procedure open in their work areas (a standard practice with laboratory methods), or will they use it only as a reference

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(a customary practice in manufacturing environments). How frequently will users perform the task? How much training will they be given? The answers to these questions shape the amount of detail contained in your procedure.

3. Deciding SOP detail.

A major decision to make before writing any SOP (or before revising a procedure system) is defining the level of detail that should be met. The minimum amount of detail in a procedure should include the "critical *whats*" (the required steps defining what is to happen), the "critical *hows*" (the substeps defining how each step is to be performed), and when applicable, the "*whos*" (that is, who performs those steps and substeps) if more than one person is involved. *Criticality* is defined as that which is necessary for a performer to be successful in accomplishing the goal of the procedure. In part, criticality depends on the performer's training, experience, and education. As the detail level increases (along with the length of the document), the definition of criticality widens. For SOPs with "high" levels of detail, less critical "*hows*" are included.

Risks exist by using high levels of detail. These procedures can be hard to read and follow. They can also be unforgiving: If one of the very fine details changes, the procedure is technically wrong. The challenge exists to create a useful document that defines the process or task only to the necessary level of standardization.

All SOPs throughout the company do not need the same level of detail; a reasonable consideration is writing to user needs. Different sites or departments may have different needs. Companies that write work instructions typically focus on a particular task and the particular person (or job position) responsible for that task.

4. Generating a Procedure

With the preliminaries completed, you know which processes or tasks need to be defined by SOPs and for whom they are intended, the level of detail needed, and the format to be used. You are ready to begin writing. Sitting in front of a fresh piece of paper or before a blank computer screen is intimidating. Where you do start? "Writing comes more easily if you have something to say."

Before writing a procedure, create a sketch that includes a simple flow chart, a telegraphic description of what is done at each step, the critical hows, when the step is performed (the "cue"), any specifications that need to be met, and any warnings, cautions, or notes. An SOP can be written easily from that sketch using an approved corporate documentation template. An advantage is gained by creating a procedural sketch with personnel most familiar with the process or task - the subject matter experts (SMEs). Once the sketch is completed, a skilled writer can easily and quickly write the procedure.

Style issues are a concern when writing an SOP: How many words do you use? Narrative statements - with lots of words - can be difficult to work with. Actions or requirements are typically buried in such statements. Remember, when in the review and approval process, more words provide more interpretations for people to present and dispute. Writing in clear, active tense is best. Telegraphic wording (i.e., sentence structures that initiate with an action) is useful. Most writers are familiar with the rule of thumb that suggests using active verbs to begin sentences (for example, "Disassemble the product feed tray"). Studies have shown that when reading, we look at the first several words, skip over the middle, look for the period mark, and then, going backward from the period, read the last three to four words in the sentence. Procedure writers can use this information to their advantage by placing important information for SOPs at the start or at the end of statements.

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Use ranges whenever possible. Consider this procedural example: "Adjust gas flow to a target of 5.0 SLPM (+/- 0.5 SLPM)", noting the allowable range in parentheses to reduce deviations. If ranges are used, be sure that they are consistent with the registrations, approvals, and validation studies. SOP users also need sequence flexibility in procedures. When it is appropriate, use bullet points instead of numbers or letters. Numbers or letters indicate a sequence definition that the steps should be performed in that order. Bullet points, on the other hand, indicate the absence of hierarchy or sequence. An alternative is to put a note above the numbered or bulleted steps ("Note: the following three steps can be performed in any sequence").

Once the draft procedure is written, prior to distribution for "formal" review, approval, and implementation, a "peer" review should be executed. I have found that sites, which are ISO-9000 regulated, call this exercise "validating" draft procedures, but in the pharmaceutical industry, while attention to detail during procedures review is required, it is a much less rigorous task than cGMP validation. It can be as simple as showing the SOP to others performing the task, or talking through the steps in a small group of three or four people. The goal is to ensure the draft document is complete, correct, and achievable. Taking these steps can assist facilitation of document formal review.

5. Review and Approval

As mentioned earlier, when draft procedures emerge from the generation phase, they are ready for review - typically two types of review, peer and formal. In *peer reviews,* someone (it doesn't have to be a content expert) looks at the draft document to be sure it looks right; that it has proper spelling and grammar, a unique title and number, all the pages and attachments are present, etc. Next comes the *formal review*, which does require expertise from Subject Matter Experts, or an individual with the specific knowledge base to verify the document meets expected criteria.

This would include the quality assurance, validation, and regulatory affairs departments and other departments as appropriate. A key to rapid, effective reviews is to make sure all reviewers know the style and level of detail required and also know the specific things to look for during their review. Having those criteria assigned (perhaps in your "Procedure on Procedures") minimizes the chance that something will fall through the cracks or that everyone will be a wordsmith. (Also, if the SOP was written in a telegraphic fashion using fewer words, fewer words will be worked over.)

The direction I have provided may not be a cure all for procedural documentation problems experienced globally. Yet by taking the suggested time to identify procedural objectives, determine procedural scope, determine procedural details, generating unambiguous procedural traceability, and using a rational method for procedure review and approval will help avoid creating documents that are inadequate or improperly written prior to implementation. A theme that repeats itself throughout GMPs for the United States, Canada, and the European Union is: "There shall be written procedures for . . ." Any one who has spent time developing, using, and maintaining documented procedures in a pharmaceutical environment, knows well that proper documented procedures are a constant for regulated compliance.

About the Author: Gregory Davenport is a Pharmaceutical Validation Consultant with Lloyd's Register Serentec. Greg has a Bachelor of Science Degree in Information Systems Management. He has over 12 years combined regulated environment experience in Manufacturing Quality Engineering, ISO-9000 System Assessment, QS-9000 System Assessment and Pharmaceutical Computer/ Automated Systems Validation. Phone: (252) 916-2947 or E-Mail: greg_davenport@serentec.com

PDA Southeast Chapter 2003 Calendar

Tuesday, September 23, 2003, PDA Southeast Chapter Fall Meeting and Exhibit Show, McKimmon Training and Conference Center (NEW LOCATION), Raleigh (Off Western Blvd. near NCSU). Registrations Forms are available at pdase.org.

Directions: From I-40 traveling east from airport. Take Gorman Street Exit #295. Turn left onto Gorman Street. Go apporoximately 1 mile. McKimmon Center is on the right past Avent Ferry Rd. before Western Blvd.

From I-40 traveling west. Take Gorman Street Exit #295. Turn right onto Gorman Street. Go approximately 1 mile. McKimmon Center is on right past Avent Ferry Rd. before Western Blvd.

FDA INTELLIGENCE REPORT (April –June 2003)

Compiled by Gregory Davenport, a Validation Specialist with Lloyd's Register Serentec, Raleigh, NC.
For the latest on industry events visit: http://www.fda.gov/.

APRIL 2003:

Proposed rule for bar codes on drugs is not intended to induce manufacturers to package their solid-dosage products in unit-dose blister packs. To see the proposed rule published in March Visit - http://www.fda.gov/OHRMS/DOCKETS/98fr/03-5205.pdf - . . . Due to the challenges of regulating drug compounding and growth in that industry, the FDA is revising a draft compliance guide on the matter released last May and plans to reissue it for comment. . . It has been announced that Final 21 CFR Part 11 guidance will be released in July. The FDA has promised a narrower interpretation of the original Part 11 guidance withdrawn. . . FDA extended until June 15 the comment period for its draft guidance on marketing applications submission under the International Conference on Harmonization (ICH) Common Technical Document (CTD) format. . . Concerned the FDA could soon allow generic biologics, the biotech industry urged the agency to refrain from approving generic applications. . . The Biotechnology Industry Organization (BIO) called for debate on the scientific, legal and policy questions concerning generic biologics. The organization requested a withdrawal of the 1999 draft guidance allowing generic approvals under the 505(b)(2) statute. . .

MAY 2003:

The FDA could require drug manufacturers to place bar codes directly on tablets because the technology to do so exists. . . Biotech companies with clinical trial using novel or unorthodox approaches for study or analysis, the agency company may seek external help if they doubt the FDA has the internal expertise to evaluate clinical study protocols, however consultants will only review studies that serve as the primary basis of an efficacy claim. . . Both a draft guidance and a pilot program for dispute resolution within current good manufacturing practices guidelines soon to be released. CDER acknowledges the pilot program and guidance will require a great deal of industry input. . . Drug manufacturers seeking approval in Europe would face a single, standardized, FDA-like process under a innovative European Union (E.U.) proposal recently implemented. . . The FDA, PhRMA and the Institute for Safe Medication Practices to discuss tools the industry could use to reduce medication errors resulting from drugs having look-alike or sound-alike names. . .

JUNE 2003:

The FDA agreed to give drug manufacturers more time to comment on a proposed rule to streamline pre- and postmarketing safety reporting regulations, bringing the U.S. in line with international guidelines. In a proposed rule, released March, the agency said it wanted drug firms to report serious suspected adverse reactions and turn over reports of actual or "near-miss" medication errors within 15 days of the event. Responding to requests for extra time from industry, the agency extended the comment period to Oct. . . The FDA to consolidate the therapeutic review functions of the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER). A website update by CBER is expected this month with the identification numbers of investigational new drug applications, biologics license applications and new drug applications that will be transferred – visit: http://www.fda.gov/cber/. . . A bipartisan group of senators unveiled a patent reform plan that includes a provision to let generic drugmakers countersue brand firms to remove patents from the FDA's Orange Book. The generic drug bill, S. 812, including limiting brand firms to one 30-month stay when they sue a generic firm over a patent challenge. The bill passed overwhelmingly in the Senate but never made it out of a House committee . . .

PDA

Southeast Chapter 2003 Fall Exhibitor Show & Meeting

Southeast Chapter

Tuesday, September 23, 2003
9:30 am-4:00 pm

McKimmon Conference and Training Center

Join PDA Southeast Chapter for our Fall 2003 Exhibitor Show and Meeting at the McKimmon Conference and Training Center, Raleigh, North Carolina. The event will be held Tuesday, September 23, 2003. Registration begins at 9:30 AM and the day concludes at 4:00 PM.

About Our Topics

CAPA - Effective Management of Deviations

CAPA is the FDA acronym for "Corrective Action & Preventative Action". In the pharmaceutical industry, this is how we in Quality Assurance all want things to work. When a deviation occurs, it is appropriately investigated, corrected, and preventative measures implemented so that it never happens again. All deviations associated with the manufacture and support of the GMP products can be readily tracked, reviewed, trended, and QA can be assured that action has been taken appropriately and in a timely fashion.

It seems fairly simple, but why is it so difficult to achieve? Consistently?

Deviation reporting has developed over the years and pharmaceutical companies have developed their internal methodologies with the changing industry. Consequently, SOPs have been revised, added to, and replaced, and little time has been devoted to evaluating the entire process from beginning to end.

In this interactive presentation we will discuss the problems with the "management" or "mismanagement" of deviation reporting, and more importantly, some of the solutions that have been proven towork.

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

Ronnie Brooks will be addressing the differences in GMP vs. non-GMP for packaging inspection of raw materials, particulate reduction, and sampling. There is value of cGMP manufactured raw materials vs. Non-GMP manufactured raw materials for use in the Pharmaceutical industry. Mr. Brooks will address the issues of impurities, possible origination and types of impurities. His interactive presentation will discuss the acceptance criteria for raw materials, acceptable limits, and particulates found in raw materials. These are all issues currently concerning the pharmaceutical and biotech industry.

Schedule of Events

9:30 am	Registration
9:30 am	Exhibitor Show Area Opens (Continental Breakfast in Exhibit Hall)
10:30 am	PDA SOUTHEAST CHAPTER Business Meeting
11:00	CAPA - Effective Management of Deviations *Carol Brandt*
12:00	Lunch (Rm. 2 a, b, & c) With Dessert in Exhibitor Area
1:30 pm	Impurities Found in GMP Raw Materials For Use in the Pharmaceutical and Biotech Industry Does your company know the difference between GMP vs. non-GMP when addressing raw material issues? *Ronnie Brooks*
3:00 pm	Refreshments in the Exhibit Hall
3:30 pm	Door Prizes Awarded
4:00 pm	Exhibitor Show Closes

Registration Form (please print)

Name _____
Your first name as you wish it to appear on your nametag

_____

Address _____

Firm/Company _____

City, State, Zip _____

Phone _____ Fax _____

Email _____

Registration Fee:
Before September 5, 2003 $75 per person (includes lunch)
After September 5, 2003 $100 per person (includes lunch)

_____ *No. of people x $75.00 each=* _____
_____ *No. of people x $100.00 each=* _____

TOTAL ENCLOSED _____
(Please feel free to make multiple copies of this registration form)

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Deadline: **September 5, 2003**

Questions ? Contact: Diane S. Williams, Event Planner
phone: 919.463.0615 fax: 919.463.0588
Email: proflink@bellsouth.net
www.PDASE.org

If you are interested in being an exhibitor, please contact Diane Williams at proflink@bellsouth.net

About Our Speakers

Carol Brandt- CAPA - Effective Management of Deviations

Carol Brandt is the director of life sciences at Clarkston Consulting, a nationally recognized management and technology consulting firm that has worked with many of the world's top pharmaceutical companies. She has served as the Vice President of Quality Assurance for a major pharmaceutical contract manufacturer and has worked for Glaxo Wellcome (GSK), Haemonetics Corporation, and Bayer Corporation.

Ms. Brandt is an accomplished writer. She is the author of several white papers including Agency Response and CAPA: A Reference Paper and Computer Systems Validation and Compliance. She has also written articles appearing in industry publications such as Contract Pharma and Pharmaceutical Technology.

Ms. Brandt received a M.S. in Analytical Chemistry from Purdue University and a B.A. in Chemistry from Chatham College in Pittsburgh, PA.

Ronnie Brooks- Impurities Found in GMP Raw Materials for Use in the Pharmaceutical and Biotech Industry

Ronnie Brooks has 14 years of experience in Quality Assurance and 8 years of experience in the Diagnostic Field. Currently he plays an important role in Quality Assurance for Mallinckrodt Baker Incorporated.His current job responsibilities include cGMP and ISO Training, Compliance, Quality Auditing, Product Release, Supplier Assessment/Approval and Validation. Mr. Brooks works with Product Impurity Projects specifically relating to repackaging and manufacturing impurities.

Directions to the McKimmon Conference and Training Center

Directions: From I-40 traveling east from airport. Take Gorman Street Exit #295. Turn left onto Gorman Street. Go apporoximately 1 mile. McKimmon Center is on the right past Avent Ferry Rd. before Western Blvd.

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