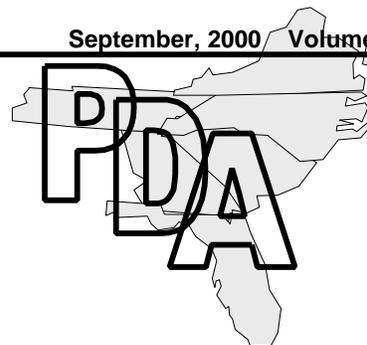


NEWSLETTER

**Editors:**

Catherine Cates, AAI
Robert Guardino, AAI
Cindy Smith, Serentec, Inc.

State Affiliations:

Virginia
North Carolina
South Carolina
Tennessee
Georgia
Florida

SOUTHEAST CHAPTER

<http://www.pdase.org>

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PRESIDENT'S CORNER

Bill Jones

President, PDA Southeast Chapter

The PDA Southeast Chapter will hold its second meeting of the year on October 31 (Halloween) at the Sheraton Imperial Hotel and Convention Center located in RTP, North Carolina. This meeting will feature our "Annual Vendor Show". It will be our third, "Annual Vendor Show". In keeping with the season, the theme of the meeting will be, "What Issues **Scare** You the Most in Manufacturing in Today's Pharmaceutical Industry." This meeting is typically our highlight meeting of the year. It will provide us with an excellent opportunity to hear and learn from technical, scientific, and regulatory industry experts. Additionally, it will allow us a unique opportunity to view technical demonstrations and talk with our vendors. We expect to have over 30 vendors present at this show. You really don't want to miss this Annual Event. We are planning to have door prize drawings during the Vendor show. It promises to be a real **treat!!** What an excellent opportunity to hear and learn from technical and scientific presentations as well as a chance to meet and talk with our vendors. We are expecting a full meeting, so please register early.

As always, we need your continued feedback, help, and participation in chapter activities and on project committees. If you are interested in serving on a committee or want to provide input, then please contact me at the following: Phone No. (919-359-7906) or email (William.Jones.B@Bayer.com). Please send me an email and let me know how we are doing and what we can do differently or better. We welcome your suggestions and input.

Again, thanks for your support and we hope to see you at our Annual Vendor show on Oct. 31 (Halloween) at the Sheraton Imperial Hotel and Convention Center located in RTP, North Carolina.

PROGRAM COMMITTEE UPDATE

Lisa Eklund and Teresa Frisone

We would like to thank all of you who took the time to fill out the questionnaire at the last SE Chapter of the PDA meeting. It has helped us as we look forward to upcoming meetings in 2001. We are always looking for people to join our committee. We would welcome any of you to assist us in selecting speakers and/or topics. Your assistance would be greatly appreciated. We are constantly looking for speakers for upcoming

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meetings. If you are interested in presenting or if you have heard any speakers at other meetings that you would like to hear at a SE Chapter of the PDA meeting please let us know. We would like thank those individuals who have volunteered to serve on the committee and/or speak at an upcoming meeting. Please forward any ideas or suggestions to us. Your input is welcomed. Thanks, Teresa Frisone, 800/645-5476, ext. 6137 and Lisa Eklund, 919/553.3831, ext. 1901.

HOLOPACK INTERNATIONAL SETS UP SHOP IN SOUTH CAROLINA

By Don Eddington

South Carolina has a great business environment and the state is well known for the business management support provided by state and local officials. The business climate in South Carolina has been very successful in attracting innovative international businesses. The 246 acre Carolina Research Park near Columbia is home to Holopack International, a rapidly growing contract pharmaceutical manufacturing facility.

Holopack utilizes state-of-the-art Blow/Fill/Seal packaging equipment that produces hermetically sealed containers in a single automatic operation. In many cases, these are ophthalmic products that can not be autoclaved. The Blow/Fill/Seal process works extremely well as an aseptic process because the product container and closure system is molded almost at the same instant it is filled with product, all without human intervention.

Holopack International received FDA approval for processing at the Colombia location in 1997. The company already had a very long track record of pharmaceutical

packaging in Europe, where they are related to the German-based Holopack Verpackungstech, GmbH, which opened in 1975, and the Swiss-based Maropack, which opened in 1980. Together the three companies produce over one million containers per day for customers all over the world.

The varieties of design and closure systems for individual containers or multi block packages of unit doses are remarkably complex. Pharmaceutical companies can rely on specialized contract facilities that can meet their high standards and have experience with the intricacies of packaging design. This can result in a cost-effective way of rapidly bringing new products to market.

Holopack initially installed two packaging lines. Immediately after getting those lines in production, two more were planned, with even more to follow. Eventually, Holopack International is expected to employ about 200 people at the Columbia location.

JOIN THE SOUTHEAST CHAPTER OF THE PDA!

MEMBERSHIP IS FREE!!

Anyone interested in joining the PDA Southeast Chapter should contact:

Susan Moore
Millipore Corporation
Phone #: (800) 645-5476 ext. 6929
Fax #: (919) 831-2349
E-mail: susan_moore@millipore.com

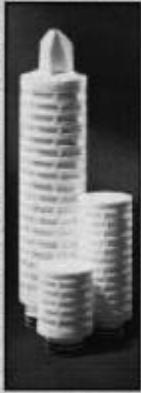
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**ATTENTION
ISOLATOR USERS:**
The PDA Southeast Chapter
is interested in forming an
Isolation Technology
Interest Group Committee

The committee will be responsible for preparing topics and/or leading discussions on isolation/barrier technology at chapter meetings. We would like to provide this networking and educational opportunity for those interested in isolation technology but we need your help to do so. If you are interested in serving on this committee, please contact Jennifer Rayner at Jennifer_Raynor@Serentec.com or 919-831-1166 or Mary Carver at mary_carver@eisai.com or at 919-474-2149.



PDA Southeast Chapter Officers, Committee Chairs and Contacts

President - Bill Jones	(919) 359-7906	William.Jones.B@Bayer.com
Vice-President - Mary Carver	(919) 474-2149	Mary_Carver@eisai.com
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Program Chair - Lisa Eklund	(919) 553-3831, ext 1901	lisa eklund@fresenius-kabi.com
Membership Chair - Susan Moore	(800) 645-5476, ext 6929	Susan_Moore@Millipore.com
Communications Chair - Cindy Smith	(252) 756-9611	cindy_smith@serentec.com
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Sponsorship - Jerilin Paith-Kenny	(800) 596-3462, ext 226	jepaith@mindspring.com
Program Co-Chair - Teresa Frisone	(800) 645-5476 ext 6137	Teresa_frisone@millipore.com

S.E. CHAPTER FINANCIAL UPDATE

By John Shirtz, Catalytica
Pharmaceuticals, Inc.

The Southeast PDA Chapter is fiscally sound. We will have some expenditures for door prizes at the Fall meeting.

We are seeking committee members for a PDA Southeast Chapter award. The committee will determine the award criteria and specifications. Contact John Shirtz at (252)707-2848 or jshirtz@catalytica-pharm.com to inquire.

ATTENTION ALL PDASE MEMBERS:

- Do you have technical expertise in any pharmaceutical or GXP area?
- Have you read any recent books relevant to pharmaceutical manufacturing, technology, or regulatory affairs?
- Maybe you know a guru whose expertise and opinions you admire?
- Could it be that you have suggestions, ideas, or opinions regarding the proper performance or treatment of a production, laboratory, regulatory, or manufacturing issue?

- "Best Practices" or "How To" articles describing successful resolution of problems or issues encountered in your daily experience.

Articles of any length are welcome. However, if extensively lengthy items are received, we reserve the right to split the topic into segments for sequential publication. All articles will be reviewed by the editorial staff of the newsletter for relevance and will be accompanied by a disclaimer stating that the author's viewpoint is not necessarily reflective of endorsement by PDASE. These articles should be primarily informational and informal discussions, rather than technical treatises, as this forum is not to be considered a replacement for the function served by the PDA's technical journal. The deadline for submissions is one month prior to the newsletter publication. The publication months for the 2001 issues will be March, June, September, and December.

If this is the case, we of the PDASE Communications Committee want to know! We are actively soliciting items for publication in the 2001 issues of the quarterly newsletter.

These items should be of general relevance to the pharmaceutical industry and to our local membership, and could be in one of several content styles:

- Short technical issues discussion essays, on topics such as validation, sterilization, filtration, calibration, lab methodology, manufacturing issues, or any related area. These could be experiential discussions, or similar to a "points-to-consider" style
- Book reviews
- Question and answer interviews with a knowledgeable person regarding a single, specific topic related to pharmaceutical industry issues

Please contact Rebecca Buede at valwoman@msn.com or anyone on the editorial staff or Communications Committee for further information.

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PDA Southeast Chapter Bulletin Board

The PDA Southeast Chapter Bulletin Board will be available at the October 31st vendor show. Please contact Cindy Smith at cindy_smith@serentec.com or (252)756-9611 to make arrangements to bring your job openings to post on the bulletin board.



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VENDOR/SPONSOR REGISTRATION PDA SOUTHEAST CHAPTER FALL VENDOR SHOW AND MEETING 2000

Exhibits and sponsorships are still available for the upcoming vendor show and meeting. The event will be located at the Sheraton Imperial Hotel in Research Triangle Park, NC on Tuesday, October 31, 2000.

For more information please contact:

Teresa Bradford
Event Coordinator
4092 Barrett Drive
Raleigh, NC 27609
(919) 788-0560 Fax: (919) 788-0480
E-Mail: PDASoutheastchapter@bradfordmarketing.com

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SOUTHEAST CHAPTER

“WHAT SCARES YOU MOST IN TODAY’S PHARMACEUTICAL MANUFACTURING INDUSTRY?”

October 31, 2000

9:30 AM - 4:00 PM

**Sheraton Imperial Hotel & Convention Center
Research Triangle Park, NC**

Join PDA Southeast Chapter for our Fall Vendor Show and Meeting 2000 at the Sheraton Imperial Hotel and Convention Center in RTP, North Carolina. The event will be held Tuesday, October 31, 2000. Registration begins at 9:30 AM and the day concludes at 4:00 PM. In keeping with the theme of the season, the meeting is titled “ What scares you the most in today’s pharmaceutical manufacturing Industry?”

For our out-of-town guests, a block of rooms has been blocked at the nearby Homewood Suites for the night of the 30th. Please call 1-800-225-5466 and identify yourself as a PDA conference participant for a special rate of \$129.00. A full breakfast and complimentary shuttle service to the Sheraton Imperial Hotel and airport is included.

About Our Speakers

ROBERT (BOB) C. COLEMAN joined the FDA in 1972 in the Atlanta District Office as an Investigator. He soon began specializing in inspections of pharmaceutical manufacturers, especially those producing sterile drug products. Bob was promoted to the Atlanta District Drug Specialist position in November 1977. Also in 1977, he joined FDA’s Foreign Inspection Program. Bob was the Atlanta District’s Drug Preapproval Manager until March 1994, when he was selected as a National Expert Drug Investigator. He now works for the Division of Emergency and Investigational Operations of FDA’s Headquarters and is stationed in Atlanta. He has been involved as an instructor in several FDA training courses, including the Orientation to International Inspections, Basic Drug School, and Industrial Sterilization Course for Drugs/Devices. Bob is a native of Atlanta and his wife, Karen, is one of the FDA Medical Device National Experts.

AGILENT TECHNOLOGIES (SPEAKER TBD) will discuss 21CFR part 11: Understanding FDA Requirements for Electronic Records and Signatures.

SCHEDULE OF EVENTS

- 9:30 am Registration
- 10:30 am PDA SOUTHEAST CHAPTER Business Meeting
- 11:00 am Agilent Technologies - 21CFR part 11: Understanding FDA Requirements for Electronic Records and Signatures
- 11:00 am Vendor Show Area Opens
- 12:00 pm Lunch in Crystal Coast Ballroom With Dessert in Vendor Area
- 1:00 pm Bob Coleman, FDA - Current Compliance Issues: Inspectional Issues, OOS/Deviations/ Nonconformances, and Drug GMP Inspections
- 2:00 pm Formal Vendor Show Begins
- 2:30 pm Isolator Users Interest Group/Glove Integrity Testing
- 4:00 pm Vendor Show Ends

REGISTRATION FORM

Name _____

Firm/Company _____

City, State, Zip _____

Phone _____ Fax _____

E-mail _____

Registration fee:
Before October 23, 2000: \$50 per person (Includes lunch)
After October 23, 2000: \$75 per person (Includes lunch)

_____ No. of people x \$50 each = _____

_____ No. of People x \$75 each = _____

TOTAL ENCLOSED: = _____

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

Payment: Check made payable to PDA Southeast Chapter

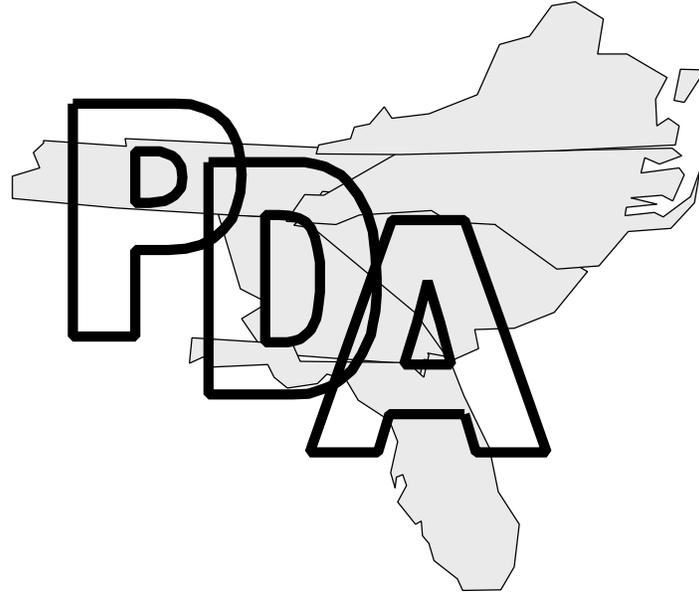
Return this form:

By Mail: PDA Southeast Chapter
4092 Barrett Drive
Raleigh, NC 27609

Deadline: October 23, 2000

Questions: Teresa Bradford, Event Planner
919-788-0560 (Fax: 919-788-0480)

September 2000 Newsletter



SOUTHEAST CHAPTER

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