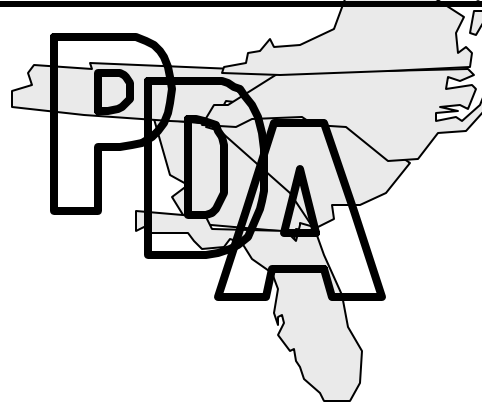


NEWSLETTER



State Affiliations:

Virginia
North Carolina
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Florida

SOUTHEAST CHAPTER

<http://www.pdase.org>

Editors:

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**Developing Chemistry
Into Medicine**

2320 Scientific Park Drive
Wilmington, North Carolina
28405

Message from the President

Well, we did it! We saw the vision and made it happen – TOGETHER. We can now say, with enthusiasm and pride, that there IS a PDA local chapter in the Southeast and it's alive and prospering. We should all be patting ourselves on the back about now because this was no small feat that we've accomplished. The charter members, officers, committee chairs and members, vendors, and sponsors have all contributed over the past two years to help make this vision a reality. But as with all successful endeavors comes transition, and so it is with feelings of both happiness and sorrow that I write my last letter to you as President of the Southeast Chapter. Happiness – because of what we've achieved; sorrow, because I have truly cherished the trust and faith you put in me when you elected me as your President two years ago and so this represents the end of something that's been very special to me. Certainly a technical organization should be about professional development, but all of the people whom I have met and worked with are what have made this such a wonderful experience for me. However, we must continue to look to the future because the continued success of our creation is riding on our continued vision and commitment. The recent elections have brought new officers with new ideas and fresh enthusiasm to mesh with those former officers and committee chairs that are continuing on as members of the Chapter Executive Committee. We are solvent, we have good leadership, and we have committed members and sponsors – all the ingredients for continued success. And that's what I wish for you and this organization.

Thank you for the privilege of serving as your President, and best wishes for your continued success.

Terri Polson
President, PDA Southeast Chapter

THE RESULTS ARE IN! **PDA Southeast Chapter Officers Elected**

As the new millenium begins, the PDA Southeast Chapter will welcome new officers for the upcoming term January 1, 2000-December 31, 2001.

Bill Jones, Manager of Validation and Metrology at Covance Biotechnology, will be the Chapter's new President. Bill has over 20 years combined experience in the pharmaceutical, biological, and biotechnology industries with approximately 15 years in a supervisory/management capacity. He was a charter member of the PDA Southeast Chapter and served as Vice President during the last term.

The new Vice President will be Mary Carver, Microbiology Research Scientist at Eisai Pharmaceuticals. Mary has worked in the medical device/pharmaceutical industries for the past 14 years primarily in microbiology and quality control. She has been a member of the national PDA organization since 1991 and has served as Chairperson of

the Membership Committee since the inception of the Southeast Chapter.

Kim Hughes, Senior Microbiology Scientist at Glaxo Wellcome, will be the Chapter's new Secretary. Kim has 10 years of experience in pharmaceutical microbiology working in both commercial operations and R&D. Her background includes validation and auditing and managing the product testing/release function. Kim has helped with the Chapter Newsletter and attends many of the local chapter meetings.

John Shirtz, Manager of QC Microbiology at Catalytica Pharmaceuticals was re-elected as Treasurer. A charter member of the Southeast Chapter, John was selected as Treasurer in the inaugural election. He has over 30 years experience in the pharmaceutical industry, including positions at Bristol Myers, Burroughs Wellcome, and Glaxo Wellcome.

PRESENTATION HIGHLIGHTS: PDA Southeast Chapter 1999 Fall Meeting and VendorExhibit

Cindy Smith, Serentec, Inc.

"Strategies for Streamlining Validation" was presented by Mr. James Agalloco, President of Agalloco & Associates in Somerville, NJ. "Validation never used to be so hard!". Three validation problems were discussed: Ensuring Compliance, Time to Market, and Resource Limitations. These problems can be minimized by applying a combination of "sound science, proven engineering principals, and a healthy dose of common sense."

Ensuring compliance can be achieved by maintaining a cGMP compliant facility (including setting higher standards for training, vendors/suppliers/contractors), developing working relationships with inspectors and compliance officers including honoring commitments and respecting their concerns. Seek input early from these agents when problems

arise or compliance strategies need to be formed.

Reducing time to market can be accomplished by some standard administrative and team skills. Thoroughly planning activities and enhancing communication skills are essential. Plan for the mistakes that could happen given a worst case scenario. Demand as much technological information from R&D as possible. Planning is much easier if all the variables are covered. Standardize procedures for production and quality control. If time to market is essential, changing suppliers for production equipment or introducing new technology into the process may need to wait. Accepting reasonable risk is important. Track the progress of the activities and then be flexible. Determine which activities can be integrated. Can IQ/OQ be done in one document to minimize the number of documents being reviewed for example?

Resource limitations require reviewing the process to focus only on value-added activities. Avoid excess paperwork! Use pictures and tables whenever possible. The effort needed to create these tools will be well worth the effort if they are used to communicate clearly with other project members. Outsource or contract activities when necessary and when possible in order to share the workload. Only use reliable and reputable outside sources and be cautious of hidden costs, etc. Look for ways to restructure the project timeline.

Mr. Agalloco may be contacted by e-mail at Jagalloco@aol.com. His presentation and other information are available at www.hometown.aol.com/Jagalloco.

"Educational Opportunities in Biotechnology" was presented by Dr. Michael Korczynski, from the PDA Training & Research Institute (PDA-TRI), Baltimore, Maryland. Since the introduction of the first genetically engineered product in 1982 (Humulin™) a transitioning of educational requirements is needed in the pharmaceutical industry. By the year 2000, 50 percent of pharmaceutical products will be biotech derived covering an array of disease states. The future trend includes treating diseases on the molecular level. This trend includes gene therapy as genetic sequencing is

discovered for various disease states. PDA-TRI and East Carolina University (ECU) have jointly developed a program designed to meet the interests and needs of the pharmaceutical/biopharmaceutical industry. If this initial course series is successful, then a training program designed to certify biotechnologists would be offered. The initial courses to be offered are Introduction to Biotechnology, January 12-14, 2000, Introduction to Basic Laboratory Techniques and Methods in Biotechnology, February 8-10, 2000, and Understanding Genomics, March 15-16, 2000.

Dr. Korczynski is the Vice President and Director of Education at the PDA-TRI. To request more information, contact Dr. Korczynski by e-mail mikkor@pda.org or by phone at (410) 455-5800.

SOUTHEAST ISOLATION TECHNOLOGY GROUP (SITUG)

The chapter affiliation with the Isolator Users Group was presented by Jennifer Raynor. This is the first discussion group for the PDA Southeast Chapter and it generated a lot of interest among the meeting attendees. Some of the issues addressed by this User's Group are: regulatory expectations, validation, environmental monitoring, and investigations. If you wish to join this group or would like more information, please contact Jennifer Raynor at Doe & Ingalls, Durham, NC (919)598-1986 extension 232.

BUSINESS MEETING HIGHLIGHTS:

PDA Southeast Chapter 1999 Fall Meeting and Vendor Exhibit

Cindy Smith, Serentec, Inc.
Committee Reports:

Financial Committee, John Shirtz (via Terri Polson). The PDA Southeast Chapter annual report will include the chapter financial statement, but the chapter is in the black after a 2-year struggle for start-up.

Communication Committee, Lucia Clontz. The committee goal is to publish the newsletter 4 times a year. We need other people to participate on the committee and to contribute to the newsletter. We would like a very active committee to continue to grow and develop not only the newsletter but the website. Please contact Lucia (jlclontz@email.msn.com) or Cindy Smith (cindy_smith@serentec.com) to share ideas. Membership Committee, Mary Carver (via Terri Polson). Many thanks to Mary Carver and the committee members for all their help in writing and distributing (folding, mailing, etc.) the vendor show flyer. All mailings except the newsletter goes through this committee. The mailing list is also updated and maintained.

Program Committee, Norma Noble (via Terri Polson). This was the last meeting of 1999. Committee members are needed and also a chairperson. Norma is stepping down to pass the baton to a willing and capable colleague. Could this be you?

Elections Committee, Kevin Miller (via Terri Polson). See the results posted in this newsletter. Many thanks to the committee members for their hard work in presenting the candidates to the chapter and handling the election process.

ADVERTISING AND SPONSORSHIP POLICY

The PDA Southeast Chapter offers vendors and companies the opportunity to place advertisements in the quarterly newsletter for the following fees:

Business card size: \$100

Quarter page: \$150

Half page: \$300

Full Page: \$500

Ads submitted for publication in the newsletter may be related to services and/or products offered by the vendor/company, and may also include employment opportunities.

In addition to the newsletter ads, companies/vendors may also sponsor events presented by the PDA Southeast Chapter (for example: technical seminars, golf outings and facilities tours), the newsletter (or other publications), and the PDA Southeast Chapter Web Page.

Sponsors for the newsletter or Web page are entitled to a quarter page ad in the publication they are sponsoring. Sponsors of events will receive recognition in conjunction with the event being sponsored, and may also elect to provide a booth with up to two company representatives at the event.

For more information about sponsor-ship or advertising, please contact Cindy Smith at (252) 756-9611 or via e-mail at cindy_smith@serentec.com.

JOIN THE SOUTHEAST CHAPTER OF THE PDA!

Anyone interested in joining the PDA Southeast Chapter should contact:

Mary Carver
Eisai, Inc.
900 Davis Drive
RTP, NC 27709
Phone number: (919) 474-2149
E-mail:
mary_carver@rocky.eisai.com

Please include all available information:

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Title
Company
Address
Telephone
Fax
E-mail Address

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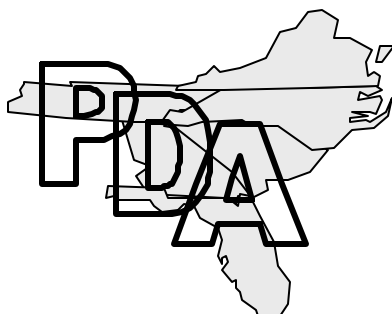
69 CHESTNUT ST. • P.O. BOX 485 • PEPPERELL, MA 01463
tel 978-433-6279 • fax 978-433-0442 • www.masy.com

PDA Southeast Chapter Vendor Directory

COMPANY	REP	ADDRESS					TELEPHONE
AAI	Deryl Hester	6-F Harbour Oaks	Carolina Beach	NC	28428		910-458-0321
"Alma, Inc"	Linda Wallin	180 Primrose Lane	Freehold	NJ	07728		732-308-2366
Becton Dickinson	Tim Lince	P.O. Box 816	Danielsville	GA	30633		800-456-9174
"bioMerieux, Inc"	Debbie Thompson	595 Anglum Road	Hazelwood	MO	63042		214-731-8500
Carlisle Barrier Systems	Patrick Oles	618 State Street	New Lisbon	WI	53950		914-726-3425
Chemunex Inc	Michael David	1 Deer Park Dr, Ste H-2	Monmouth Junction	NJ	08852		800-411-6734
CRB Consulting Services	Bo Crouse Feuerhelm	1200 Crescent Green Ste. 100	Cary	NC	27511		919-852-5400
CRB Consulting Services	Claudine Clarke	7410 NW Tiffany Spring Prkwy	Cary	NC	27511		919-852-5400
Data Medical	Chuck Ward	277 Fairfield Rd	Fairfield	NJ	07004		972-882-1183
Data Medical	Gabe Lederer	277 Fairfield Rd	Fairfield	NJ	07004		972-882-1183
Data Medical	James O'Brien	277 Fairfield Rd	Fairfield	NJ	07004		972-882-1183
Doe & Ingalls	Jerilin Paith	1301 Person St	Durham	NC	27703		919-598-1986
Doe & Ingalls	John Hollenbach	1301 Person St	Durham	NC	27703		919-598-1986
Dow Corning Corp	Nelson Rodriguez	P.O. Box 994	Midland	MI	48686		517-496-8183
Dow Corning Corp	Rich Gettings	P.O. Box 994	Midland	MI	48686		517-496-8183
Eagle Picher/ESAT	Rob Greer	200 B.J. Tunnell Blvd East	Miami	OK	74354		
Eagle Picher/ESAT	Rod Neal(Mike Turzai)	200 B.J. Tunnell Blvd East	Miami	OK	74354		
EM Science	Glenna Clark	2936 Forest Hills	Rock Hill	SC	29732		803-817-1944
InterMetro Industries	Glen Theiss	4708 Delta Ridge Court	Raleigh	NC	27612		919-571-8199
IsoTech Design	Magdi Moussa	5778 Boul Thimens	Quebec	CANADA	H4R2K9		514-956-1602
Kaye Instruments	Roy Snipes	P.O. Box 64	Bailey	NC	27807		
Kuhlman Technologies	Kris Erickson	10512 NE 68th St	Kirkland	WA	98033		425-822-8282
Lab Support	Charissa Sturino	1513 Walnut St, Suite 215	Cary	NC	27511		919-319-9950
Lab Support	Stephanie Burgess	1513 Walnut St, Suite 215	Cary	NC	27511		919-319-9950
Miller Products	Ernie Guadoso	2220 91st St	North Bergen	NJ	07047		570-586-5117
Millipore Corp	Susan Moore	3202 Clark Ave	Raleigh	NC	27607		919-831-2436
Millipore Corp	Teresa Frisone	629 Trueneck Ave	Raleigh	NC	27603		919-831-2436
Pall Gellman Labs	Juan Sanata	2839 Meadow Drive	Marietta	GA	30062		770-971-8454
Pall Gellman Labs	Laua Hanes	4 Waldrop Trace	Fletcher	NC	28732		828-628-3074
Pentagon Technologies	Dan Milholland	8100 Brownleigh Dr	Raleigh	NC	27612		919-781-9777
Pentagon Technologies	Rich Regruto	3274-B Metlock Bridge Rd	Norcross	GA	30092		770-446-5400
PGC, Inc	Clay Hile	1104 Old US Hwy 70 West	Black Mountain	NC	28211		828-669-8717
PGC, Inc	Hugh McKenna	1104 Old US Hwy 70 West	Black Mountain	NC	28211		828-669-8717

COMPANY	REP	ADDRESS					TELEPHONE
Pharmaceutical Dev Center	JoAnne Jacobs (Dr Suresh Dixit)	4221 Faber Place Drive	Charleston	SC	29405		843-746-2516
Remel Inc	Elena Cordero-Garcia (Brian Griffin)	12076 Santa Fe Dive	Lenexa	KS	66215		800-255-6730
Remel Inc	Pat McElraft	12076 Santa Fe Dive	Lenexa	KS	66215		800-255-6730
Sartorius Corp	Charles Smith	P.O. Box 216	Delmar	DE	19940		302-846-2995
Sartorius Corp	Mark Trotter	131 Heartland Blvd	Edgewood	NY	11717		800-368-7178
Sartorius Corp	Rich Malfa	5504 Lake Edge Rd	Holly Springs	NC	27540		919-557-1538
Sartorius Corp	Roger Brooks	945 Crestmark Blvd, #408	Lithia Springs	GA	30122		770-941-4964
Steris Corp	Pam Proctor Webb	Committee Chair Person					
The Texwipe Company	Kathy Miscioscio	650 East Crescent Ave	Upper Saddle River	NJ	07410		800-648-9473
The Texwipe Company	Kathy Wiglesworth	3523 Terrault Dr	Greensboro	NC	27410		336-856-2162
Veltek Associates	Art Velutato	1039 West Bridge St	Phoenixville	PA	19460		703-242-8908
Veltek Associates	Margaret Wanca-Daniels	600 Kingsley Rd SW	Vienna	VA	22180		703-242-8908
VWR	Charles Clawson	1323 Chenoworth Dr	Apex	NC	27502		800-348-6388
VWR	Kerri Campbell	1323 Chenoworth Dr	Apex	NC	27502		800-348-6388

December 1999 Newsletter



SOUTHEAST CHAPTER

**The PDA Southeast Chapter would like
to thank all of the vendors listed above
for participating in our
1999 Fall Vendor Exhibition!**