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Connecting People, Science and Regulation

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Upcoming Event

December 10
5:30 - 7:30 pm
Winter Social
Bogart's
510 Glenwood Ave.
Raleigh, NC

From the PDA Southeast Chapter President...

Greetings to my fellow PDA SE Members, Sponsors & Guests,

What a busy year it has been! Our Spring Conference, Summer Golf Social and Fall Conference/ Vendor Show were a success thanks to you and our Chapter Volunteers. The Laboratory Conference which was held on Thursday, November 12 at the BTEC Center at the NCSU's Centennial Campus has received excellent reviews as well.

The Winter Social is just around the corner. It will be held at Bogart's on Thursday, December 10th. At the Winter Social we acknowledge the outstanding students in our profession.

Hope you enjoy your Newsletter and as always, please don't hesitate to contact one of your Chapter Officers if there is anything specific we can do for you. See you at one of our upcoming events!

Michele Creech, President
PDA Southeast Chapter

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Cleaning Validation: Approach, Program Development, and Resourcing

Provided by our Platinum Sponsor PharmaSys

The validation of cleaning procedures used in FDA-regulated pharmaceutical and biotech industries is understood to be a necessary, time-consuming, and often resource-intensive activity. The FDA requires that cleaning procedures be developed and validated to ensure product quality and patient safety. A successful cleaning validation program involves establishing resource needs up front, developing proper cleaning procedures and justifiable rationales, generating and executing protocols, and maintaining the program once the cleaning validation exercise is complete. Effective validation approaches and resourcing ensures that the efforts exerted during cleaning validation efforts are maximized for efficiency and compliance adherence.

Establishing a solid process for the validation of cleaning procedures starts with identifying the regulatory requirements and expectations: what are the guidances, the laws, and the general requirements that will help dictate the course of action. Next, a cleaning validation program – often under the guise of a Validation Master Plan – will be put in place; this will establish company policies on validation and associated procedures, the available resources, and the prerequisites such as health and safety data, equipment and facility design, and equipment qualification. Data gathering is then performed that encompasses the assessments of equipment and contact surfaces, of products, and of cleaning procedures. Subsequently, the cleaning validation approach to be adopted for the validation testing will be defined based on the assessment of the level of validation required and the range of the equipment and products to be covered, followed by the test protocols. Limits and acceptance criteria, which are required but have not been defined in documents published by

regulatory authorities, must also be established and be logical, scientifically sound, and based on knowledge of the materials involved. After these processes are complete, post-validation procedures must be established; these are ongoing requirements to ensure that the standards defined within the initial cleaning validation exercise are maintained once the cleaning validation exercise has been completed.

Many of the problems that arise from a company's identification and implementation of validated cleaning procedures concern the lack of experience or direction. The inability of an internal quality assurance or regulatory affairs department to have the capability to identify customer and regulatory requirements, along with providing internal control and compliance, can doom a bottom line and bring regulatory authority scrutiny to bear on operations. After all, cleaning validation is really a customer requirement because it ensures the safety and purity of the product; this is also driven by regulatory expectations to ensure that residues from one product will not carry over and cross-contaminate the next product. Meeting these two conditions, along with ensuring the quality of the process from an internal control and compliance point-of-view, will make customers happy and oversight easier.

PharmaSys is a full service life science service company that specializes in validation and compliance including cleaning validation. With offices local to RTP, we've been serving the industry worldwide for over 10 years. For more information visit our website (www.pharma-sys.com) or call 919.468.2547.

The North Carolina Research Campus

The North Carolina Research Campus (NCRC) (www.ncresearchcampus.net) has ushered in a new era of human health, nutrition and agriculture research, where public/private partnerships play a key role in the translation of ideas from the bench to the public. The 350-acre research campus, located near Charlotte in Kannapolis, North Carolina, opened its doors in October 2008 and has been a model of collaboration for the country, with the presence of eight major North Carolina universities and several companies. Add to the mix a hospital system, a community college biotechnology training program, and several support businesses such as venture capitalists, attorneys, and entrepreneurs. Together, these components are transforming this former mill town into a thriving center for innovation, discovery, and translation of research projects to the marketplace.

The brainchild of Mr. David H. Murdock, sole owner of Dole Foods and Castle & Cooke, the research activities at the NCRC are focused on the intersection of human health and disease, nutrition, and agriculture. Long-term objectives of researchers include discovering how biologically-active natural plant compounds confer protection against chronic diseases and innovative approaches to understanding the role of diet and activity in normal brain development, cancer prevention, and the prevention and treatment



The 350-acre research campus, located near Charlotte in Kannapolis, North Carolina, opened its doors in October 2008.

of obesity. Biomarkers discovery for diseases such as diabetes, osteoarthritis, cardiovascular disease, and cancer is being initiated through a longitudinal study of 50,000 local residents in the region.

The David H. Murdock Research Institute (DHMRI) (www.dhmri.org), located at the center of campus, houses state-of-the-art scientific capabilities, including genomics, proteomics, metabolomics, light microscopy, and NMR. Key instrumentation includes a 950 MHz Bruker NMR and a beta testing site for Carl Zeiss Microimaging. The DHMRI offers an integrated approach to doing science, where collaborative approaches between laboratories are fortified through hands-on participation from laboratory directors and managed through a strong bioinformatics infrastructure. As the campus evolves, the DHMRI

will continue to grow and acquire capabilities to fit the needs of the researchers on campus and beyond.

Currently, several of the partner companies are focused on studying health, nutrition, and agriculture. This is exemplified by the presence of Dole Foods, which will be working closely with the universities to obtain research and resources for future products. As the NCRC grows, the companies that will inhabit the campus will focus on a wide range of activities and interests, including nutraceuticals, medical devices, pharmaceutical development, and even information technology. Looking ahead, the possible collaborations and applications available at the NCRC are endless.

For more information on the NCRC, please contact partner@castlecooke.com

Please donate this holiday season



PDA Southeast Chapter Annual Winter Social

Register by December 7th!

PDA Southeast Chapter Winter Social
Thursday, December 10th
5:30 - 7:30 pm
Bogart's Restaurant - Raleigh, NC

Greetings PDA Southeast Chapter Members and Supporters,

You are cordially invited to our Annual Winter Social to mingle with your colleagues and celebrate the accomplishments of our 2009 Student Scholarship Winners on Thursday, December 10, 2009 from 5:30 - 7:30pm. The event will be held at Bogart's Restaurant located at 510 Glenwood Avenue, Ste. 109, Raleigh.

This year we are asking attendees to "pay it forward" by supporting the Helping Hand Mission by bringing an item(s) from their most needed list.

Most Needed Items. Food, Clothing, Blankets, Toys, Hygiene Items (Toothpaste, Shaving Items, Soap, etc.) and Infant Products (Diapers, Wipes, Formula, Infant Cereal)

We will arrange for all the items to reach the Mission the day after the event.

Enjoy hor d'oeuvres and a complimentary beverage.

Introduce your peers to the PDA Southeast Chapter by inviting them to this special event.

DONATIONS NEEDED!

Please consider donating warm clothing, or non perishable food items. Your donations will be greatly appreciated by a needy family this year!

Register NOW!

To register, please send an e-mail with your name and company name to pdase@bluestarservices.net by December 7th.

Please include your member number and if you will be bringing a guest.

Please provide your guest's name and their contact information.



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On the Road from Albany to Zurich

How to become an international scientist

Provided by Kelly Scientific

Many scientists dream of working overseas. Some are lured by thousand-year-old cultures or cuisine, while others are interested in the opportunity to ratchet their careers up a notch. As research and development have become increasingly globalized, so too is the job market. But before packing up their belongings, scientists vying for an overseas career move should compare their geographical wants and talents with the global need.

Rome and Prague may be popular destinations for those looking for a break from the daily grind, but they may not be realistic options. Scientists who follow the money will have more success in their job search, says Josée Paradis, who heads up Kelly Scientific Resources in Europe. Look for countries with strong economies and ample investment into R&D. It's better to target Switzerland, United Kingdom, Denmark and Sweden than Italy and Spain, where the market may already be saturated with local candidates.

Asia is quickly becoming a popular destination for mid-level career scientists. Doors previously closed to foreign researchers are opening. Singapore, for example, has been building up its biomedical sciences industry through private and public in-

vestments since 2000, notably through the construction of Biopolis, a biomedical research hub within the vicinity of the National University of Singapore and the National University Hospital. The investment, along with excellent intellectual property rights, has drawn many of the world's top pharmaceutical companies to the country including, GlaxoSmithKline, Merck, Eli Lilly, Novartis and Becton Dickinson.

Jobs at pharmaceutical companies and clinical research organizations are particularly abundant. "Everyone wants clinical research professionals from associates to clinical team leaders. It's a candidate's market – many of them have two job offers in hand," says Meeta Bhagat, consulting manager for Kelly Scientific Resources in Singapore. Individuals who have worked on clinical trials at the international level, whether in project management, regulatory affairs or data management might consider Singapore or the rest of Asia for their sojourn.

India, China and Japan are also eager to draw international talent inside their borders. Researchers with five years of post-graduate training will fare well on their job search there, says Rich Pennock, vice-president of Kelly Scientific Resources. "There's a high demand for

the more experienced researchers in the biotech and pharmaceutical sectors," he says. Both the government and private sectors are seeking to expand their contract laboratory services in all three countries; Japan is keen to enlarge the medical device industry.

When putting together your C.V., bio, or cover letter, be sure to highlight your specialized skills. In most cases, scientists are being hired from other countries because they have experience that stands out. "The more specialized the skill, the more willing the customer is to take foreigners," says Paradis. Pennock agrees and suggests candidates emphasize previous international experience, mastery of a foreign language and any background that would benefit many disciplines, like synthetic chemistry or business-related skill sets. "With solid chemistry, biology or biochemistry skills tied with, for example, bioinformatics, you'd be in good shape, especially as the pharma and biotech industries mature in Asia."

Although English is the language of science in most countries, it can be helpful to speak another. English will suffice for mid-level recruits in R&D or manufacturing, but some fluency in the host language is useful for in-

On the Road from Albany to Zurich (continued)

ternational recruits supervising local employees at a plant or on research floors and higher-level executives who deal with government officials and policy makers. Bhagat says that many of her clinical research clients are looking for multilingual capabilities, where having the extra language means you can interact with patients, doctors and the principal investigators at the clinical trial site. "It eases the process of site monitoring and coordination," she says.

Some countries, including India and China, are highly focused on bringing expatriates home. Individuals who left their home countries as graduate students may find they are hot commodities after years of education and post-doctoral work in North America and Europe. These people tend to have solid technical or business experience in the science or medical sectors and speak two or more languages, including English.

"There are a lot of post-docs in the U.S. who kept working there because they couldn't see a role for themselves at home," says Paradis. "We're trying to bring them back."

Worldwide investment in R&D and manufacturing has globalized the job market for mid- and upper-level scientists. By showing off their specialized skills, international experience and language abilities, those eager to work and live overseas can turn their dream into reality.



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A special thank you to Kelly Scientific for their contribution to the PDA Southeast Chapter Newsletter.

The Pharmaceutical Industry: A Future of Change as the Constant

By: Larry R. Miller, Ph.D.

The pharmaceutical industry faces unprecedented challenges that will force re-evaluation of core business strategies as well as the creation of new business paradigms. The very survival of the industry is at stake in an increasingly complex and demanding external environment.

What are some of the drivers that will force pharmaceutical giants to re-tool in the upcoming years? One key external force on the industry arose following increased demands from both private and government reimbursement authorities. In the future, such agencies will award premium pricing only to new products that truly meet novel and unmet medical needs. The days of top-level reimbursement following incremental improvements in factors such as dosage form, dosage schedule, new salts, or extended release preparations are all but over the horizon.

Increased regulatory scrutiny, particularly in the area of both short- and long-term safety, will also raise the bar for firms developing new medicines. Such additional requirements will drive up development times and clinical costs. Trial size and duration will climb, especially when cardiac or other outcome studies will be needed. For example, many firms in the area of diabetes were developing drug candidates impacting the peroxisome proliferator-activated receptors (PPARs). Following issues of carcinogenicity in recent years, the Food and Drug Administration now requires extensive oncogenicity studies to be completed before PPAR-active compounds can be registered.

A number of additional business factors combine to add pressure on the pharmaceutical industry. Most of the large corporations have significant patent expiries looming. Yet these same firms do not have projected revenues from their maturing late-stage pipelines to replace the value that will be lost from these patents. The rapid rise of the speed in which generic replacements can reach the marketplace will exacerbate the drop in revenue

when key products lose patent protection.

What can the industry do to overcome such potential adversity? Many large companies are looking to their colleagues in the biotechnology industry for at least part of the answer.

The answers lie at least in the following:

- Increase the novelty in drug pipelines so that more products addressing serious medical needs can be developed
- Decrease internal spending including facilities, human resources, and by creating smaller, more focused pipelines
- Increase the fraction of work carried out by collaboration and contracts outside the walls of the firm
- Develop new biomarker and other technologies that will reduce the incidence of costly, late-stage clinical failures
- Drive toward personalized medicines, including therapies with paired diagnostic tests

The last point will be particularly important with recent emphasis by regulators on comparative efficacy and with the recent history of drug recalls following serious adverse events in small groups of patients. Methodologies that target medicines to the right patients, thereby maximizing efficacy while preventing administration to patients who might have serious side effects will increase therapeutic impact and optimize success in the marketplace.

An instructive example of how one pharmaceutical giant is coming to grips with these realities can be gained by studying the changes recently put in place by the Research and Development Division at GlaxoSmithKline (GSK). Recently, GSK announced that it would re-structure its entire research approach. Seventeen therapeutic area reviews were conducted to identify scientific areas ripe for drug discovery in the future. Senior management then assigned budgets to drug discovery divisions

The Pharmaceutical Industry: A Future of Change as the Constant *(continued)*

based on this analysis and required that division heads develop business plans for a three-year funding cycle to justify their budgets. In an attempt to emulate successful biotechnology cultures, GSK broke up long-standing management lines in biology, chemistry, pre-clinical pharmacology, and early clinical development in favor of smaller, multi-functional units of 50-60 employees. Each of these units will focus on a small biological space, must produce a business plan of its own, and will be tasked with building an entrepreneurial culture that hopefully will lead to quicker decision making and increased innovation. GSK also very substantially reduced internal R&D headcount while channeling more funding to third parties with the goal of accessing the best science, drug discovery targets, drug molecules, or technologies, wherever they might be.

All across the industry, firms will also need to reduce the dependence on a small number of molecules that can be built by marketing or other strategies into "blockbusters." Such an approach leads to huge drops in revenue as each of a small number of assets reaches the end of its patent protection. To survive, corporations will need to find new ways to develop more molecules, develop them more quickly, and to target them to the correct patients. Scientists will also need to stretch approaches to less familiar biochemical territories, particularly to focus on biochemical pathways that regulate central processes. For example, the aging population across the globe will drive needs for medicines of the future. Pharmaceutical companies of the future will need to work toward finding ways to address central mechanisms of aging leading to more healthy aging and improved function in the elderly.

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Comments or questions for the author may be submitted by email to Larry.Miller19@yahoo.com.

Larry Miller last served as Director of Business Operations, Global Drug Discovery for GlaxoSmithKline, Inc. He previously served as Director of Operations and Communications for the Metabolic and Viral Diseases Drug Discovery Division and built a de novo diseases of aging drug discovery unit within GSK. Larry completed his doctoral training in biochemistry at the University of California at Los Angeles and served nearly five years at the National Institutes of Health in Bethesda, MD.

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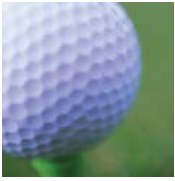
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Golf Social Highlights

The PDA Southeast Chapter held their annual Golf Social on Friday, June 12, 2009, at the Lochmere Golf Club in Cary NC. There were a total of sixty golfers and fourteen sponsors. It was a best ball game, and prizes were given out to the top three teams.

After golf, everyone enjoyed a Southern style barbecue lunch while a drawing was held for golfing gifts. Everyone received a gift. A special thank you to Lochmere Golf Club for their contributions and hospitality!

The day was a hit, everyone fully enjoyed themselves, and even left with a commemorative photo of their foursome.

Thank you to all our sponsors, volunteers, and members for making this social such a success. We look forward to seeing you on June 18th at Lochmere Golf Club for the PDA-SE 2010 Golf Social!

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Congrats to our 2009 Golf Winners

1st place Team

Terry Kimball Tom Parmalee
Mike Putnam Mark Levanites

2nd Place Team

Keith Peacher John Payne
Adam Sheriff Ike Griffin

3rd Place Team

Jackie Scialabba Darrell Coleman
Todd Pruden Steve Ferguson

Closest to the Pin Winner

David Brande

Longest Drive Winners

Dorie D'Haene
Sean Kerrigan

CDG takes a head on approach to Calibration Programs

by Evan Moniuszko, PCI, LLC



Todd McCulloch provides a brief overview of the CDG Electronic Blackboard used by nearly 100 members across 3 countries. The on-line forum allows members to post questions to a large group of calibration professionals for a wider variety of feedback.

Wednesday, March 18th marked the 8th annual PCI sponsored Calibration Discussion Group. This annual event was formatted in a different way from years past, restricting participants to a small focused group of instrumentation personnel from a select group of local operating companies. The morning session centered on Calibration Program focus, highlighting program opportunities and the matrix that can be used for program evaluation. Afternoon session topics included technical local instrumentation specific training available, controlling program cost and determining instrument classifications. This year's event was held at the Talecris Biotherapeutic training facility in Clayton.

Phil Sheridan, discussed the Custom Training Programs Available through NC BioNetworks, an organization designed to educate local resources to supply the various manufacturing and research facilities in the area.

Carson Price, Talecris Biotherapeutics Maintenance Manager, discussed risk based programs, the system KPI's generated and the trends, stressing the importance of site-wide operations training and with an emphasis on PM rather than relying on a reactive system. Kevin Pait, Director of Plant Engineering & Maintenance at Talecris's Clayton Facility assisted by examining these efforts at a whole and discussed incentives for training that have been successful for this initiative.

This sentiment was echoed by Todd McCulloch who spoke about the efforts of achieving these

goals through facilities chosen calibration system, and how to make these systems work for the end user. Mr. McCulloch also discussed process tolerance assignments and the group explored methods to reduce the utility cost associated with certain types of calibrations.

A few of the companies represented included: Alphavax, BioMerieux, Biogen Idec, Catalent Pharma Solutions, Hospira, Novartis, NovoNordisk, NNE Pharmaplan, Sandoz, Talecris Biotherapeutics, and Wyeth Vaccines. Previous events co-hosted by Wyeth Vaccines, GSK, Cardinal Health, NC Biotech Center, Eisai and Biogen Idec.

Pharmaceutical professionals who have process, laboratory or utility instrumentation responsibilities who would like to participate in future annual events should email Todd McCulloch at tmcculloch@pci-llc.com or C-D-G@yahoo.com. This is not limited to instrumentation & controls personnel. This forum is also for those in quality assurance, quality control, engineering, and production.



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