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# **Pharmaceutical NEWS**

Spring 2010

 **Lancaster  
Laboratories**  
Celebrating **50** Years



An interview with Dr. Wilson Hershey, President

As Lancaster Laboratories moves into its 50th year in business, it is a time of reflection as well as projection. No one in the original three-person business in 1961 could have imagined what we would look like 50 years later. Having joined Lancaster Labs 38 years ago as a bench chemist and serving as president for the past 15 years, Dr. Wilson Hershey shares his historical perspective.

#### Dr. Hershey, what was the basic objective for helping clients meet their goals in the early days?

It was determined early on that delivering outstanding quality and service were absolutely essential for clients' success as well as ours.

#### How has Lancaster Labs' steady growth benefited client relationships?

Today, with 1,000 employees and sites in the U.S. and Europe, we are better recognized and better positioned to serve clients than ever before. In industry surveys, clients say they prefer us based on scientific and regulatory expertise, meeting project deadlines, client service and price. And because of this, the companies that trust us are nearly all of the largest pharmaceutical companies, more than half of the largest chemical and petrochemical firms and large tobacco companies.

#### What have we learned in the first 50 years that is unlikely to change?

**Continuous renewal** is essential. We must always add new services and improve existing ones. We must continue to

## The next 50 years

become more efficient. We must never get comfortable with the status quo and must continue to "reinvent" the business.

**Personalized client service** is a must. It is one way to provide real value and differentiate ourselves. All labs deliver certificates of analysis. Our goal is to have service, quality and technical expertise set us apart.

**Size matters.** Having grown from a 2,500 square-foot lab in 1961 to 225,000 square foot state-of-the-art facility in Lancaster, demonstrates our ongoing financial stability and commitment to respond to clients' growing needs. Our three tier service model – fee for service, FTEs at our lab and Professional Scientific Staffing<sup>sm</sup> (PSS) at client sites—is resonating with our large clients.

**Employees are key.** We are audited by 100 or more companies and agencies per year. Often during the wrap-up meeting after the audit, we are complimented not only on the technical expertise of our employees but on their can-do attitude, smiles and camaraderie—something not found at many of our competitors.

#### What will change in the next 50 years?

**Technology** will continue to change at an ever increasing rate. In 1961 an instrument was capable of running one amino acid sample per day. Today, a sample can be run in 12 minutes using UPLC. Computerization and information management has improved at an even faster pace. Staying ahead of the curve will continue to be a differentiator.

**Regulations will change.** While the US EPA and FDA are unlikely to relax the official regulations, it remains to be seen how they will enforce those regulations for laboratories. Offering new regulatory methods and ensuring our customers projects are compliant is paramount.

**More testing will be done in Europe and Asia.** We need to remain adaptable to the needs of these markets and act accordingly.

In summary, our long-term vision is to be the best lab, the gold standard for our industry. With a keen eye on the horizon, we will continually strive to do better for our clients. And backed by our rich 50-year history of delighting clients, Lancaster Labs will work hard to remain the trusted lab for the next 50 years.

## Professional Scientific Staffing<sup>sm</sup> growth doubles

Lancaster Laboratories cites 100 percent growth for its Professional Scientific Staffing<sup>sm</sup> (PSS) service model in 2009, while having expanded to 14 sites in North America and Europe since its inception seven years ago.

"Driven in part by the economy and the resulting staffing challenges coupled with the outstanding service we provide, our PSS model is being well-received in the industry," says PSS managing director Beth DiPaolo. "Therefore, we are continually working on great opportunities to add staff at existing sites and are pursuing business at several new sites. And we expect to have another strong performance this year."

Lancaster Laboratories' PSS delivers innovative staffing solutions, placing its highly-qualified scientists at the customer's site dedicated to the success of their drug development projects. Infusing its 50-year track record of scientific expertise and HR best practices, Lancaster Laboratories hires, trains and manages its employees to perform laboratory services at customers' sites, using their quality systems.

IRS 20-Factor compliant, PSS provides the same level of services, expertise and cGMP compliance available at the Lancaster Labs facilities. Eliminating the co-employment risk for the customer, PSS provides a "non-permanent" workforce at a lower cost than fixed headcounts. For more information, call Beth DiPaolo at 717-656-2300, ext. 1259.

Find out more about PSS director Beth DiPaolo in her feature on page 7.

# EU Biologics Release Testing supported at Lancaster Laboratories' site in Ireland

Bringing a biological product through development and to the market requires a tremendous amount of time, money and effort. Therefore, biopharmaceutical companies must market their products to as broad a geographical area as possible to get the most return on their investment. One challenge they face is the European Union's (EU) legislation which requires that every batch of a marketed medicinal product be tested on European soil.

There are 27 member states in the EU and three other associated European Economic Area (EEA) states. Legislation passed at the EU level applies to these countries and is administered by the European Medicines Agency (EMA) for pharmaceutical products. Directive 2004/27/EC replaces the text of previous legislation to read:

*In the case of medicinal products coming from third countries, irrespective of whether the product has been manufactured in the Community, that each production batch has undergone in a Member State a full qualitative analysis, a quantitative analysis of at least all the active substances and all the other tests or checks necessary to ensure the quality of the medicinal products in accordance with the requirements of the marketing authorization.*

Therefore, release testing - the quality control testing of each batch of finished product - must be performed in the EU. Many biopharma companies do not have testing facilities in the region. Consequently, marketing of their products in the EU will require outsourcing of the batch release testing to an EU-based facility. EU legislation does allow the batch testing to be contracted out to third parties. Those methods and specifications for release testing listed in the marketing authorization application (MAA) will need to be transferred to the contract laboratory. The table to the right indicates typical batch release tests.

Batch release testing for the European market can be supported at Lancaster Labs' location in Dungarvan, County Waterford, Ireland. Facilities and equipment in the lab include:

- Cell Culture Laboratories
- Class C constructed cell culture suite and airlock room
- Class II Biological Safety Cabinets
- Multifunctional M5e Microplate reader, Part 11 compliance
- Cryogenic storage facilities
- Residual DNA suite
- Class C constructed laboratories with airlock corridor
- Applied Biosystems 7500 RT-PCR, Part 11 compliance
- Class II Biological Safety Cabinets

- Protein and Molecular Biology Laboratory
- Alpha Innotech Gel Imaging System
- SDS-PAGE/IEF/Western blot equipment
- Best 2000 Biokit automated ELISA system

With Lancaster Labs' sister facilities in Fisher Clinical Services and Fisher BioServices providing GMP importation and storage, Lancaster Labs has an impressive infrastructure to support biologics import testing. The European laboratory site often works in conjunction with the US laboratory facility to transfer methods post characterization and method development to provide seamless supply chain support into the European Union. Many clients are transferring methods between facilities as their investigational and commercial supply chains expand.

<u>CLASS</u>	<u>TEST</u>	<u>TECHNIQUE</u>
Appearance	Appearance	Visual
Identity	Peptide Mapping Western Blot Gel Electrophoresis Isoelectric Point	HPLC ELISA SDS-PAGE Isoelectric Focusing
Purity and Impurities	Chromatographic Purity Host Cell Proteins Residual DNA Gel Purity	HPLC ELISA qPCR SDS-PAGE
Potency	Potency	ELISA/Cell Based
Quantity	Concentration	HPLC/UV
General	pH Osmolarity	pH Osmolarity
Compendial	Sterility Endotoxin Microbial Limits Particulate Matter Moisture content	MF/DT Kinetic  Light Obscuration Karl Fisher

# Cleaning Validations: Alternatives for monitoring non-soluble compounds

by Dr. Thomas Lehman and Eric Lingenfelter, Method Development & Validation Department

With cleaning validations becoming more of a regulatory requirement across the pharmaceutical industry, many manufacturing companies are experiencing the pressure to ensure their equipment is being cleaned to a satisfactory level. This pressure, in combination to the economic state we are experiencing, is leading companies to develop and validate cleaning methodology at as low a cost as possible. One such approach to evaluate and monitor cleaning validations is to develop a nonspecific total organic carbon (TOC) cleaning validation method.

Advantages to using a TOC approach is that a TOC method is not specific. The instrumentation will measure all organic carbon in the sample solution whether the carbon is contributed by the active in the drug product, from cleaning agents, from other excipients, or even from contamination. Therefore, because we cannot determine the source of the carbon in sample, one must assume that all carbon measured in the solution is due to the compound of interest. This approach is beneficial when monitoring products that may degrade while being cleaned, because even though the original product may no longer be present, the total amount of carbon present doesn't change. Another advantage to TOC methods are that they are easy to develop and relatively inexpensive to perform.

On the other hand, TOC has some disadvantages as well. For cleaning validations, even though TOC being non-specific is viewed as an advantage, it can also be viewed as a disadvantage. If it is critical to monitor an individual compound, whether it is an API or a residual cleaning agent, a TOC method cannot meet the method requirements. In addition, TOC samples are

very susceptible to contamination. One has to be careful with how the glassware and equipment is cleaned and handled if a TOC method is going to be used. Organic solvents cannot be used as rinse solutions because they will drastically increase the amount of carbon on the equipment surfaces and thereby artificially bias sample results. Another disadvantage is that all compounds to be monitored by TOC need to be water soluble. Or do they?

Historically, if a compound was rendered by the Merck Index to be only slightly water soluble, everyone immediately ruled out the option of TOC. Lancaster Laboratories has developed methods utilizing TOC for compounds that are not fully water soluble. In order to be TOC compliant, compounds only need to be slightly soluble in water. For example, if a maximum contamination limit (MCL) is set to 10 ppm, the compound only needs to be soluble at 11 ppm in water to be measured in the range of interest. This is a very interesting concept that is growing in popularity across the industry.

Sensitivity is always a concern when dealing with only slightly soluble compounds. The typical concentration detection range for TOC analysis is approximately 100 ppb to 2000 ppb. However, if solubility is limited, the concentration range is usually restricted to an even smaller range of approximately 100 ppb to 500 ppb for performing appropriate spike recovery studies. One limitation that must be determined during method development: is the compound water soluble enough to accurately perform spike recovery studies and still maintain the sensitivity to be detected within the allowable range of the instrumentation? This question may not be answered until suitable laboratory work is performed.

Another consideration is that sufficient carbon needs to be present in the sample matrix. Many cleaning detergents on the market today do not contain any carbon, thereby eliminating the possibility of TOC detection. When deciding whether or not TOC is the right approach for detection during a cleaning validation, one needs to understand that swab and rinse procedures must have the ability to collect the residue of interest from a surface with only the assistance of water. Although water is preferred, sometimes greater surface recoveries are obtained for swab samples by using a weak base or a weak acid as swabbing solvents. When collecting swab samples with alternative solvents, TOC instrumentation may require higher oxidizer and/or acid rates to effectively analyze the sample. This methodology should be determined during method development.

In summary here are some key factors to evaluate when determining if TOC is the correct approach for a cleaning validation:

- **Is the carbon content of the sample great enough to be detected once the sample is appropriately diluted?**
- **Is the compounds solubility in water above the concentration of the desired MCL?**
- **Does the method need to be compound specific?**
- **Can acceptable surface recoveries be achieved by rinsing with water or swabbing with water, a weak acid or base?**

For more information, contact Pharmaceutical Business Development at 717-656-2300.

# Oligonucleotide Sequencing by Mass Spectrometry with New OligoSeq Ion Calculator

by Dr. Robert Duff, manager of the Biochemistry Department

Demands for purified synthetic oligonucleotides have increased due to their use in applications such as primers in polymerase chain reactions, as artificial genes for site-directed mutagenesis studies, as probes for in-situ DNA hybridization and also potential therapeutic use as antisense DNA/RNA strands, aptamers and most notably, RNAi. Clinical use of these molecules requires a high degree of quality control, including sequence confirmation and the identification of minor impurities/degradants. Additionally due to the nuclease resistant composition of certain oligonucleotides, older techniques of sequencing as based on nuclease degradation are precluded. Newer analytical techniques that use mass spectrometry must be developed for the pre-clinical evaluation of nucleic acid-based therapeutic products.

Each facility or pharmaceutical company will be required to test if their synthesized oligonucleotide is truly what they claim it to be. It is critical that the synthesized sequence be confirmed as not to contain base reversals or chemical mutations that if left unnoticed could have a devastating effect on the bioefficacy of the oligonucleotide and the therapeutic outcome of a clinical trial. The software used to interpret the raw data from the sequencing by mass spectrometry is definitely behind the available peptide sequencing software.

To bridge this gap and aid in this process, a proprietary program was written and built within the Laboratory Information Management System at Lancaster Labs. The program is named OligoSeq Ion Calculator, and it is able to calculate the accurate mass and CID fragments of modified or unmodified oligonucleotides. There are no restrictions for the number or type of modifications on the oligonucle-

otide. Furthermore, unlike on-line calculators, there is no upper size limit to the oligonucleotide used in this calculation. Overall, this program aids the analyst in the sequencing of the oligonucleotide by predicting the mass-to-charge for the many characteristic "a," "a-B," "b," "d," "w" and "y" ions formed by collision induced dissociation. A table is produced that contains the theoretical CID fragments. The sequence is then matched to the fragments for 100 percent coverage. Clearly the need for sequence confirmation exists and with the appropriate method and software, this testing can be made routine and validated.



Dr. Robert Duff, manager of Biochemistry, works with Thermo Scientific LTQ XLTM Orbitrap Mass spectrometer to confirm oligonucleotide mass and sequence.

## FDA issues new guidance on viral vaccines

by Dr. Kate Bergmann, manager of viral safety and viral clearance

Virus vaccines are produced in cultured cells, usually of human or animal origin. Cell lines and viral seed material could contain contaminants whose presence is undesirable in the vaccine. Whole virus vaccines are often only minimally processed after being harvested from cell culture, and it is not usually possible to validate the process for clearance of adventitious agents. Therefore, the strategy for ensuring safety and purity of vaccines relies heavily upon comprehensive testing and qualification of starting materials, along with lot-by-lot testing for adventitious agents.

Previously, there was no FDA guidance specifically for viral vaccines, but recommendations were included in several different regulatory documents. The FDA issued draft guidance on vaccines in 2006. In February 2010 the FDA issued the final guidance, regarding the characterization and qualification of material used for the

production of viral vaccines for human use. This document describes recommendations for selection of a cell substrate, production and characterization of cell banks, production and characterization of viral seeds, and selection and characterization of biological raw materials. It describes tests and testing procedures to be used for each material and each stage of production.

Lancaster Laboratories provides testing services to support virus vaccines. Contact us to discuss your needs at 717-656-2300.

"Guidance for Industry: Characterization and Qualification of Cell Substrates and Other Biological Materials Used in the Production of Viral Vaccines for Infectious Disease Indications" is available at <http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Vaccines/UCM202439.pdf>.

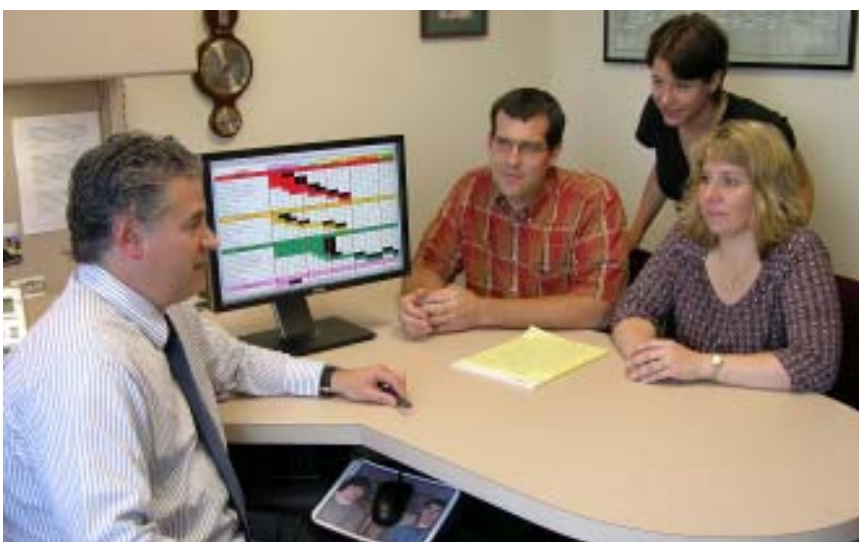
# Positive project outcomes through enhanced project management

Outsourcing of laboratory services in the pharmaceutical industry has matured from a temporary cost saving tactic to long-term formation of strategic alliances among partners focused on innovative, timely scientific solutions. As this change has evolved, Lancaster Laboratories has developed project management and communication systems designed to make interactions with clients more seamless and efficient. Because logistical issues can contribute to the cost of managing complex projects, the ability to track and share information between outsourcing partners is a key to success.

As part of the project initiation phase, Lancaster Labs works collaboratively with clients to determine a schedule that will meet their needs. Tools, such as Gantt charts, are used to identify milestones, key activities and required resources. Regular conference calls with the project team are scheduled to review progress, resolve roadblocks and share data via a web interface. Analytical method development and validation require a variety of documents and protocols, many of which need to be reviewed and approved by technical, management and quality assurance personnel at both the client and laboratory locations. This can be a time consuming, repetitive process when multiple parties contribute to editing the documents. Lancaster Labs can reduce these inefficiencies by using secure, web-based interface tools that allow for quick review and editing of the real-time project documents prior to finalization. Features like version control and "track changes" are employed to highlight recent edits and ensure that everyone is reviewing the most current revision. "For clients that want to be involved in their protocol development, reviewing and editing the document together can eliminate going back and forth with drafts. It can save a lot of time," says Cindy Eby, group leader of the Protocol Development and Technical Support Department.

As projects progress, clients have access to their laboratory data on a real-time basis through LabAccess.com, Lancaster Labs' innovative, web-based software. Project information, submitted samples, data notebooks, chromatograms, test results, certificates of analysis, summary project reports and invoicing information are all available through this secure, easy-to-use interface. Clients have the ability to perform paperless data audits from off-site locations, which can streamline the process of data gathering, and the system can also be used to share

In addition to laboratory data, Lancaster Labs can provide performance measures to verify that positive project outcomes are obtained. Metrics such as test turnaround time, report generation, investigation summaries and invoicing reviews provide ongoing management information that can be used to diagnose problems and identify barriers to successful collaboration. By tracking these indicators for clients, Lancaster Labs ensures that both technical and administrative project elements are under control.



Dr. Jon S. Kauffman, director of Method Development & Validation and Biopharmaceutical Services; Dan Peckman, group leader of Biochemistry; Kelly Morris, Pharmaceutical Client Services; and Cindy Eby, group leader of Protocol Development, review Gantt Chart of Milestones for large drug development projects.

specialized data presentations, such as chromatographic overlays from multiple sample injections. When testing is complete, the laboratory offers a variety of report formats and data deliverables, which can also be customized. While most clients find that LabAccess.com meets their need for a versatile interface with the laboratory, some firms have specific data systems that are an integral part of their operations, and their requirements may include transferring data from the laboratory data system into the client data system. Collecting chromatography runs and entering data directly into client LIMS are among the requests that Lancaster Labs has successfully answered.

"As the variety and complexity of outsourced tasks increase, we're finding that projects have to be managed differently to ensure positive project outcomes for our clients," says Jon S. Kauffman, Ph.D., director of Method Development, Validation and Biopharmaceuticals.

## Contact us

For information on services, literature requests, or address changes, please contact:

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717-656-2300  
pha@lancasterlabs.com

*At Lancaster Laboratories, we believe that our people provide our strength. Their dedication to quality, professional competence and hard work is the key element in the company's success. In this regular feature, we introduce you to some of the people who have helped make Lancaster Labs an industry leader.*

Beth DiPaolo is the managing director of Professional Scientific Staffing<sup>sm</sup> (PSS), Recruiting and Organizational Development at Lancaster Labs. Championing a company slogan, "People are the most important element in our chemistry," Beth has hired hundreds of people since her career began in 1987. Seven years ago, Beth took her knack for discovering talented employees and began a new innovative business model for Lancaster Labs, Professional Scientific Staffing<sup>sm</sup>. Placing our people at the customer's site, PSS grew 100 percent in 2009 and expanded to 14 sites in North America and Europe since its inception. (See article on page 2.) Beth earned a B.S. in Business Management/Human Resources from the State University of New York and is currently pursuing a Ph.D. in Human and Organizational Development. She is certified as Senior Professional in Human Resources (SPHR).

#### **What does your current job entail?**

I am responsible for ensuring PSS is providing service excellence to our clients. We place our professional teams in client environments to provide insourced scientific services. This involves establishing partnerships with our clients to see how we can best serve them, recruiting and hiring the best, setting metrics and communicating that service excellence vision to our employees so they in turn can take great care of our clients. Most importantly, developing and leading our on-site technical leaders are key so they ensure our people are motivated and happy, operations are efficient and quality-focused, and most importantly, our clients are delighted.

#### **What is the scope of PSS?**

With approximately 200 PSS employees at client sites throughout the U.S. and Europe, the PSS program is receiving global interest to expand this service due to emerging market needs and the success we are having with our current clients. Consequently, PSS is growing technically and geographically. And because we are part of Thermo Fisher Scientific, this more easily and effectively expedites and supports our global implementations and operations.

# People are the Chemistry



#### **Given all of your responsibilities, how would you describe a typical workday?**

Given the varied PSS sites, travel to these locations is essential to ensure our employees and clients are happy. My responsibilities range from managing PSS business development efforts, establishing client relationships by understanding their needs and expectations, coordinating the recruiting and hiring efforts of each project, ensuring we are exceeding our performance metrics, facilitating leadership training, motivating teams by creating a shared vision of service and quality excellence that fosters collaboration, developing people, and most importantly, rewarding and recognizing the efforts of our staff by celebrating successes along the way. It is a great job because you get to connect, appreciate, and value our employees' and clients' efforts, input and commitment.

#### **How would you characterize your leadership style?**

One of the reasons I returned to graduate school is to focus on inspirational and transformational leadership. I believe my style is one that uses positive use of self that inspires people to do the same and transforms people, teams and client organizations. I believe in our people and try to see the positive and

potential, create and inspire people to a shared vision through listening and getting people's ideas and inputs, and transform that into a collective transformational effort. I value teamwork and collaboration and am very grateful for the people I work with; they inspire me daily. Letting people know you care and believing in them and are there to develop and support their success is what makes people, teams and organizations even greater.

#### **You've been here for more than 23 years and seen countless changes. Is there anything that hasn't changed during your tenure?**

Absolutely, that "people are our chemistry," (and biology for that matter)! Our founder, Dr. Earl Hess, one of my personal heroes, created an environment where if you found great people and took great care of them, they in turn will take great care of your clients. That is still alive and well today. Also, our foundation was built on high quality, ethics and service standards. This is core to our business and hasn't changed. Our vision with PSS continues to demonstrate those core values of quality, integrity and service, through taking great care of our people.

#### **What is the thrust of your work as it relates to clients?**

Our PSS technical services include routine testing, method development, and validation for both large and small molecule testing in chemistry, biochemistry, microbiology, immunology, molecular and cellular biology. We also do cell bank manufacturing, engineering and medical device testing, genomics, bioinformatics, sample management, quality assurance, technical training, physical testing, environmental monitoring sampling, project management and clinical submission support. We haven't had a situation yet where we were asked to provide a service where we weren't successful in doing so. This is one of the reasons why we have grown at such an exponential rate.

#### **What awards/special corporate recognitions have you or your team received?**

We are very excited and honored for the recognition our clients have given us. At two locations where team sizes included more than 70 and 80 people, we received the vendor of the year awards for outstanding quality and service. In both scenarios the clients recognized us for outstanding HR practices in addition to laboratory expertise.

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### **CASSS Practical Application of MS**

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### **BioProcessing International**

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### **PDA Annual Global Conference**

October 25-28, Washington, DC

### **BMS Scientific Symposium**

November 1, Princeton, NJ

### **AAPS Annual Meeting**

November 14-18, New Orleans, LA

### **Well Characterized Biologicals**

November Washington, DC

## Newsmakers

**Heather Bridwell**, group leader/chemist; **Jennifer Roark**, group leader/chemist; and **Dr. Thomas Lehman**, method development manager, authored Part II of the article, "Perspectives on Method Validation II: Validation is a multistep process with USP regulatory guidelines at each step," in *Pharmaceutical Formulation & Quality*, February/March 2010.

**Heather Bridwell**, group leader/chemist; **Dr. Vikas Dhingra**, group leader/biochemist; **Dr. Daniel Peckman**, group leader/biochemist; **Jennifer Roark**, group leader/chemist and **Dr. Thomas Lehman**, manager, authored Part I of the aforementioned article titled, "Perspectives on Method Validation: Importance of adequate method validation," in *Pharmaceutical Formulation & Quality*, December/January 2010.

**Dr. Jon S. Kauffman**, director of Biopharmaceutical Services and Analytical Method Development & Validation, published "Analytical Strategies for Monitoring Residual Impurities—Best methods to monitor product-related impurities throughout the production process," in *Biopharm International*, January 2010.

**Beth DiPaolo**, managing director of Professional Scientific Staffing<sup>sm</sup>, Recruiting and Organizational Development, published "Do You Have The Workload But Not The Workforce?" in *Life Science Leader*, January 2010.

*\*Please visit [lancasterlabs.com](http://lancasterlabs.com) to view the aforementioned presentations and articles.*

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