

People

Science

Regulation

# PDA Letter

Volume XLIX • Issue 5

[www.pda.org/pdaletter](http://www.pda.org/pdaletter)

May 2013



## Take Charge of Your Career!

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Receive the Largest Registration Savings  
by Registering Before **July 8th!**



*The Parenteral Drug Association presents the...*

# **2013 PDA/FDA Joint Regulatory Conference**

*Driving Quality and Compliance throughout the  
Product Life Cycle in a Global Regulatory Environment*

**September 16-18, 2013**

Renaissance Washington DC Hotel | Washington, D.C.

Each year the *2013 PDA/FDA Joint Regulatory Conference* serves as the forum where PDA and the U.S. FDA join forces with the common goal of sharing information with the pharmaceutical industry. In this exchange, participants gain knowledge of best practices that can be readily applied upon returning to their organization and interact directly with global regulatory agency representatives to pass along those insights to colleagues.

At the completion of this conference, participants will be able to:

- Understand industry measures and regulatory expectations on the drug shortage issue currently facing patients in the industry
- Examine approaches to managing supply chain concerns interruptions or crises related to their products
- Effectively handle post inspectional follow-ups including responding to 483's or regulatory expectations and meeting requests
- Understand the importance of a robust quality agreement and supplier oversight

PDA's Training and Research Institute will be offering five courses designed to expand on what you've learned immediately following the conference. We invite you to take advantage of the opportunity to extend your stay for a day or two and make the week an even more valuable experience!



Visit **[www.pda.org/pdafda2013](http://www.pda.org/pdafda2013)**  
for more information and to register.

Exhibition: September 16-17 | Post-Workshop: September 18-19 | Courses: September 19-20

## Upcoming Laboratory and Classroom Training for Pharmaceutical and Biopharmaceutical Professionals

### JULY 2013




#### **Fundamentals of an Environmental Monitoring Program**

July 23-24 | Bethesda, Maryland  
[www.pda.org/environmental2013](http://www.pda.org/environmental2013)

#### **PDA TRI Filtration Week**

July 29-August 2 | Bethesda, Maryland  
[www.pda.org/filtrationweek2013](http://www.pda.org/filtrationweek2013)

- Filters and Filtration in the Biopharmaceutical Industry – Basics Course (July 29-30)
-  Filters and Filtration in the Biopharmaceutical Industry – Advanced Course (July 31-August 2)



### AUGUST 2013



#### **Aseptic Processing Training Program**

Bethesda, Maryland  
[www.pda.org/2013aseptic](http://www.pda.org/2013aseptic)

- Session 4: August 26-30 and September 23-27, 2013
- Session 5: October 14-18 and November 4-8, 2013

#### **Pharmaceutical Products Supply Chain Integrity: A Five Day Training Series**

August 12-16 | Bethesda, Maryland  
[www.pda.org/pharmaintegrity](http://www.pda.org/pharmaintegrity)

- Global Regulations and Standards: Influences on Cold Chain Distribution, Packaging Testing and Transport Systems (August 12-13)
- From Cold Chain to Temperature Controlled Good Distribution Practices (GDP) (August 14-15)
- Pharmaceutical Products Supply Chain Security (August 16)



#### **Single-Use Systems for Manufacturing of Parenteral Products**

August 20-21 | Bethesda, Maryland  
[www.pda.org/singleusemanf2013](http://www.pda.org/singleusemanf2013)



**For more information on these and other upcoming PDA TRI courses, please visit [www.pda.org/courses](http://www.pda.org/courses)**

Laboratory Courses



The PDA Training and Research Institute is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education.





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### 18 Take Charge of Your Career! Practical Guidelines for Career Planning and Advancement

Careers can be summarized as the time a person spends working at their individual jobs and all of the experiences, education and professional relationships that go along with those jobs. However, career planning and advancement often defines what a person's body of work will look like and the degree of satisfaction they will gain. Many times we see people owning what they perceive to be their career, only to be taken back a step when challenged as to what they truly are striving for professionally, or put another way, what is the last seat they desire to sit in prior to retirement.

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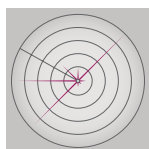
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Since the Great Recession took hold, the pharmaceutical manufacturing sector has held a unique position in the economy. Traditionally, and according to the U.S. Bureau of Labor Statistics, this industry has not been prone to wavering economic conditions. After all, when we are sick, we still need our medicine. We still need the innovative work of the pharmaceutical industry to keep us healthy so we can cope with all the other challenges that life brings.



### 30 U.S. Pharma Manufacturing Jobs in 2012

This issue's infographic uses 2012 data from the U.S. Bureau of Labor Statistics to build a profile for the state of management, science and production jobs in drug manufacturing.

#### PDA's MISSION

To develop scientifically sound, practical technical information and resources to advance science and regulation for the pharmaceutical and biopharmaceutical industry through the expertise of our global membership

#### PDA's VISION

To be the foremost global provider of science, technology, and regulatory information and education for the pharmaceutical and biopharmaceutical community



Connecting People, Science and Regulation®

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## Four Reg Speakers Announced for Virus Safety Forum

PDA is pleased to announce that four high-level regulators from agencies around the globe will speak at the *Virus & TSE Safety Forum*, June 4—6 in Berlin, Germany. They are:

- **Dinesh Khokal**, PhD, Health Sciences Authority, (Singapore)
- **Anton Andonov**, PhD, Public Health Agency of Canada
- **Rebecca Sheets**, PhD, National Institute of Allergy and Infectious Diseases, National Institutes of Health (United States)
- **Noel Gill**, National Centre for Infectious Disease Surveillance and Control (NCIDSC), Public Health England 🇬🇧

## PDA Participates in VISION PHARMA Conference

Creixell Espilla-Gilart, PDA and Thomas Peither, Maas & Peither

This February, PDA Europe participated in the *Vision Pharma/Lounges 2013 Conference and Trade Show* in Karlsruhe, Germany. More than 8,000 visitors attended.

PDA's involvement included contributions from the Prefilled Syringes, Inspection Trends and Visual Inspection of

Parenterals Interest Groups and Knowledge Management in Manufacturing Task Force (part of PCMO). Representing these groups were: **Thomas Peither** (PCMO), **Markus Lankers** (Visual Inspection of Parenterals), **Thomas Schönknecht** (Prefilled Syringes), and **Ulrike López** (Inspection Trends).

Member **Manuel Zahn**, PhD, spoke about design of experiments. Each talk helped introduce the vast spectrum of PDA activities to the audience.

The two PDA sessions were well-attended, helping PDA expand its visibility within the German pharmaceutical industry. 🇩🇪

Save BIG by Registering Before **July 8th!**



The Parenteral Drug Association presents the...

## 2013 PDA/FDA Improving Investigations Workshop

*The ICH Q10 Workshop Series: The Practical Approach to Sustainable Compliance*

**September 18-19, 2013** | Renaissance Washington DC Hotel | Washington, D.C.

The 2013 PDA/FDA *Improving Investigations Workshop* is designed to share current regulatory expectations and deliver practical solutions to improve a crucial part of a CGMP-compliant quality system: the capability to do investigations of failures, complaints and deviations. The workshop will include U.S. FDA and industry experts will share their insights on how to assess and conduct thorough investigations that lead to sustainable improvement to quality and compliance.

Hear from experts such as:

- **Thomas J. Arista**, National Expert Investigator, ORA, FDA
- **Veronica Cruz**, Vice President, Quality and Compliance, *McNeil Consumer Healthcare*
- **Shane Ernst**, Vice President of Quality, *Hospira*
- **Swroop K. Sahota**, PhD, Vice President, Quality Operations, *Catalent Pharma Solutions*
- **Juan Torres**, Senior Vice President, Quality, *Biogen Idec*



Visit [www.pda.org/investigations2013](http://www.pda.org/investigations2013) for more information and to register.

**Exhibition: September 18-19**



## 2013 PDA Europe Emerging EU Regulations and Inspection Trends

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11 - 12 July 2013

**Process Validation and Verification**

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**9-10 July 2013**  
**Dublin | Italy**



**CONFERENCE | EXHIBITION**

<https://europe.pda.org/EU2013>


## Volunteers Needed to Support PDA in St. Petersburg, Russia

PDA members looking to expand their network in Russia have an opportunity to volunteer with the Training and Research Institute (TRI) to support the development of a training center in St. Petersburg.

PDA entered into an agreement with the St. Petersburg Chemical and Pharmaceutical Academy to help establish the training center, which will be designed and operated in a manner similar to that of the TRI facility in Bethesda, Md.

To be successful, the effort requires the support of the entire PDA community. Volunteers are needed in the following areas:

1. Project Management Support: Manage different aspects of the project—Design, Demolition, Construction, Equipment Shipping/Installation
2. Architecture and Engineering:
  - a. Review drawings and specifications for facility
  - b. Review mechanical, electrical and plumbing drawings
  - c. Ensure it meets specifications set by Functional Design Document
  - d. Suggest/Recommend changes or alternatives
  - e. Conduct on-site reviews to assess progress
3. Procure Donations
  - a. Identify and secure donations of equipment and laboratory supplies
  - b. Coordinate packing and shipping of equipment
  - c. Navigate legal requirements of shipping to Russia from other countries
4. Translation Services: Translate various documents from English to Russian, and vice versa. Potential documents include agreements, contracts, design and engineering documents or training materials
5. Fundraising: Secure financial donations for PDA to support employee and volunteer international travel, temporary hires, contract services, etc.
6. Training
  - a. Deliver instruction to SPCPA faculty
  - b. How to use and maintain equipment
  - c. Future training with students and regulators

Please contact Robert Dana ([dana@pda.org](mailto:dana@pda.org) or 301-656-5900, ext. 224) for more information and/or to volunteer. 



# PDA Volunteer Spotlight

## Karl Kussow

- Manager, Quality
- FedEx Custom Critical
- Member Since | March 2007
- Current City | North Canton, Ohio
- Originally From | Madison, South Dakota

*I've gained knowledge and a network that enables me to continue to bring new value back to my business*

**What are some important new advances in packaging and distribution that you think are important for our readership to know about?**

Transportation of temperature sensitive materials, whether in the supply chain or the distribution chain, continues to be an innovative and exciting area to work.

**Recently, you have been very involved in creating new PDA technical reports, why do you think these publications are so important for the industry?**

While there are a continually increasing number of regulations and standards being published related to GDPs, there is not as much written about how to implement them in ways that are sustainable for our industry. These technical reports help meet that need for the global pharmaceutical industry.

**What have you gained by being a PDA volunteer?**

Volunteering with PDA has given me a chance to make a real contribution to this important industry while making real friends that I may never have even met without being involved. I've gained knowledge and a network that enables me to continue to bring new value back to my business.

**What is your advice for a new PDA member who would like to become more involved?**

PDA gave me an avenue for contributing to the health and safety of our nation in a way that is bigger than what I could do alone. PDA offers many avenues for volunteers to make an impact. The best way to get started is to discover your area of interest and bring data and knowledge to share.

**What film character do you most relate to and why?**

I've always been a science fiction fan, so Captain Kirk, of course!



*Captain Kirk is Karl's favorite fictional character*

# Is Your Wiper A Hand Me Down?



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# NE Chapter Celebrates 25<sup>th</sup> Year with Jam-Packed Schedule

Chapter President Roland Bizanek, PhD, Compass Pharma Consulting LLC

My name is **Roland Bizanek**, PhD, and I am the incoming president of the PDA New England Chapter for 2013-14. Our chapter was formed in 1988, and represents approximately 750 members from the six New England states: Massachusetts, New Hampshire, Rhode Island, Vermont, Maine and Connecticut. I am supported by my colleagues on the chapter board: **Jonathan Morse**, President Elect, **Mark Plucinsky**, PhD, Treasurer, **Jeff Anderson**, Secretary, and two Members-at-Large, **Rusty Morrison** (immediate Past-President) and **John Masiello**. Additionally, several of our members volunteer by actively participating within our committees. Without the continuous support of our chapter's volunteers and generous sponsors, we would not be able to engage in our various activities throughout the year.

We have an exciting and eventful year in front of us as we are celebrating our 25<sup>th</sup> anniversary this year. We started the year with our first dinner meeting in January on "Current Trends in Lyophilization", where **Ed Trappier**, President, Lyophilization Technology, presented on "Current Lyophilization Initiatives: Integrating Good Science and Regulatory Perspectives" and **Mark Staples**, PhD, Principal, Cusp PharmaTech Consulting, discussed "Fast Track Lyophilization Development for Early Phase Programs". The meeting was preceded by a tour of Rapid Micro Biosystems in Bedford, Mass.

Our second meeting was held in March on "Current Trends in Supplier Quality" with **Irwin Silverstein**, PhD, Vice President and Chief Operating Officer, IPEA, and President IBS Consulting in Quality LLC, presenting on "How Excipient GMP Certification Enhances Patient Safety," and **Helena Champion**, Principal Consultant, Drug Quality Assurance, discussing "Pharmaceutical Supplier Quality for the 21st Century."

On May 8 we are having our third dinner meeting of the year on "Current Trends in Compliance" with **David Chesney**, PAREXEL Consulting, as the

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*We have an exciting and eventful year in front of us  
as we are celebrating our 25th anniversary*

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Register Before **July 26th** to Save Up to **\$400** on Registration!



*The Parenteral Drug Association presents the...*

## 2013 Analytical Methods Development & Validation Workshop

*Navigating the Biotechnology Product Life Cycle*

**October 7-8, 2013** | Renaissance Baltimore Harborplace Hotel | Baltimore, Maryland

PDA is pleased to host the 2013 *Analytical Methods Development & Validation Workshop* to offer attendees an in-depth view of all analytical method lifecycle steps. This Workshop will bring together industry professionals of all levels to network and benefit from updates on recent regulatory guidances regarding developing and validating analytical methods.

Featured speakers include U.S. FDA representatives from CBER and CDER such as **Dr. Rajesh Gupta**, Deputy Director, Office of Compliance and Biologics Quality, CBER, FDA, and industry speaker **Dr. Stephan Krause**, Principal Scientist, *MedImmune*, Task Force Chair of PDA's *Technical Report No. 57: Analytical Method Validation and Transfer for Biotechnology Products* and author of *Validation of Analytical Methods for Biopharmaceuticals: A Guide to Risk-Based Validation and Implementation Strategies*.

Attendees of this workshop will gain practical information from plenary sessions such as the ability to:

- Maximize the value of all method lifecycle steps
- Design strategies of development, qualification and validation studies
- Write defensible protocols and reports using risk-based protocol acceptance criteria



Visit **www.pda.org/amd2013** for more information and to register.

**Exhibition: October 7-8**





# PDA Conference Recordings – Interactive Online Learning

PDA's Conference Recordings allow you to affordably hear from today's top presenters in the bio/pharmaceutical industry with no traveling!

**Recordings from PDA's 2012 events are now available for purchase. The events include:**

## 7th Annual Global Conference on Pharmaceutical Microbiology

Recordings from the entire conference are available for purchase for **\$215 Member/\$255 Nonmember**. Price of recordings includes:

- Eight (8) recorded sessions from the 2012 Conference
- Access to 19 downloadable presentation handouts
- Unlimited access to all session recordings for **90 days from receipt of login information**.

## 2012 PDA/FDA Pharmaceutical Supply Chain and Pharmaceutical Cold Chain/Good Distribution Practice Conferences

Recordings from both conferences are available for purchase for **\$255 for members and \$295 for nonmembers**. Price of recordings includes:

- Seven (7) sessions from each 2012 Conference
- Access to 32 downloadable presentation handouts
- Unlimited access to all session recordings for **90 days from receipt of login information**.

## 2012 PDA/FDA Vaccines Conference

Recordings from the entire conference are available for purchase for **\$215 Member/\$255 Nonmember**. Price of recordings includes:

- Eight (8) recorded sessions from the 2012 Conference
- Access to 18 downloadable presentation handouts
- Unlimited access to all session recordings for **90 days from receipt of login information**.

Members Save More: Receive 30% off the member price of a single event recording or session recordings bundle when you purchase or renew your PDA Membership!

**For more information on all PDA conference recordings please visit: [www.pda.org/onlinelearning](http://www.pda.org/onlinelearning)**



Roland Bizanek, PhD, New England PDA Chapter President (left) and Mark Staples, PhD, Principal, Cusp PharmaTech Consulting

invited speaker. On Aug. 21, our chapter will celebrate its 25<sup>th</sup> anniversary aboard the *Spirit of Boston* with a dinner symposium. We will then meet Sept. 11 at the Sheraton in Framingham, Mass. to hear about "Designing and Maintaining a Robust Equipment Cleaning Program for Biologics." Our last dinner meeting is scheduled for Nov. 13.

Besides these dinner meetings, we meet for regular board meetings, which are open to all chapter members, in the months between dinner meetings. If you want to get actively involved in the chapter, or seek more information on our meetings, please do not hesitate to contact me at [rbizanek@yahoo.com](mailto:rbizanek@yahoo.com). 🌐



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## 8 Reasons Why You Never Hear Back After Applying for a Job

Margaret Buj

**JOB** seekers often wonder why they never hear anything back after they hit 'send' on the email with a resume attached or on the online job application.

Sometimes you might have a preliminary email exchange with a recruiter and then never hear from them again. It's a depressing experience, and one that also casts a shadow on the hiring company's reputation. So why does it happen? Is it you, is it them or is it just something every candidate must prepare for in the hiring process?

There's no question job seekers face an uphill climb and competition for jobs is high. Many recruiters (including myself) complain that as much as 50% of people applying for a given job simply aren't qualified. So, how do you break through?

Here are my eight reasons you're not hearing back after applying for a job (and what to do about it).

### 1 You really aren't qualified

If a job description specifies a software developer with 3-5 years of experience and you're a recent graduate with one internship, it's unlikely you'll get a call. Avoid disappointment—don't apply for

jobs for which you lack qualifications. Most job descriptions are written with very specific requirements. In my recruitment job, on a daily basis I am amazed at the amount of people applying for jobs for which they have no relevant experience—I have finance people applying for senior business development roles or graduates applying for director level roles! It is a waste of their time and my time, as employers are looking for a very close match to their requirements.

### 2 You haven't keyword-optimized your resume or application

Job descriptions are salted with keywords specific to the skills or attributes the company seeks in applicants. A close read of the job description is a necessity, as is keyword-optimizing your resume and cover letter, if you're using one, or email. If the job description lists words in a certain order, e.g., a list of programming languages required, use the same order in your resume.

### 3 Your resume isn't formatted properly

You might think distinctive formatting will set your resume/CV apart, but automated programs don't care if a docu-

ment is pretty. Help a machine out. Be consistent in formatting—consider using separate lines for former employer, job title, and years worked. I'd recommend using a simple Word version of your resume, as all the fancy formatting gets lost in recruiting databases.

### 4 Your resume is substantially different from your online profile

I've had a number of Hiring Managers who decided not to interview candidates as their LinkedIn profile looked different to their resume. Jobs worked, employers, years on the job and other details should match on both your resume and LinkedIn profile.

### 5 The company received 200 resumes for one job posting, and yours was 199th

Looking for a job *is* a job. Do your research—know which companies you want to work for and which organizations where you sense culture fit. Every morning scour the job postings and jump on anything for which you're qualified (and in which you're interested.) Being early with your resume or application *does* matter. Check back often in the first few days

to make sure the listing hasn't changed. Often a company will post a job and halfway through the process change the description. Or you will apply by the time the company is already at a final interview stage for this role, in which case you have most likely missed out.

## 6 You didn't reach out

Sending tons of unsolicited resumes and cover letters isn't going to make you look like an attractive candidate, but rather a nuisance. I've recently seen the same candidate apply for 17 positions within the company—none of which he was really qualified for. Before you send over your application materials, reach out first. Try engaging with the hiring manager—or even an existing employee—on their public social media networks first. Starting a conversation can help you to find common ground, and it will show your interest lies in the company—not just any open position.

## 7 Your online brand stinks

With many companies using social profiles to research candidates, you can't afford to leave your online presence unattended. Run a Google search of your name to ensure all results are favorable, and tailor your public profiles to reflect your career goals. Make sure your LinkedIn profile is up to date and engage with professionals in your desired industry on Twitter by sharing relevant industry news and insights. Hiring managers use online profiles to see whether you present yourself professionally and it can help them to determine if you'd be a good fit with their company culture. Don't skip this step!

## 8 You didn't read a job spec properly

Too many job seekers apply for positions without really knowing anything about the company or what the position en-

tails. If you can't demonstrate a working knowledge of the company and position from the get-go, hiring managers will write you off.

So what can you do to get noticed?

Determine exactly what skills are needed for the job, and carefully review your past experience to make relevant connections. Search for keywords in the description that also apply to your experience and include them in your application materials. Remember, there's no such thing as a one-size-fits-all resume or cover letter, you have to tailor each document to each individual employer.

### You're much more likely to land a job at your ideal company if you've reached out to existing employees

Forge a connection with an existing employee by reaching out to them on Twitter or LinkedIn to express your interest in what they do and ask any questions.

Consider proposing meeting up for coffee or an informational interview to get all the insight you need and really cement the connection. Bring a copy of your resume and follow up with a thank-you afterwards. Your new connection could be just what you need to get a recommendation that could land you the job.

### Research interesting companies on social media

Find out who the recruiters are and follow them. Many will tweet new postings, so watch their streams and jump on anything for which you are qualified. And if they tweet news saying the company's had a great quarter, retweet the news with a positive comment.

### Consider starting a blog in your area of interest or expertise

It's a social world; time to build a trail of breadcrumbs leading to you. Include the blog, and links to any especially relevant

posts, in your emails to recruiters with whom you're working

### Get professional help with your resume

Either a resume writer or an interview coach can help you increase your odds of getting through the talent management software. If you can't afford this step, read the top career blogs for advice.

### If at all possible, don't wait until you're out of work to find your next job

I realize for many people this isn't possible or might even be offensive, but your chances of finding the next job are best when you're still employed.

### Network


Old advice, but still true. Be visible, be upbeat, be informed about industry trends and news in your area of expertise.

Finding a job is tough, no question. I've talked to other recruiters who say they only respond to 30% of applicants. The odds are good you'll be in the over 60% who hear nothing a lot of the time. Don't take it personally—it's not a rejection of you, it's a reflection of the times. If you don't hear back, know you're not alone.

Instead of feeling discouraged when you don't hear back from a hiring manager, use the opportunity to assess your experience and determine where you might have gone wrong. Regularly evaluating your performance—and taking steps to properly prepare for next time—can mean the difference between landing that interview and not hearing back.

Good luck!

### About the Author

**Margaret Buj** is an interview coach who's helped hundreds of professionals across Europe and the United States to get the jobs and promotions they really wanted. She also has eight years of experience recruiting for a variety of positions at all levels across Europe and in the United States, primarily in the technology and e-commerce sectors. 



# Technical Report Involvement Produces Career Results

Rebecca Stauffer, PDA

PDA’s line of technical reports has been recognized as one of the industry’s prime resources for technical knowledge on emerging and “hot” topics. But did you know that by volunteering your time to work on the task force behind a technical report offers potential career benefits as well?

**Robert Tomaselli**, who recently retired as Senior Director, Aseptic Processing, J&J, and worked on *Technical Report 54: Implementation of Quality Risk Management for Pharmaceutical and Biotechnology Manufacturing Operations* as well as *Technical Report 30: Parametric Release of Pharmaceuticals and Medical Device Products Terminally Sterilized by Moist Heat*, said he has benefited from the collaboration opportunities that arise during the development of a technical report.

“You’ve got a lot to offer. I would think from a career standpoint...you’ve gained a lot from your experiences and you’re willing to have an open dialogue with others about whether this works for you and hear what they’ve said,” he emphasized.

**Ghada Haddad**, Associate Director, Engineering, Biosterile Validation, Merck, also agreed that the close collaboration with other task force members has been beneficial for her professional life.

“Working on technical reports gave me the opportunity to collaborate with experts from the industry, academia and regulatory bodies. It allowed me to expand and grow my knowledge base and become an expert in a particular subject,” she said. “Working on technical reports for PDA has provided me greater visibility and positioned me to be successful and known in the industry.”

Haddad is currently chair of the task force working on the Paradigm Change in Manufacturing<sup>SM</sup> (PCMO) technical report, *General Approach to Implementing Quality Risk Management (QRM) for Pharmaceutical and Biotechnology Manufacturing Operations: Case Study Examples for Quality Risk Management in Packaging and Labeling*.

As a consultant, **Peter Levy**, Principal, PL Consulting, has also received advantages from working on technical reports; in fact, after working on his first technical report in the early 1990s, he received a job offer through one of his connections on the task force. Now, he sees his work on technical reports as an opportunity to exchange ideas with other professionals, particularly since he no longer works for an employer.

*Continued at top of page 17*

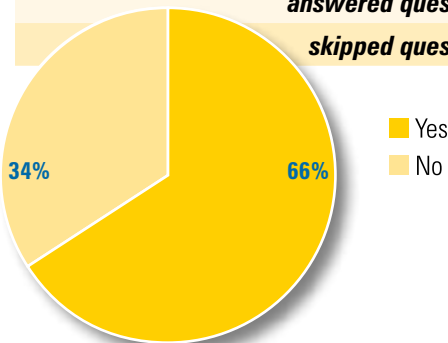
## In Print

### PDA Survey: Glass Quality: 2011 and 2012 Results and Comparison

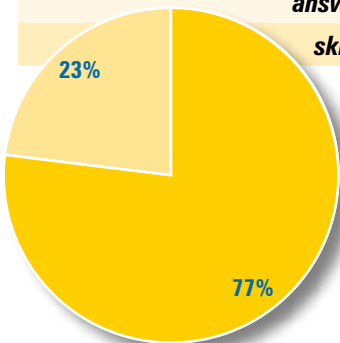
Recently, PDA published its glass quality surveys for 2011 and 2012 as part of the “PDA Survey” series of books. We’ve reproduced some of the survey’s key questions here, starting with Question 38 which explores the number of respondents utilizing PDA Technical Report No. 43, followed by Question 45 which looks at manual vs. automated inspections. Lastly, Question 49 explores the economic impact of glass defects.

#### 38. Does your company inspect for glass defects after filling the final product using the practices recommended in PDA Technical Report No. 43?

2011 Answer Options	Response Percent	Response Count
Yes	65.7%	46
No	34.3%	24
<b>answered question</b>		<b>70</b>
<b>skipped question</b>		<b>52</b>



2012 Answer Options	Response Percent	Response Count
Yes	77.2%	44
No	22.8%	13
<b>answered question</b>		<b>57</b>
<b>skipped question</b>		<b>62</b>



*Continued on page 16*

## Tech Trends

### Laser Tech Offers New Tool for Cleaning Verification

Rebecca Stauffer, PDA

Laser technology has come a long ways since 1950s science fiction writers depicted spacemen firing laser guns at little green men. Nowadays lasers are used to correct eyesight, scan for unstable rock masses on volcanic slopes, pinpoint distances between objects in the solar system and cut materials used in industrial manufacturing. And now pharmaceutical companies are utilizing lasers as a tool to evaluate the effectiveness of cleaning processes as an alternative to swabbing for residue measurement.

In January, Pfizer announced plans to partner with Block Engineering to develop a new cleaning verification technique that uses quantum cascade laser (QCL) spectroscopy technology. At this time, Pfizer is conducting feasibility studies of the new technology, which is expected to reduce cross-contamination as well as minimize process bottlenecks. In addition, other companies are looking to laser (or other technologies) to evaluate cleaning processes, including Amgen, Bristol Myers-Squibb and Novartis.


The system is not fully automated, according to **Destin LeBlanc**, Consultant, Cleaning Validation Technologies. "It still requires an operator to point the device at the surface to obtain a reading of the residue present. It is an improvement in that the readout of the residue on the surface is 'instantaneous,'" he said.

"It is not like swabbing where you have to extract the residue from the swab and measure the residue in the extraction solution by an analytical technique such as HPLC or TOC...the benefit of laser technology is that you don't have to touch the surface. You are still measuring by the use of infrared spectroscopy, however, so you will probably need an appropriate library of possible residues for analysis."

Another similar technology used within industry is a device produced by Remspec. According to LeBlanc, this device "must be placed directly on the surface since it operates by an ATR mode...the Remspec device has definitely been limited by the fact that it doesn't work well on nonflat surfaces, which are more likely to be worst case locations."

Even if your facility is not utilizing laser technology for cleaning verification, you can't argue that what were once considered science fiction technologies are becoming science fact across the industry. Who knows what further technologies will cross the line from fantasy into reality over the coming decades?

#### About the Expert

**Destin LeBlanc** is a cleaning validation consultant with over 35 years of experience in technical services and product development. He has spent the last 20 of these years working in the areas of cleaning and cleaning validation within the pharmaceutical and medical device manufacturing industries. 



## Task Force Corner

### TF Behind TR33 Revision Expects Positive Impact

Rebecca Stauffer, PDA

For the past five years, the task force behind the revision of *Technical Report 33: Evaluation, Validation and Implementation of Alternative and Rapid Microbiological Methods* has been diligently working on developing the most complete and up-to-date guidance for the application of new microbiology technologies. And with the ongoing revisions to alternative microbiological method informational chapters in both the U.S. and European Pharmacopeias, the importance of completing this task is paramount. Now, the task force leader, **Michael J. Miller**, PhD, Microbiology Consultants, LLC, has told the *PDA Letter* the group hopes to have the TR33 revision ready for final review, approval and publication by the middle of this year.

"It was important for the PDA task force to make sure that we provided a technical report that was going to be not only robust in nature, but comprehensive and understandable, taking into account all of the changes that have happened over the last five years in terms of new technologies that have been introduced and new regulatory policies that are making it easier to implement these changes within the industry," he said, adding, "It's been a long road but it's been exciting coming to the end."

Miller referred to the task force members as some of the "best-qualified" subject matter experts in the area of rapid and alternative microbiology testing. They comprise industry experts responsible for QC microbiology laboratories in addition to U.S. and European regulators, statisticians, rapid methods technology suppliers and consultants with more than 25 years of experience as pharmaceutical microbiologists.

Thanks to input from these experts, Miller expects the release of the technical report to have positive repercussions.

"The impact is going to be tremendous," he emphasized. "In a time when the use of rapid technologies are being encouraged by global regulatory authorities, this technical report will provide all of the tools necessary for firms to successfully select, validate and implement rapid microbiological methods for a wide range of applications."

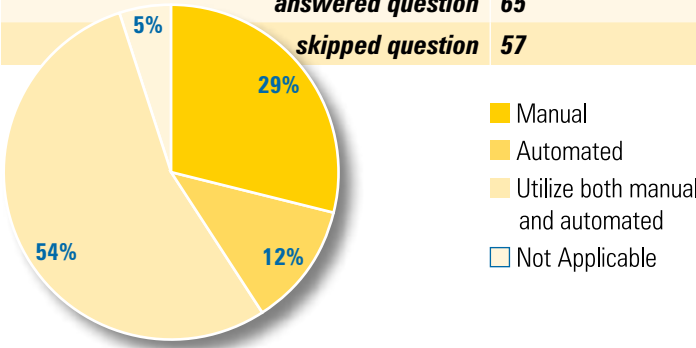
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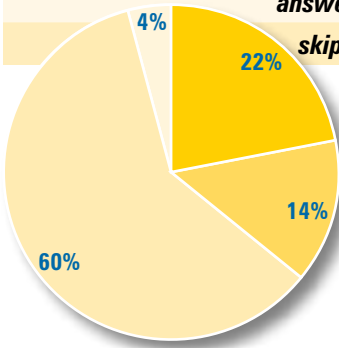
In Print continued from page 14

45. Is your inspection of product filled in glass containers manual or automated?

2011 Answer Options	Response Percent	Response Count
Manual	29.2%	19
Automated	12.3%	8
Utilize both manual and automated	53.8%	35
Not Applicable	4.6%	3
<b>answered question</b>		<b>65</b>
<b>skipped question</b>		<b>57</b>



2012 Answer Options	Response Percent	Response Count
Manual	21.8%	12
Automated	14.5%	8
Utilize both manual and automated	60.0%	33
Not Applicable	3.6%	2
<b>answered question</b>		<b>55</b>
<b>skipped question</b>		<b>64</b>

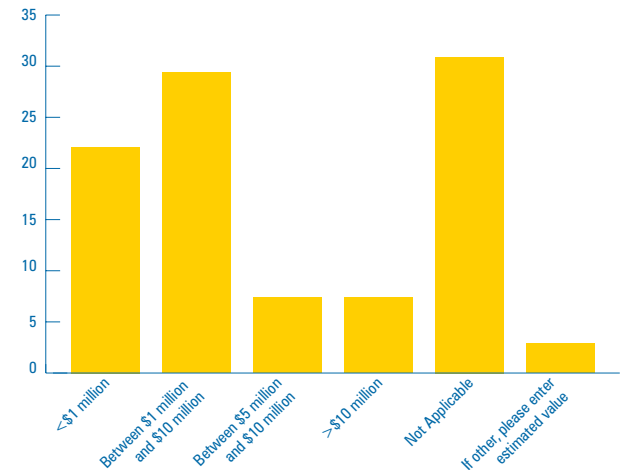


49. If final product batches have been rejected due to glass defects, over the past 3 years, then what was the value of the product rejected?

2011 Answer Options	Response Percent	Response Count
<\$1 million	22.1%	15
Between \$1 million and \$10 million	29.4%	20
Between \$5 million and \$10 million	7.4%	5
>\$10 million	7.4%	5
Not Applicable	30.9%	21
If other, please enter estimated value \$ _____	2.9%	2
<b>answered question</b>		<b>68</b>
<b>skipped question</b>		<b>54</b>

Other estimated values included:

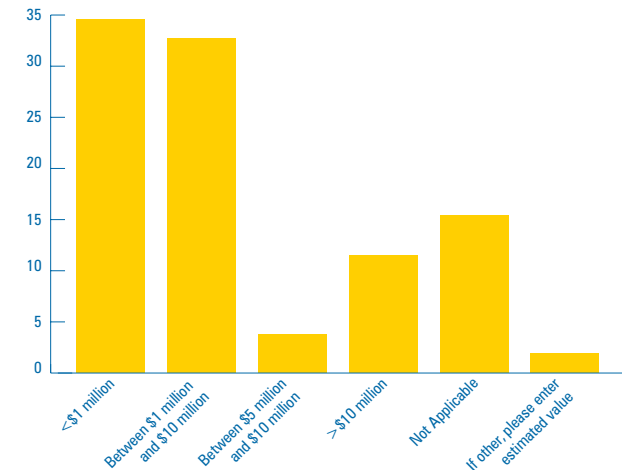
- 0
- Don't know



2012 Answer Options	Response Percent	Response Count
<\$1 million	34.6%	18
Between \$1 million and \$10 million	32.7%	17
Between \$5 million and \$10 million	3.8%	2
>\$10 million	11.5%	6
Not Applicable	15.4%	8
If other, please enter estimated value \$ _____	1.9%	1
<b>answered question</b>		<b>52</b>
<b>skipped question</b>		<b>67</b>

Other estimated values included:

- Not aware





*Technical Report Involvement Produces Career Results continued from page 14*

"It's a way for me to share ideas and develop different concepts with a group of other professionals that I don't normally have as an independent worker," he said.

**Kathy Stetson**, a Regulatory Intelligence Process Manager for GlaxoSmithKline, and a contributor to *PDA Technical Report No. 55: Detection and Mitigation of 2,4,6-Tribromoanisole and 2,4,6-Trichloroanisole Taints and Odors in the Pharmaceutical and Consumer Healthcare Industries*, also enjoyed the camaraderie of working toward a common goal with members of her task force.

"As a member of the Task Force Benchmarking Team, I was able to work with this team to conduct an industry benchmarking survey and author the 'Industry Benchmarking' section of the report. In addition, I worked with task force members and PDA's copy editors to pull the report together and incorporate industry comments," she said. "It was very rewarding to be a part of this process to work with top experts in the field to provide industry guidance and solutions for such a complex problem."

Ultimately, involvement with technical reports offers professional benefits beyond just the tangible end-product of the report itself.

"There's something in the process of shaping the ideas that I have about these subjects and seeing them critiqued and getting input and different outlooks from the other people on the task force that's been very positive, both in terms of shaping how I think about things and also seeing how ideas get developed into something that represents a consensus among the people working on it," concluded Levy. "I would recommend such work to all PDA members regardless of

your years of PDA service or level within your organization," Stetson urged. "In regard to my personal development, I have strengthened and developed skills that will help me in my current role at GSK as well as developed connections within the PDA and industry."

## About the Experts


**Ghada Haddad** has over 15 years of experience working in the Biotech and Pharmaceutical industries in the areas of QRM, validation, quality and regulatory. She has been involved in developing and deploying QRM programs.



**Peter Levy** has over 30 years of experience working in pharma. His industry experience includes large and small biopharmaceutical companies, equipment suppliers, and contract organizations.

**Katherine Stetson** is a Regulatory Intelligence Process Manager at GlaxoSmithKline. She has over 20 years of experience within the pharmaceutical industry as a R&D/manufacturing chemist and quality/regulatory expert.




**Robert Tomaselli** is a quality systems and aseptic processing and technology leader. He is currently embarking on a consulting career. 

*Task force Corner continued from page 15*

In addition, he explained that the new testing methods discussed in TR33 are vital for the continuous improvement of pharmaceutical products and processes.

"These types of technologies are going to provide us a much greater understanding of how we control our products and processes from a microbiological contamination control standpoint, and do so in a much faster timeframe as compared with traditional microbiological assays" Miller concluded. "Rapid methods are also nicely aligned with Quality by Design and Process Analytical Technology initiatives, which emphasize sound science, quality risk management and a model for continuous improvement."

## About the Expert

**Michael J. Miller, PhD**, is an internationally recognized subject matter expert in pharmaceutical microbiology and the design, validation and implementation of rapid microbiological methods. He is currently the President of Microbiology Consultants, LLC (microbiologyconsultants.com) and maintains an educational website for the advancement of rapid method technologies (rapidmicromethods.com). 



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***“Talent is only the starting point.”***—*Irving Berlin*

A portrait of Winston R. Brown, a man with short brown hair, smiling. He is wearing a dark pinstripe suit jacket, a white dress shirt, and a yellow patterned tie. The background is dark and out of focus.

# Take Charge of Your Career!

## Practical Guidelines for Career Planning and Advancement

**Winston R. Brown**

Careers can be summarized as the time a person spends working at their individual jobs and all of the experiences, education and professional relationships that go along with those jobs. However, career planning and advancement often defines what a person's body of work will look like and the degree of satisfaction they will gain. Many times we see people owning what they perceive to be their career, only to be taken back a step when challenged as to what they truly are striving for professionally, or put another way, what is the last seat they desire to sit in prior to retirement. Career planning requires a person to invest considerable time and careful thought in defining, and then revisiting, their overall goals, aspirations, trajectory and what really makes them happy.

The principles and insights that will be shared in this article are lessons learned and are applicable regardless of stage in career. On a personal note, I believe that no one should take as much interest in your career as you. One of my passions and points of pride has centered on career mentoring, coaching, and then seeing the end results through people fulfilling their aspirations. Throughout my own career, I have been afforded many opportunities, within and outside of industry, due in no small part to some great leaders and established meaningful relationships—all tempered with personal career ownership.

## Backwards Planning—The Journey Begins

Emphasized again, no one should take as much interest in your career than you. A major part of career advancement begins with understanding where you eventually want to end up. The journey starts with the end in mind, or “backwards planning.” To effectively plan, you should answer three key questions:

- How much time realistically do you have in your career? In other words, what is your window?
- What is the last seat you desire to sit in prior to retirement? Modified slightly, what area and position level is your ultimate goal?
- Does your career or development plan provide a realistic blueprint and pathway to meet aspirational goals?

The workplace and workforce are different today than from many years ago. In most cases, it is uniquely uncommon for a person to stay at one company for an entire career. In fact, recent research suggests that individuals will change companies at least three or four times over their lifetimes. Does that mean dissatisfaction with their jobs and company? Not necessarily. The realities of today’s industry are mergers and acquisitions, planned and unplanned downsizing, and startup/venture companies. Both employee and employer have had to adjust to globalized markets, price and profit pressures, economies of scale and other factors where the impact is felt throughout the organization in the form of change.

So how do you effectively backwards plan? First, you start with your career window. As an example, you may decide to work 20 years prior to retirement. This being the case, list out the career areas in which you have strong or even potential interest. For instance, you may be currently working in the quality organization, yet have potential career interests in regulatory affairs, operations, project management or R&D. Once areas have been identified for interest, work backwards from the desired position or level. If your long term goal is to become a vice

president of regulatory affairs, then what are the logical grade-level positions that you should obtain prior to getting there? For instance, if you are not yet at the management level, you should assume spending so many years as a manager, senior manager, director and so forth.

**Figure 1** provides an example where the person goes from a junior to senior level. The figure depicts potential assignments along the way. Also noteworthy in this example is that a career trajectory can go across multiple career field boundaries, not just functionally specific.

Now the focus narrows, so your career path should begin to get more specific. General rule of thumb is that you should expect to be in a role for at least two+ years to have any type of meaningful impact to the organization. With the current example, given the number of anticipated grade levels, it is assumed that you can average around five years per role to obtain your overall goal. That is, a 20-year work window/four anticipated role levels = five years. Granted this is a paper exercise and purely hypothetical, but it still provides an idea for the types of roles and in what areas you should target.

Consideration must be given at this point and going forward as to what technical, leadership and managerial skills must be attained or developed to get to that next level or lateral move. You should be strategically looking at what skills and competencies are needed at least two levels ahead. More will be discussed later around rotational roles and lateral moves.

While performing backwards planning and defining anticipated roles, you need to assess your mobility and travel ability, both for the short and long term. Accepting international assignments and experiencing different cultures can significantly enhance a person’s ability to understand the global marketplace. Part of your branding strategy is letting people know how willing you are to locate, or relocate, for domestic and international roles. Additionally, as a person gets promoted, travel may become more of a factor. In these cases, you should truly assess your own personal situation to understand the

impact of both. Moving with young children is much different than for empty nesters or singles. Moreover, saying that a person’s willingness to travel greater than 50% of the time is usually a label for “road warrior.” Many times over 50% becomes 75% in actuality, so make sure the commitment is realized up front. Likewise, with relocation. If one agrees to an international assignment without consulting their family, Christmas may not be so bright! Be flexible and look at the bigger picture. Though the situation for travel and relocation may be static for one to three years, it does not mean that will be the case in five or ten years, so along with the career map and timeline, travel and location requirements should be communicated so that people get an entire profile about you as a candidate for advancement. **Figure 2** is one example of a template you could use in keeping track of mobility and relocation requirements:

### Pitfalls

Through coaching, mentoring and having lived career planning over several years you can appreciate a few of the key aspects that remain relevant today. Some of the more important pitfalls to avoid regarding career planning are listed as follows:

- Waiting on someone else to take control of your career
- Lack of effective or realistic career goals
- Believing that it is only during performance appraisal times that career development matters
- Believing that doing a good job is sufficient enough to be recognized and advanced—while this is mostly true, there are other aspects, discussed later, that come into play

### Article at a Glance

- Begin planning your career with an end goal in mind
- Being open to learning and collaboration enhances reputation
- Observe the positive and negative traits of leaders around you



- Not understanding or having thought about where you want to go in your career
- Lack of an updated resume/CV and not keeping track of your career accomplishments
- Ignoring lateral move opportunities
- Not realizing that being a manager does not necessarily mean being a leader and vice versa. Both are needed and required
- Not realizing your limitations, strengths and opportunities for improvement
- Not realizing that communication is an art, you have to practice being good at it

### Career and Personal Branding

Those that have had any type of marketing experience should understand and remember the “Four P’s”: Product, Place, Price and Promotion. When candidates are looked at to fill a potential role, technical skillsets and core competencies garner interest, but equally important are the person—both manager and leader. Being able to stand out from the competition gets attention, and branding is a key.

### Personal Inventory

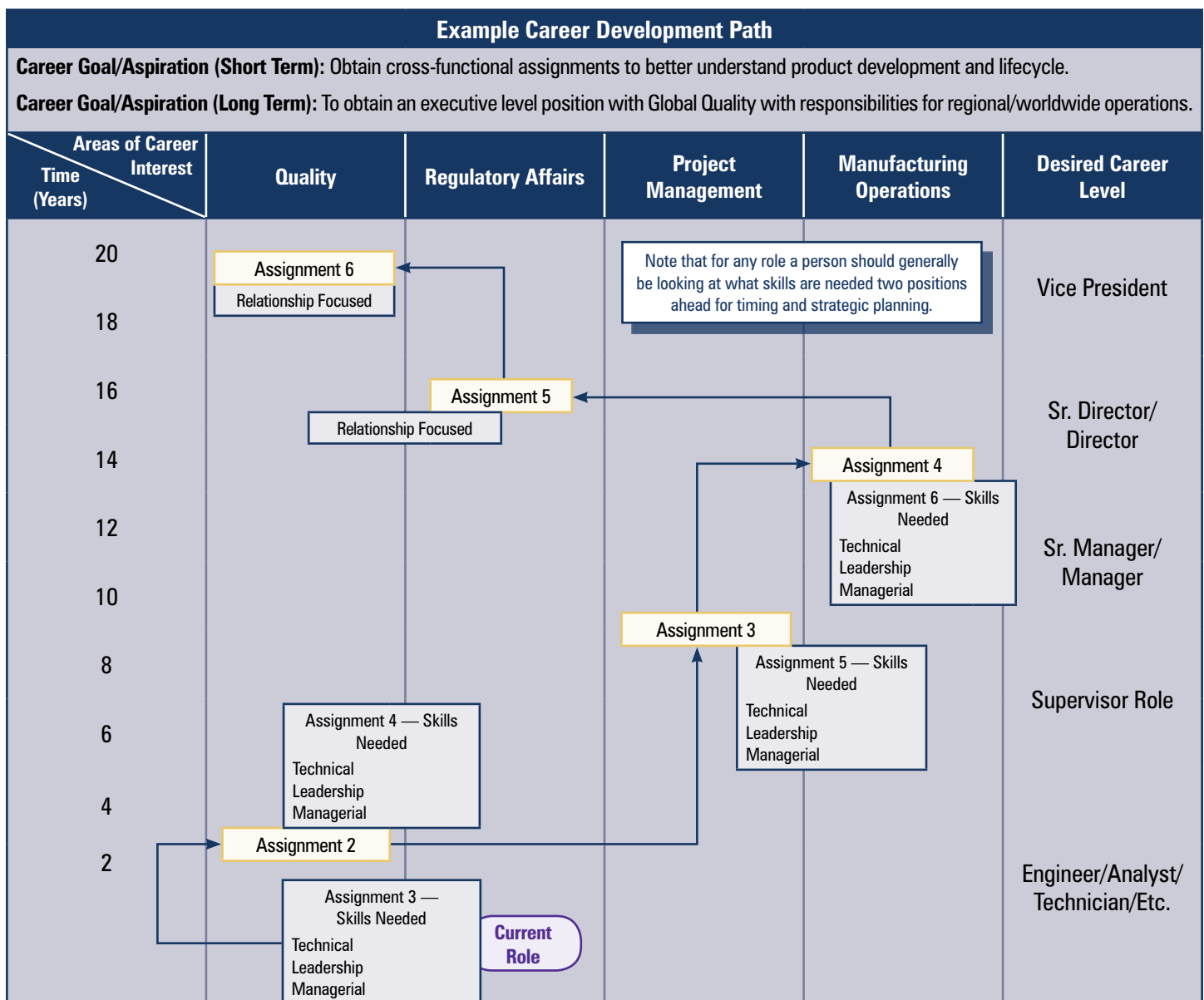
The branding process starts with the person realizing their current identity versus reality. Everyone, regardless of industry or length of career, has had a reality

check at some point or another. Some examples of reality checks are:

- Perceptions about yourself versus how others view you
- Preparedness to take on a new or difficult role
- Uncontrollable circumstances such as layoffs, mergers, acquisitions and reassignment
- Entry into or exit out of the labor force

If you are unsure about how people perceive you (current reality), there are tools that can be used to provide this type of feedback. Your supervisor or human resource professional should be able to assist greatly in this area.

**Figure 1** Example Career Development Path







By recognizing reality, and then doing something about it, reality can then be turned into opportunity.

Turning reality into opportunity applies for both planning and advancement. One of the first steps in career planning is to take a personal inventory of your key strengths, weaknesses and how you are perceived by colleagues.

This can be a very enlightening and sometimes humbling experience, but take the time to go through the rigors. Sharing your list and seeking feedback with close colleagues, immediate supervisors and the like will go a long way in either validating or changing a person's perception.

Now, take action! Don't develop a plan for yourself just to change perceptions. People are fickle sometimes and opinions

vary greatly. However, look at the collective feedback overall to discover themes and blips that are not currently tracked on your personal radar of self-reflection.

### Technical vs. Relationship Skills

When starting out early in a career, a person naturally spends more time developing their technical skills and competencies. As that same person gets promoted and goes through the rank and file, technical skills are assumed and the emphasis is more heavily placed around strategic leadership and relationship skills. Think about how much time on average you spend in meetings, networking, actively listening, doing business globally in different cultures, selling ideas and providing feedback. You can have strong technical acumen yet be devoid of the professional relationships and social col-

lateral to be personally enriched while still accomplishing your goals. No matter the technology and platform, people are still the centerpiece of the industry. For your own enrichment and career satisfaction, developing meaningful relationships is key.

### Do Tell

Regardless of stage in career, a person should always be prepared to provide three to five minutes about themselves, their background, goals, experiences, and interests to others within and out of their respective network. Opportunities for advancement can come from gradual relationships over time or on the spot, so be prepared and be genuine. People are pretty intuitive and can generally tell if a person is coming across as too canned versus legitimately interested and en-

**Figure 2** Example Template for Career Path Requirements

20xx High Level Career Development Plan—Name							
Year	Position	Function	Area	Skills needed to obtain before leaving position (include status of completed items)	Profess. Development goals before leaving position	Areas of Improvement to focus	Duration
Current	Manager I			This area should be reserved for the specific job and managerial related skills sets that need to be obtained or enhanced prior to leaving the role or moving to the next level assignment.	Professional Development goals could coincide with the previous "Skills" column, but is more specifically focused on areas such as leadership, certifications, degrees, projects and other related professional accomplishments.	Areas of improvement should drive what skills and professional development goals you pursue. They should be provided through self, managerial, or peer reflection.	Try to quantify to the timing for completion for all stated skills needed and goals identified. Revisit this and all other areas with your manager at least once per year.
	Manager II						
	Director						
	Sr. Director						
	Vice President I						

Place an "X" in the area(s) to where you feel most confident. This is your opportunity to indicate areas of interest, work arrangement flexibility, and overall travel preferences. For relocation areas, indicate which region you would be willing to relocate to, if appropriate. For the U.S., indicate if you would be willing to locate to "U.S.—Any" any location in the United States with no particular preference, or, "U.S.—Restricted" to where you would only be willing to locate to certain regions / states.

Year	Travel						Relocation		Relocation Areas					
	0%	5-15%	15-25%	26-50%	51-75%	>75%	Yes	No	U.S.—Any	U.S.—Restricted	European Union	Canada	Latin America	Asia Pacific
Current														
1-3														
3-5														
5-7														
7-9														
9-11														
11-13														
13-15														
15-17														



gaged. Having this information fluid in conversation helps in networking and establishing relationships (and it is not a bad thing during those times you are put on the spot!).

There are, and have been, a number of articles published about the rules and nuances of resumes, using social media and getting the right picture out there on places such as LinkedIn. All good information, but a bit tiring to go through, so here are a few suggestions, in no specific order, to enhance your branding strategy:

- Keep resumes updated, accurate and relevant. By maintaining personal information, it provides the latest insight to accomplishments, assignments and shows personal career interest.
- Think about your next career move, even when you're not actively looking for it. It makes sense to keep your CV up to date, just in case. Hurriedly putting together a CV at the last minute for a job application or posting doesn't give you a chance to do yourself justice and polish it. If you keep it up to date all the time you'll have plenty of time to present your skills in their best light, check and double check everything and take care of the presentation.
- Social Media. Several articles have been written about prospective employers (both internal and external) searching social media sites to find out more about prospective candidates, and even existing employees. Use good judgment when posting and providing information/comments on social media. View it from a neutral party standpoint. If something seems questionable or in poor taste, why take an unnecessary chance?

### **Collaboration**

There are significant personal and professional rewards from collaborating and networking with others in industry. Really, the value should be at a premium

for establishing relationships, rather than the number of contacts on LinkedIn or number of business cards passed out at an event. You can become engaged and collaborate in a number of different ways, either internally within your own company or externally within industry. Sharing ideas, experiences and obtaining best practice are definite positives. It is working towards the common good of the industry to solve complex problems and present a common front; however, that represents the spirit of collaboration.

Meeting people within industry and establishing long-lasting relationships is the personal reward. Being able to reach out to those very same people to help in times of need both for them and yourself extends the reward even further. By gaining different industry perspectives through collaboration, and establishing meaningful relationships, you become better-rounded but also better connected through outreach.

### **Personal Career Branding Also Continues Through Lifelong Learning**

The current landscape in industry is ever-changing. Being able to keep abreast of changes, technologies, ideas and basic information is not only necessary, but an expectation. Learning simply does not cease once a person has obtained a degree or certification. Conversely, commitment to lifelong learning does not necessarily mean going back to school. Learning can be facilitated through online courses, workshops, in-house training, reading, shadowing and mentoring, to name just a few. Many years ago people would take up a certain degree and spend a career in that particular field. Now, learning resources have become so diverse an individual can, for example, start out in microbiology and end up in engineering. The better-rounded a person becomes, the more diversely they can contribute and advance in their own

profession. Just as with career planning, learning goals need to be identified in your development plan and need to be specifically targeted to your overall interests and ultimate career path. If one evaluates the areas of manufacturing operations, quality and regulatory, for example, there is no one degree or training background that makes for a perfect fit.

The beauty of the industry is, that it is so complex and diverse there is a need for scientific, engineering, business, medical and other cross-functional skill sets. Life-long learning and personal branding should not only be relegated to technical skills but leadership skills as well. Too often we find many technically competent professionals within industry that often lack leadership and management skills. Emphasis should be placed on a balance of technical and leadership skills so that a person's brand is holistic, not just one-sided.

The following are sound tips and pitfalls to avoid for career and personal branding:

- Stick to label claim. Don't be one thing on paper and translate the complete opposite in actions. People are intuitive and if not genuine, you and your career will stagnate at best.
- Avoid selfishness, try selflessness. In order to establish meaningful relationships, a person needs to be transparent at all times. It's okay to seek assistance, but having hidden agendas takes away personal collateral.
- Get to the point when talking about yourself. A person may only have a couple of minutes at best while networking or with a prospective employer, either internal or external. Being direct about your overall career goals and aspirations, background and interests helps to set the tone for the rest of the conversation and shows you take genuine interest and are confident in your direction.

**If you wish to achieve worthwhile things in your personal and career life, you must become a worthwhile person in your own self-development.**

**— Brian Tracey**

### Leadership—Incorporating the Good and the Not So Good

Most in industry today have had their share of good leaders and those leaders which left something to be desired. Both models are excellent learning tools for those aspiring to the next level. You should have a basic leadership fabric when first starting out, weaving in the good traits and characteristics as you go throughout their career. At the same time you should have a keen eye as to bad leadership traits so that you do not repeat the mistakes made by others. By the way, people should not confuse bad leadership with unpopularity. Having the managerial courage to make a stand in the face of adversity or other pressures, can test your metal but bodes well for your integrity and future leadership experiences. Courage alone does not get promoted, but it does get recognized. Just ensure your principles are understood by others and you are acting in the best interest of the overall health interest and mission. At the same time, being too staunch in your position as a default mechanism, without listening and taking into consideration different perspectives can put you on similar unequal footing. Leadership tempers both.

### Developing Bench Strength And Future Leaders—The Reward Of Giving Back

Developing future leaders and seeing people get to the next level the right way, leaves a very fulfilling feeling for a person in a leadership role. Not only should you be contemplating your own planning, branding and advancement, but that of your subordinates as well. Taking a personal interest shows the degree to which a leader genuinely cares. Careful planning also enables the development of well-rounded bench strength which can translate into a high-performing organization.

### Advancement: Attitudes and Aptitudes

A high degree of aptitude does not necessarily translate into the right attitude and vice versa. Having a degree of humility, being open to critique and advice, and being actionable and timely all provide the base of a high potential and high performing leader. Also, there is still a place today for proper etiquette, direct com-

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munication and being kind-spirited. These qualities should not be confused with not holding others accountable for results and their own actions. The bottom line? Leaders get promoted.

### Advancement not always to Next Level

As discussed previously, advancement does not necessarily mean the road to the next promotion is straight. Many companies today foster leadership development programs for high performing individuals. More often than not, this involves rotations through different departments and provides unique, strategic and tactical experiences. The important thing is that you are honest, both with yourself and your leadership. If you have ►

# 2013 PDA

## UPCOMING EVENTS

### MAY EVENTS

**9**

**PDA Southern California Chapter Vendor Night and Industry Summit Cruise**

Newport Beach, California  
[www.pda.org/socalcruise](http://www.pda.org/socalcruise)

**13**

**2013 PDA/FDA Container Closure Components and Systems Workshop Course**

Bethesda, Maryland  
[www.pda.org/containerclosurecourse](http://www.pda.org/containerclosurecourse)

**14-15**

**2013 PDA/FDA Container Closure Components and Systems Workshop**

Bethesda, Maryland  
[www.pda.org/containerclosure2013](http://www.pda.org/containerclosure2013)

**15-16**

**2013 PDA/FDA Glass Packaging Conference**

Bethesda, Maryland  
[www.pda.org/glass2013](http://www.pda.org/glass2013)

**16**

**PDA Southeast Chapter 2013 Spring Conference**

Raleigh, North Carolina  
[www.pda.org/sespringconf](http://www.pda.org/sespringconf)

**17**

**2013 PDA/FDA Glass Packaging Conference Course**

Bethesda, Maryland  
[www.pda.org/glasscourse2013](http://www.pda.org/glasscourse2013)

**20-21**

**2013 PDA/FDA Process Validation Workshop**

Bethesda, Maryland  
[www.pda.org/processval2013](http://www.pda.org/processval2013)

**22-23**

**2013 PDA/FDA Process Validation Workshop Course Series**

Bethesda, Maryland  
[www.pda.org/provalcourses2013](http://www.pda.org/provalcourses2013)

**29**

**PDA Canadian Chapter: Transport of Drug Products – Logistics, Risks, and the Application of Regulatory Requirements**

Montreal, Quebec  
[www.pda.org/catransportevent](http://www.pda.org/catransportevent)

### JUNE

**3**

**Pre-Conference Workshop: Virus Spike Characterization and Virus Removal by Filtration – New Trends and Developments**

Berlin, Germany  
<https://europe.pda.org/WSVirusTSE2013>

**3-5**

**2013 PDA/FDA Pharmaceutical Supply Chain Workshop**

Bethesda, Maryland  
[www.pda.org/supplychain2013](http://www.pda.org/supplychain2013)

**3-7**

**Aseptic Processing Training Program – Session 3, Week 1 (Week 2: June 24-28)**

**SOLD OUT**

Bethesda, Maryland  
[www.pda.org/2013aseptic3](http://www.pda.org/2013aseptic3)

**4-6**

**4th Virus & TSE Safety Forum**

Berlin, Germany  
<https://europe.pda.org/VirusTSE2013>

**6**

**2013 PDA/FDA Pharmaceutical Supply Chain Workshop Course Series**

Bethesda, Maryland  
[www.pda.org/supplychaincourses2013](http://www.pda.org/supplychaincourses2013)



For an updated PDA calendar of events please visit  
[www.pda.org/calendar](http://www.pda.org/calendar).



*Save these dates!*

## EVENTS

## JULY EVENTS

**10-14**

**Fundamentals of Aseptic Processing Training Course – Session 1**

Bethesda, Maryland  
[www.pda.org/apfundamentals1](http://www.pda.org/apfundamentals1)

**18-19**

**2013 PDA Aseptic Processing-Sterilization Conference Course Series**

Chicago, Illinois  
[www.pda.org/asepticsterilizationcourses](http://www.pda.org/asepticsterilizationcourses)

**20-21**

**2013 PDA Aseptic Processing-Sterilization Conference**

Chicago, Illinois  
[www.pda.org/aseptic2013](http://www.pda.org/aseptic2013)

**25-26**

**Advanced Therapy Medicinal Products**

Florence, Italy  
<https://europe.pda.org/ATMP2013>

**9-10**

**Emerging EU Regulations and Inspection Trends Conference**

Dublin, Ireland  
<https://europe.pda.org/EU2013>

**11**

**GDP – Good Distribution Practice Training Course**

Dublin, Ireland  
<https://europe.pda.org/GDP2013>

**11-12**

**An Introduction to Visual Inspection Training Course**

Dublin, Ireland  
<https://europe.pda.org/TCVisInsp2013>

**11-12**

**Process Validation and Verification Training Course**

Dublin, Ireland  
<https://europe.pda.org/Process2013>

**23-24**

**Fundamentals of an Environmental Monitoring Program Training Course**

Bethesda, Maryland  
[www.pda.org/environmental2013](http://www.pda.org/environmental2013)

**29-2 August**

**2013 Filtration Week**

Bethesda, Maryland  
[www.pda.org/filtrationweek2013](http://www.pda.org/filtrationweek2013)





no interest in taking a same grade role for a different area, express that. It does not mean that promotional opportunities will necessarily be limited; instead, it highlights your focus on the areas that you value the most.

**Figure 3** provides an illustrative example for a person that wants to remain in the manufacturing career track. As depicted, and based on selected position, you can gain some experiences in different areas without necessarily committing to a dedicated rotational role. For instance, a Project Manager or Site Director has quite a bit of visibility into other operational areas either through running a project or

having daily operational oversight. You can draw upon working closely with colleagues and performing smaller ad hoc roles in those areas to better understand some of the fundamentals.

### Final Thoughts

No one person or group should take as much interest in your career more than you. Career advancement starts with a thorough understanding of yourself that should result in an actionable career road map for both the short and long term. Personal branding enhances advancement opportunities if the right amount of time is taken to prepare and revisit. Providing leadership, mentoring,

and collaboration enriches your career trajectory but gives back in personal reward as well.

Finally, I want to thank all those who provided personal and professional guidance over the years from peers and colleagues.

### About the Author

**Winston Brown** works for Alcon, a division of Novartis. Winston is Head of Quality for R&D—Pharmaceuticals. He has responsibility for all phases of quality within the areas of research, development and clinical. Winston has worked in the pharmaceutical, medical device and bi-therapeutics industries for almost 20 years. 🌐

**Figure 3** Examples for Career Direction

Career Direction Examples					
It is important to note that career directions can go in and out of a number of different directions. For example, if a person desires to stay in manufacturing operations there are many options that can be explored to round out his or her skill base even further, should they choose not to desire to rotate into a different area.					
Time (Years) \ Areas of Career Interest	Quality	Regulatory Affairs	Project Management	Manufacturing Operations	Desired Career Level
20				Vice President Global Operations	Vice President
18					
16				Manufacturing Site Leader/Head	Sr. Director/ Director
14					
12				CMC Submission Reviewer	Sr. Manager/ Manager
10				Sr. Project Manager Operations	
8				Lead Validation Engineer Critical systems/Utilities	Supervisor Role
6					
4					Engineer/Analyst/ Technician/Etc.
2				Current Role	

# New Release at the PDA Bookstore



Published by PDA

## Pharmaceutical Legislation of the European Union, Japan and the United States of America – An Overview

Dr. Barbara Jentges  
Nobuo Tateishi  
Kate Denton  
Dr. Dr. Michel Mikhail  
Peer-Reviewed by: Karen Ginsbury

## Pharmaceutical Legislation of the European Union, Japan and the United States of America – An Overview

*by Dr. Barbara Jentges, Nobuo Tateishi, Kate Denton and Dr. Dr. Michel Mikhail*

*The Pharmaceutical Legislation of the European Union, Japan and the United States of America – An Overview* gives an overview of the pharmaceutical legislation of the three ICH regions through chapters on Regulatory Bodies and Health Authorities: Functions and Responsibilities, Pharmaceutical Legislation, Marketing Authorization Application Procedures and Drug Master File Systems. The authors of this book hope that it provides a mutual (regulatory) understanding and provide at least a sign on the promising road to harmonization.

[www.pda.org/eujusa](http://www.pda.org/eujusa)

### About the Authors

**Nobuo Tateishi**, Specialist, is a member of the audit and inspection group of the Quality Assurance Department of Chugai Pharmaceutical Co., Ltd, a member of Roche. He is also a member of the QA/QC committee and Aseptic GMP committee of PDA Japan. He has made several presentations about regulatory updates in Japan in FDA/PDA joint conferences.

**Dr. Barbara Jentges**, Senior Drug Regulatory Affairs Expert and Managing Director of PhACT GmbH Switzerland, is a pharmacist with more than 20 years of experience in Regulatory Affairs. Among others, she worked as an expert/assessor of the Federal Institute for Drugs and Medical Devices (BfArM = Bundesinstitut für Arzneimittel und Medizinprodukte) in Germany. She chairs PDA's European Interest Group 'Regulatory Affairs' and is a member of PDA's Regulatory Affairs and Quality Advisory Board.

**Kate Denton** is Regulatory Affairs Manager at Novozymes Biopharma UK Ltd, part of the global biotech-based enzymes and microorganisms manufacturer, Novozymes A/S. She has more than 16 years of experience in Regulatory Affairs, co-ordinating regulatory activities for the global registration of biotech products, specifically yeast-derived recombinant proteins.

**Dr. Dr. Michel Mikhail** has more than 25 years of pharmaceutical industry experience in senior roles in R & D and international regulatory affairs in large multinational pharmaceutical companies. Dr. Dr. Mikhail is a Chartered Expert in Pharmacology - Toxicology, a chartered Clinical Expert, and a chartered Analytical Expert. He has in-depth knowledge of the entire drug development procedure with global science-driven, patient-oriented regulatory affairs.expertise. Currently Dr. Dr. Mikhail is Chief Regulatory Officer and Executive Vice President Global Regulatory Affairs at Fresenius Kabi, a multinational pharmaceutical company. Dr. Dr. Mikhail is a member of the EGA Executive Committee and a member of the EGA Board.



# Pharma Manufacturing Recruitment in 2013—and Beyond

By Mark A. Lanfear, Kelly Services

Since the Great Recession took hold, the pharmaceutical manufacturing sector has held a unique position in the economy. Traditionally, and according to the U.S. Bureau of Labor Statistics, this industry has not been prone to wavering economic conditions. After all, when we are sick, we still need our medicine. We still need the innovative work of the pharmaceutical industry to keep us healthy so we can cope with all the other challenges that life brings.

In both good times and in bad, it seems, medicine consumption usually remains the same.

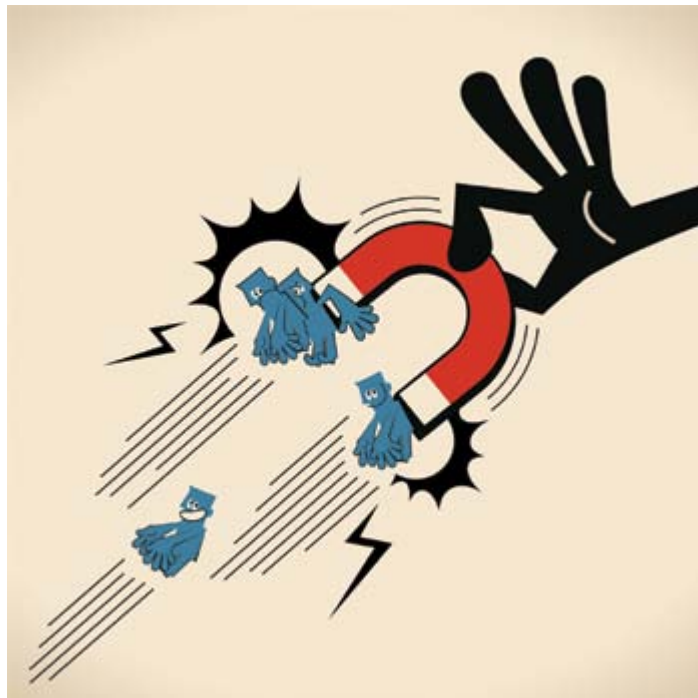
This simple truth is the backbone of the relative stability that the pharma industry has always enjoyed. But this truth hasn't meant a free pass. Pharma companies have still had to deal with economic woes in the face of big demand for their medicines and R&D breakthroughs. This means that in the last decade alone, the way Big Pharma does business has drastically changed to simply accommodate the economic realities of the global market in general.

One stark example is the demise of the so-called “blockbuster” drug. Most patents on these drugs are expiring, taking with them the blockbuster revenue streams for these companies. As a result, doing bigger and better business even as financial resources grow thin or old business models disappear has become more significant than ever. It doesn't mean that key things like research and development will ever lose their luster—it just means that pharma companies, like all organizations, will have to become more efficient in the way they do business.

As those most intimately acquainted with the pharma manufacturing job market can attest, one of the most insightful components of executing business is understanding the use of capital and that includes human capital—and how to attract the talent required for the long haul. Pharma is still hugely dependent on intellectual capital, and human expertise is driving completion on the global stage. Companies are all analyzing workforce behaviors more completely in an attempt to predict which employment factors have changed in order to stay competitive.

Not just aggressive recruiting measures, but *smart* recruiting measures are what are required in 2013 and beyond. According to Wanted Analytics, a firm that collects and analyzes hiring demand data, just since January the number of available science jobs grew by 15% compared to this time a year ago. In the life sciences in general, the number of jobs has grown by a whopping 42% since 2008 (the recession), per Wanted Analytics. Among the industries with the highest demand for scientists are pharmaceutical manufacturing.

But it's the biopharma companies that are demanding the lion's share of human capital as they strive to develop first-in-class



The pharmaceutical industry has been working to attract the best biopharma technicians and regulatory experts.

therapies. With biologics coming to dominate the sector, plant and facility expansion, as well as a growing need for regulatory support, continues to challenge drug companies as they seek new revenue streams. As a result, bioprocessing technicians, quality assurance auditors and quality control inspectors that can help companies adhere to regulations are in strong demand.

Talent acquisition will be focused on individuals with specific skill sets who already possess technical expertise coming in so as to make an immediate impact, says **Diane Barker**, Director of the Americas Scientific Product Group of Kelly Services. This is when partnering with workforce companies that have on-the-ground experience in recruiting for these jobs can tremendously help a pharma company. In fact, “Pharma companies are looking more and more to workforce partners to support them in this endeavor,” Barker says. Companies are finally recognizing just how big of a challenge it will be to find the most competent skill sets for such highly technical jobs. Demand, after all, is expected to be strong for technical skills in 2013 and beyond.

Companies have moved strongly toward “insourcing” models for manufacturing. In fact, according to PwC's *15<sup>th</sup> Annual Global CEO Survey*, 30% of pharmaceutical companies are insourcing work that has previously been outsourced. Efficiency is cited as one of the major reasons, as in the case of GlaxoSmith-Kline, a leading pharma company that wanted to gain more control over its development and manufacturing process. Fur-



## Pharma companies, like all organizations, will have to become more efficient in the way they do business

Furthermore, GSK Chief Financial Officer **Simon Dingemans** has previously stated across industry media that the move basically reflects a desire to use existing facilities more effectively and keep its supply chain working more efficiently.

Of course, while some facilities are being closed altogether in the United States, it is important to note that the reasons for doing so are related to an overall downturn in the industry—not because companies necessarily want to outsource manufacturing functions. In fact, the reverse might be true with a recent trend towards insourcing. For example, Novartis is building a new manufacturing plant in Eastern Europe instead of

moving toward CMOs. Pfizer has chosen to close plants in expensive places like Connecticut and reopen them in places like Eastern Europe. AstraZeneca and Novo Nordisk as well have built new manufacturing facilities and opened them in 2013.

Other companies like Eli Lilly are finding creative ways to insource, like bringing certain contract researchers in-house to use lab space that was previously empty because of downsizing. Some of the research work had been done in China, but with this current insourcing model, Eli Lilly is realizing that the scientists are able to communicate better and manage projects more efficiently.

As the scientific workplace continues to change, and as job opportunities grow, talent acquisition (at one time simply called recruitment) has become a primary game changer in all the science and technology categories. Evolution is the key to stay aware of rising workforce trends, and thoughtful recruiting efforts, and investment in the steps to acquire the essential talent. This is on the mind of every board room agenda.

### About the Author

**Mark Lanfear** is a global product leader for the life science vertical at Kelly Services®, a leader in providing workforce solutions. He has operated clinical trials around the world for almost two decades and has extensive experience as a talent acquisition expert in the life science space. 



Register Before **July 26th** to Save Up to **\$400** on Registration!



*The Parenteral Drug Association presents the...*

## 2013 PDA Visual Inspection Forum

**October 7-8, 2013 | Hyatt Regency Bethesda | Bethesda, Maryland**

Plan to attend the *2013 PDA Visual Inspection Forum* for an enlightening two-day comprehensive learning experience and speak with the industry leaders in visual inspection technologies, philosophies and requirements. The forum will provide access to the newest thoughts in visual inspection technologies and particulate matter control, presented by the leaders and innovators in these developing techniques. This year's event will feature the medical impact of visible particulate matter which is highlighted with FDA presentations.

Attendees of this forum will gain knowledge of various technologies and be able to:

- Identify particulate inspection methods and equipment and critical parameters that affect the inspection process
- Develop state-of-the-art methodologies which reflect current industry knowledge
- Implement an effective and economical visual inspection process

Following the *2013 PDA Visual Inspection Forum*, join us for the offered course *An Introduction to Visual Inspection*, Session 2 at PDA's Training and Research Institute.

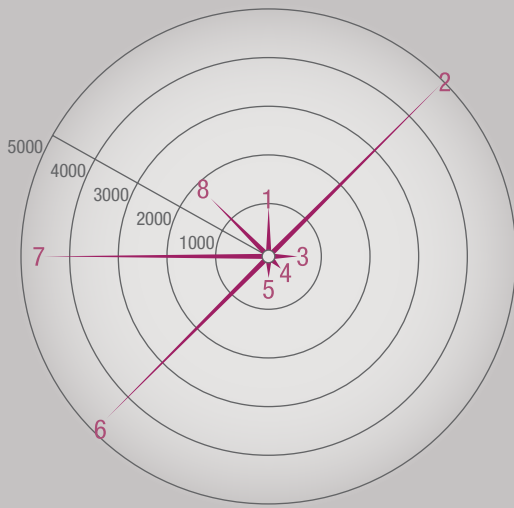


Visit [www.pda.org/visualinspection2013](http://www.pda.org/visualinspection2013)  
for more information or to register.

**Exhibition: October 7-8 | Course: October 9-10**

# U.S. Pharma Manufacturing Jobs in 2012

## Management



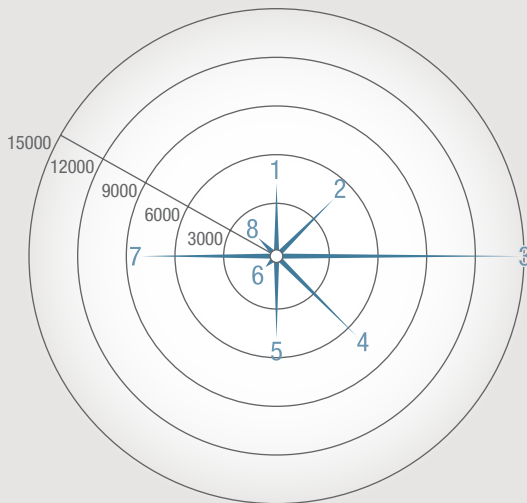
1. **Chief Executives**  
880 Employed     \$211,820
2. **General and Operations Managers**  
4860 Employed     \$139,000
3. **Transportation and Distribution Managers**  
450 Employed     \$94,000
4. **Training and Development Managers**  
210 Employed     \$118,150
5. **Medical and Health Services Managers**  
300 Employed     \$142,210
6. **Natural Sciences Managers**  
4580 Employed     \$130,870

7. **Industrial Production Managers**  
4500 Employed     \$113,250
8. **Architectural and Engineering Managers**  
1550 Employed     \$141,130

Management Median Income  
**\$134,935**



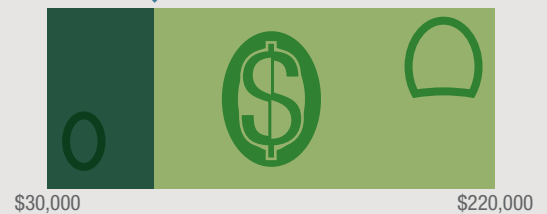
## Sciences



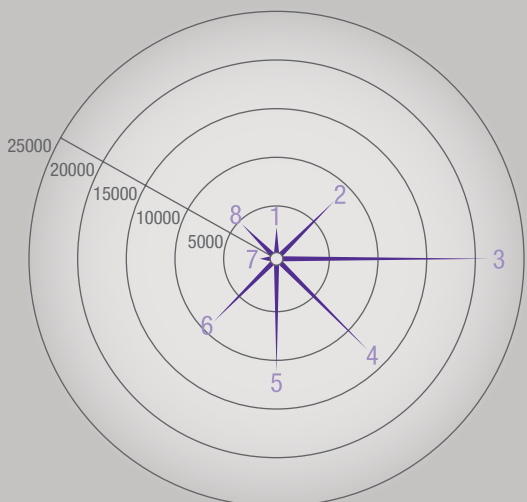
1. **Biochemists and Biophysicists**  
4000 Employed     \$87,910
2. **Microbiologists**  
4530 Employed     \$74,720
3. **Chemists**  
14620 Employed     \$75,980
4. **Biological Technicians**  
6420 Employed     \$49,410
5. **Chemical Technicians**  
4590 Employed     \$46,250
6. **Materials Scientists**  
460 Employed     \$69,260

7. **Medical Scientists**  
7860 Employed     \$101,020
8. **Biological Scientists (Other)**  
1100 Employed     \$77,780

Sciences Median Income  
**\$75,350**



## Production



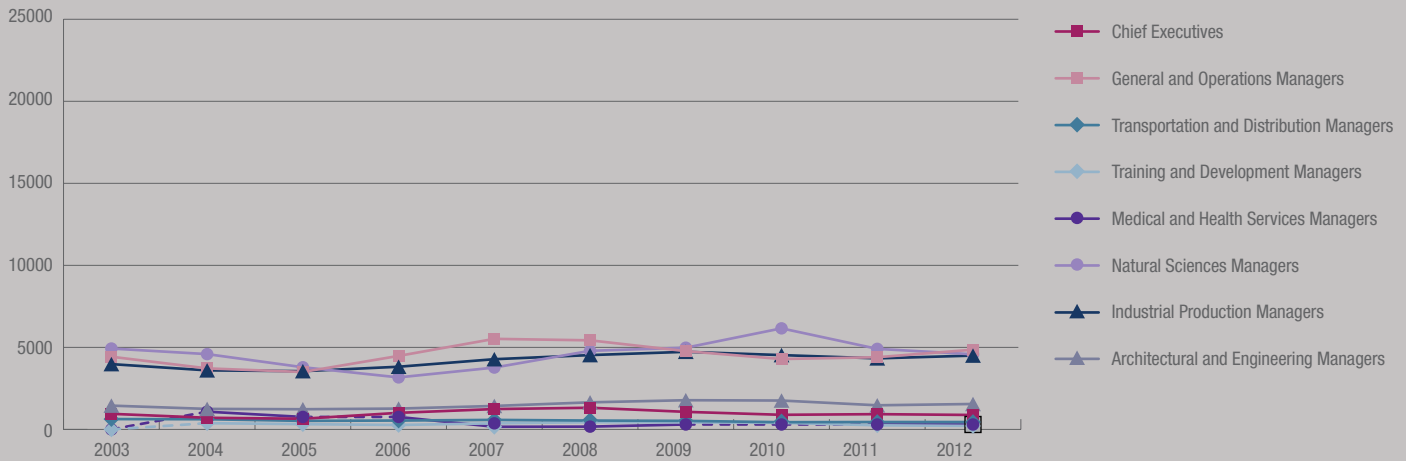
1. **Chemical Plant and System Operators**  
2610 Employed     \$48,270
2. **Chemical Equipment Operators and Tenders**  
7800 Employed     \$44,470
3. **Packaging and Filling Machine Operators and Tenders**  
21240 Employed     \$30,310
4. **Mixing and Blending Machine Setters, Operators and Tenders**  
12670 Employed     \$35,950
5. **Inspectors, Testers, Sorters, Samplers, and Weighers**  
11060 Employed     \$41,800
6. **First-Line Supervisors of Production and Operating Workers**  
8540 Employed     \$65,770

7. **Coating, Painting, and Spraying Machine Setters, Operators, and Tenders**  
1060 Employed     \$36,290
8. **Team Assemblers**  
4390 Employed     \$31,000

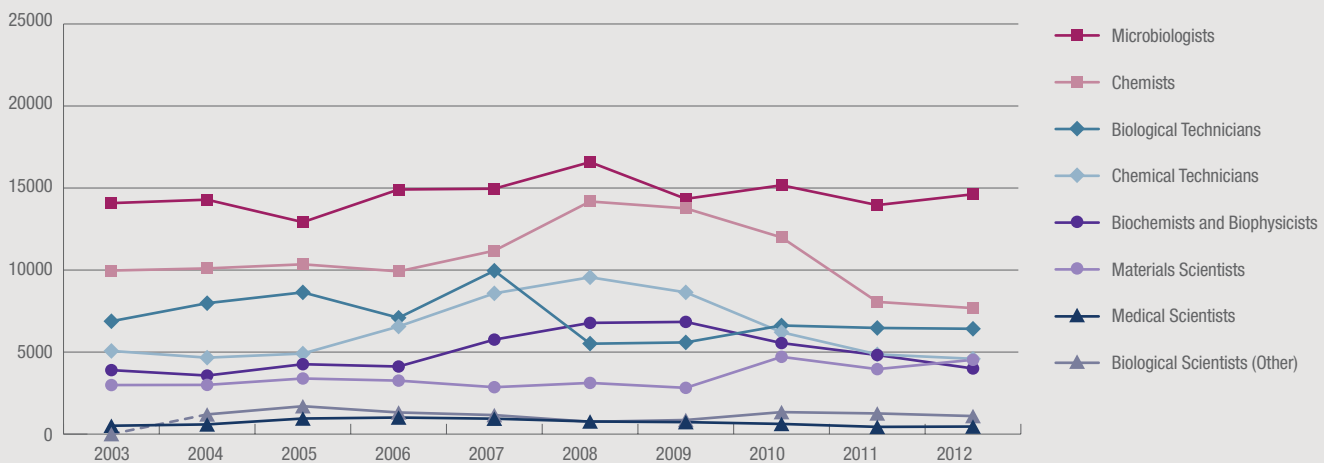
Production Median Income  
**\$39,045**



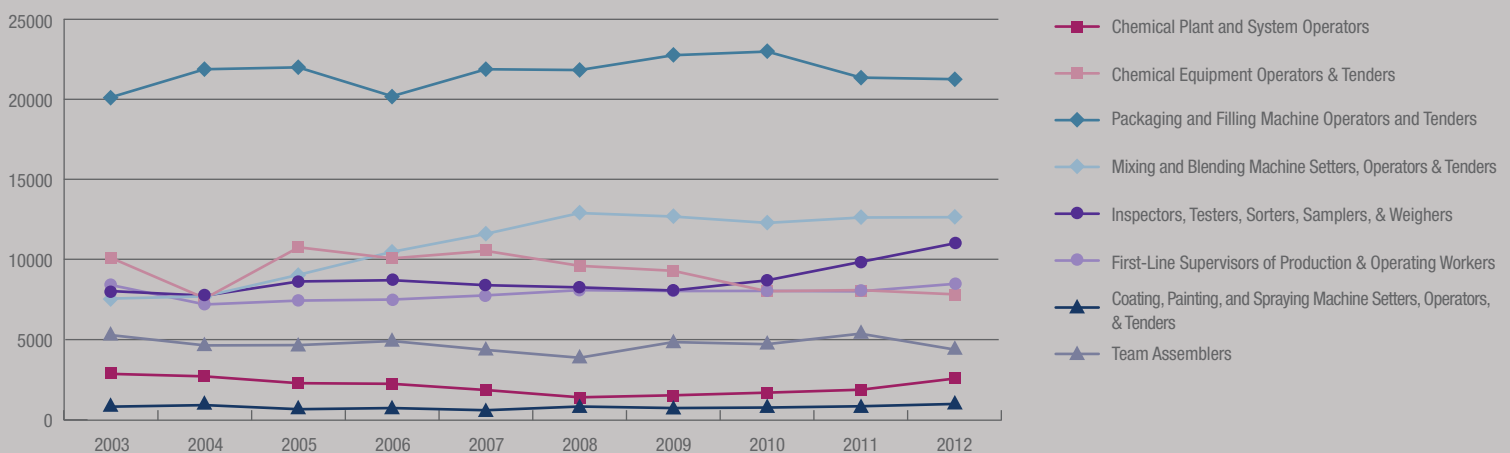
## Management Jobs Breakdown



## Science Jobs Breakdown



## Production Jobs Breakdown



# PDA Comments on Draft Regulation—The Impact is Clear

Siegfried Schmitt, PhD, PAREXEL Consulting

Many regulatory authorities publish draft versions of planned regulations and offer interested parties the opportunity to comment on these drafts for a set period of time, before being finalized. Though commenting is open to anyone, and all comments received within the specified period are reviewed by the regulators, there are several benefits for combining

and channelling reviewers' comments through PDA's commenting process.

PDA has very clear terms of reference for commenting on draft regulations, per the Regulatory Affairs Quality Advisory Board (RAQAB) handbook, which assures a high level of consistency, accuracy and professionalism in the replies.

Plus, it provides a structure for collating and editing the various comments into a concise document within often tight timeframes. The draft guidance reviews are performed by a team of volunteers and the comments collated under the guidance of a volunteer team leader, typically a member of one of PDA's advisory boards.

## EU-GMP Under Revision (Status 20.03.13)

EU-GMPs	Topic	Content/ Impact	Timelines
Chapter 1	Pharmaceutical Quality System	Including ICH Q10 (e.g. management responsibility)	In operation since 31 Jan. '13
Chapter 2	Training	GMP Training of Senior Management	Final version expected 1Q 2013
Chapter 3	Premises and Equipment	a) Investment, b) Resource intensive, c) Import testing for API?	Draft for public consultation till 18 July '13
Chapter 5	Production	a) Multi prod. Facilities b) Trainability of API supply chain, c) Testing of starting mat.	Draft for public consultation till 18 July '13
SAW guideline	Multi product facilities	Toxicological risk assessment	Draft for public consultation till 30 June '13
Chapter 6	Quality Control	Analytical Methods: Inclusion of a new section on Technical transfer of testing methods and other items such as out of specification results.	Draft for public consultation till 18 July '13
Chapter 7	Outsourced Activities	Assessing prior to outsourcing operations, Defining the responsibilities and communication processes, Monitoring and review of the performance, Monitoring incoming ingredients and materials	In operation since 31 Jan. '13
Chapter 8	Complaints and Product Recalls	Introduction of QRM, root cause analysis, reporting of quality defects	Draft for public consultation till 18 July '13
Annex 2	GMP for Biologics	Zone concept for biotech API according Annex 1 (sterile MP)	In operation since 31 Jan. '13
Annex 15	Qualification and Validation	Reworked document, Implementation Continued Process Verification	Concept paper for comments closed 28. Feb '13 12 2013 draft guidance; 1Q 2014 final
Annex 16	Batch Certification & Release	a) QP discretion, b) Relying on PQS/Auditing	Draft for consultation expected by 1Q or 2Q 2013
Annex 17	Parametric Release	Real-Time Release Testing (RTRT), if applied	Concept paper for comments closed; 28. Feb 13 2013 draft guidance; 1Q 2014 final
GDP	GDP Medicinal Product	Supply chain oversight; cold chain; transport validation	Published March 07; In operation 06. Sept. '13
GDP	GDP for API	Define and register importers	Draft for public consultation till 30 April '13
QP-declaration API	API import/registration		Final document expected 1Q or 2Q 2013
QP-declaration IMP	API import/registration		Draft for public consultation till 02 April '13
API	Trigger for API inspections	New document; content under discussion	Draft for consultation expected 1Q or 2Q 2013
Excipients	QRM for GMP for Excipients	Applicability of GMP for Excipient manufacturers	Draft for public consultation till 30 April '13
EUDRA-DB	New modules: GDP certificates & Inspection planning (Agencies only)	More information available, transparency	Dec '12 Implementation

\* Document date +6 month for implementation



As one can imagine, some draft regulations attract a vast number of comments (e.g., the U.S. FDA draft guidances on process validation), whereas others are accepted almost as is (e.g., the E.U. template for qualified person's declaration). By combining and channelling the comments from reviewers with an enormous amount of expertise and understanding of the implications, PDA provides valuable advice to the regulators. PDA comments are specific and come with a rationale. Written comments are professional, poignant and clear.

The regulators, who may receive sometimes hundreds of comments that they have to then sort and review, welcome PDA's comments as they expect and receive a set of comments that they can work with easily and that represents the voice of a large segment of the industry. Though we cannot claim that specific changes to draft regulations have been made because of our input, we do see


that we often are among the proponents of such changes. One clear indication of how much regulators value PDA's views and assistance is that PDA gets asked to organize specific meetings to discuss draft regulation. Examples are the regular PDA/FDA meetings and conferences with other regulatory agencies in addition to meetings on very specific topics, such as PDA's 2008 open meeting on the European Commission's Annex 2 in Budapest, Hungary.

This highlights another great benefit of PDA membership, namely having direct access to regulators, often the lead authors of draft regulations, which permits the exchange of views and information that can and does influence how regulations are shaped. To give the readers an idea of the number of draft regulations that PDA comments on, please see **Figure 1** listing E.U. GMP regulations currently under revision. PDA is commenting on the majority of these. Last year,

PDA submitted five comments compared to nine in 2011 and 11 in 2010.

If you wish to help shape the future of the global regulatory framework, then you are very welcome to be a member of any of the review panels and add your voice to PDA's comments. For further information and assistance, please contact PDA Senior Regulatory Advisor **Denyse Baker**, [baker@pda.org](mailto:baker@pda.org).

### About the Author

**Siegfried Schmitt**, PhD, is the President of the PDA UK Chapter and a PDA RAQAB member. He is a Chartered Chemist and Chartered Scientist with the Royal Society of Chemistry. He has been a Principal Consultant with PAREXEL Consulting since 2007. He previously served as Sr. Production Chemist at Roche and held other positions with GE Healthcare, Raytheon and ABB. 



## General Principles For Commenting

**[Editor's Note:** The following is excerpted from the *Regulatory Affairs & Quality Advisory Board Member Handbook*.]

### PDA RAQAB Policies when Commenting

- PDA comments should not 'add to' the current or proposed regulatory requirements/expectation
- When language is unclear or needs improvement we should offer proposed replacement text
- Comments should be scientifically sound, and have value for patient protection

### RAQAB Performance


- Comments should represent a verbal 'consensus approval,' not a silent 'no one objects'

### What can affect RAQAB balloting

- PDA staff may modify/ change comments to resolve issues, align with other PDA positions and to ensure PDA's reputation with regulators remains strong

- through product and process quality
- Comments should facilitate a common understanding of what is expected by the guidance, thus avoiding divergent interpretations
- Comments should represent a consensus of the task force members' expertise and not simply copying company comments

- Task force members need to participate in the process to advocate and, if necessary, explain their comments

- It is understood that comments may be changed by the approving bodies (e.g. RAQAB, SAB, BioAB & BoD) 

- Cost alone is not grounds for objection to a draft rule or guidance; exceptions must be justified
- When commenting on a revision of an existing guidance, we generally will limit our comments to new or changed elements
- A task force volunteer leader is needed as a first step in the commenting process

# PDA Suggests Expanding Discussions on Drug Shortages

For the comments grid, visit [www.pda.org/regulatorycomments](http://www.pda.org/regulatorycomments)

March 13, 2013

Division of Docket Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

Reference: FDA Drug Shortages Strategic Plan Docket No. FDA-2013-N-0124)

Dear Sir/Madam,

PDA appreciates FDA initiating this important dialog with industry regarding the drug shortage issue. PDA recognizes the seriousness of the current situation and supports efforts on the agency's part to address it. New and innovative concepts should be discussed with the goal of establishing mechanisms which will promote an industry wide sustainable quality culture that can guarantee high-quality products are consistently manufactured with no disruption to the patient.

PDA is a non-profit international professional association of more than 10,000 individual member scientists having an interest in the fields of pharmaceutical, biological, and device manufacturing and quality. Our comments were prepared by a committee of experts with experience in pharmaceutical manufacturing including members representing our Board of Directors and our Regulatory Affairs and Quality Advisory Board.

The development of consistent and transparent quality metrics across the pharmaceutical industry is a concept that requires further exploration and discourse between the various stakeholders. Multiple factors should be taken into account when determining the risk of potential shortage and appropriate contingency preparations. For example, some biological products that require long product disposition cycle times, may necessitate more stringent contingency planning with additional agency scrutiny of inventory levels to prevent and mitigate potential shortages. Other products available from multiple suppliers may require the creation and tracking of an overall market inventory.

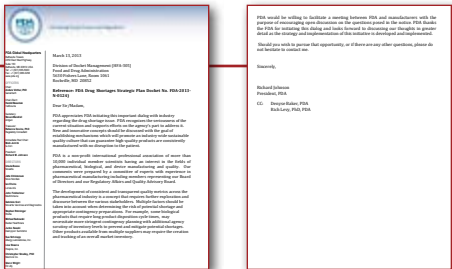
PDA would be willing to facilitate a meeting between FDA and manufacturers with the purpose of encouraging open discussion on the questions posed in the notice. PDA thanks the FDA for initiating this dialog and looks forward to discussing our thoughts in greater detail as the strategy and implementation of this initiative is developed and implemented.

Should you wish to pursue that opportunity, or if there are any other questions, please do not hesitate to contact me.

Sincerely,

Richard Johnson  
President, PDA

CC: Denyse Baker, PDA  
Rich Levy, PhD, PDA



### PDA Commenting Task Force

**Sue Schniepp**, Allergy Laboratories (TF Leader)  
**Denyse Baker**, PDA  
**Steve Mendivil**, Amgen

**Jeff Hartman**, Merck  
**Hongyang Li**, NovoNordisk A/S  
**Claudio Cappai Correa**, Roche AG

**Karen Ginsbury**, PCI

### Board Members Also Involved

**Mike Sadowski**, Baxter Healthcare  
**Ursula Busse**, PhD, Novartis  
**Hal Baseman**, ValSource  
**Anders Vinther**, PhD, Genentech  
**Lisa Skeens**, PhD, Hospira

**Rebecca Devine**, PhD, Regulatory Consultant  
**Jette Christensen**, Novo Nordisk  
**Glenn Wright**, Eli Lilly  
**Christopher Smalley**, PhD, Merck  
**John Finkbohner**, PhD, MedImmune

**Ian Elvins**, Lonza AG  
**Stephan Roenninger**, Amgen  
**Maik Jornitz**, G-Con  
**Gabriele Gori**, Novartis

# Regulatory Briefs

Regulatory briefs are compiled by PDA member volunteers and staff directly from official government/compendial releases. Links to additional information and documentation are available at [www.pda.org/regulatorynews](http://www.pda.org/regulatorynews).

## North America

### New Scale-Up and Post-Approval Changes Guidance Available

In early April, the U.S. FDA released a draft guidance for industry concerning scale-up and post-approval changes, titled, *SUPAC: Manufacturing Equipment Addendum*. The Agency has revised the draft manufacturing equipment addenda by removing equipment examples and clarifying referenced processes. This draft supersedes addenda released in 1998 and 1999.

Comments on the draft guidance are due by July 1.

### U.S. FDA Posts Glass Syringe Guidance

The U.S. FDA's Office of Combination Products released its draft guidance, *Glass Syringes for Delivering Drug and Biological Products: Technical Information to Supplement International Organization for Standardization (ISO) Standard 11040-4*, April 3. This draft guidance offers information for sponsors seeking to conform to ISO Standard 11040-4 for glass syringe product submissions. The Agency has stated that demonstrating ISO conformity does not necessarily ensure that the glass syringe can be joined properly to connecting devices.

This guidance identifies additional information that needs to be included in exemptions and applications. Companies involved in developing or marketing injection devices or components are urged to become familiar with the guidance.

Comments are due July 2.

### IPEC User Guide Aims to Reduce Redundancies

In March the International Pharmaceutical Excipients Council of the Americas published its revised *2013 Excipient Information Package (EIP) User Guide* for free on the IPEC website. This revised guide updates the 2005 guide.

The revisions address the issue of redundancies among suppliers with a goal of streamlining information between companies. The updated information includes standard questionnaires for excipient manufacturers to reveal sources of raw materials and other information. The guide also provides a product regulatory datasheet, a site quality overview and an overview of supply chain security.

## Europe

### MHRA Plans Simplification Measures

As part of the United Kingdom's government-wide streamlining initiative, the MHRA plans to introduce measures to increase industry efficiency. These measures include proposals to utilize the simplified application fee package that was introduced in April 2012 and implement a MRHA notification system that informs companies when data needs to be submitted. The goal of the process is to consolidate fragmentary regulations.

### EMA to Begin PSUR Assessments

Beginning April 1, the EMA will conduct single assessments of periodic safety update reports (PSURs) of active substances used in both centrally and na-

### Key Regulatory Dates Comments Due

**July 1 — New Scale-Up and Post-Approval Changes Guidance Available**


**July 2 — U.S. FDA Posts Glass Syringe Guidance**

tionally authorized medicine products. Until recently, EMA had only assessed PSURs for centrally-authorized products. This new assessment will require the Agency to analyze all reports for medicines containing certain active substances, including for medicines authorized in more than one member state.

## International

### INTERPOL Starts New Pharma Initiative

The global law enforcement agency INTERPOL has announced the creation of its Pharmaceutical Industry Initiative to Combat Crime (PICC). This three-year program will focus on preventing the counterfeiting of both branded and generic pharmaceuticals, including targeting organized crime networks linked to counterfeiting.

The initiative, which is based on the work of INTERPOL's Medical Product Counterfeiting and Pharmaceutical Crime unit, will involve the Agency working closely local regulatory authorities, industry security leaders, and regional law enforcement to identify and prosecute those involved in counterfeiting. 

## Industry and Regulators to Talk About Quality

**2013 PDA/FDA Joint Regulatory Conference • Washington, D.C. • Sept. 16–20 • [www.pda.org/pdafda2013](http://www.pda.org/pdafda2013)**

**Program Chairs Joyce Bloomfield, Merck and Susan Schniepp, Allergy Laboratories**

Mark your calendars now and plan on joining us in Washington, D.C. from Sept. 16–18 for a stimulating *2013 PDA/FDA Joint Regulatory Conference*. Hear directly from U.S. FDA experts and decision makers as well as industry professionals who are willing to share their insights and experience. This year's conference theme is *Driving Quality and Compliance throughout the Product Life Cycle in a Global Regulatory Environment*.

The planning committee has developed a program this year to offer attendees new and exciting topics to help make this the “go to” meeting! In joint collaboration with the FDA, the committee has designed the contents of the program to reflect how the quality culture of a company is a foundational cornerstone to at-

taining successful business goals and objectives. The conference jump-starts with “Plenary Session 1,” offering presentations assessing where the industry stands with respect to quality systems, Quality by Design (QbD) and the drug shortage crisis. The session's focus is on establishing a common objective for today's industry, regulatory authorities, health career practitioners and patients: ensuring access to safe, affordable and available medical products.

In between the opening and the closing sessions, the conference offers a second plenary session titled “Quality Culture & Partners.” **Zena Kaufman**, SVP, Quality, Hospira, and **Mary Oates**, PhD, VP, Global Quality Operations and Environmental, Health and Safety,

Pfizer, are confirmed to speak about how a strong quality culture drives effective quality systems designed to ensure right first time operations to produce high product quality. The session will explore how to implement quality culture, how the culture impacts the effectiveness of the quality system.

In addition to the track sessions there are eight breakfast sessions with a variety of topics including one on the importance of establishing, maintaining and communicating quality metrics. And, following the conference, PDA's Training and Research Institute will be hosting five courses from September 19-20th. Visit [www.pda.org/pdafdacourses2013](http://www.pda.org/pdafdacourses2013) to learn more.

We look forward to seeing you. 🍷

## Forum Focuses on Standardizing Inspections

**2013 PDA Visual Inspection Forum • Bethesda, Md. • October 7–10 • [www.pda.org/visualinspection2013](http://www.pda.org/visualinspection2013)**

**Roy T. Cherris, Bridge Associates International and Program Committee Member**

In recent years, particulate matter and good inspection practices have been in the global regulatory spotlight. There have been significant gaps pertaining to guidance on this subject over the last 30 years. We see organizations like PDA and the U.S. Pharmacopeia taking leadership roles in trying to benchmark or standardize visual inspection practices, and establish appropriate parameters for routine parenteral product quality.

For the pharmaceutical and biotech industries, this global paradigm certainly is forefront in the minds and business plans of parenteral manufacturers worldwide. In our quest for success, we must wade through the maze of obstacles and chal-

lenges that this global marketplace presents. These challenges include both the increased resources needed to apply stringent quality requirements for particulate matter control and container/closure defect inspection for our global products. Our success will be determined by our ability to navigate the regulatory expectations, harmonize inspection practices and successfully adopt newly emerging technologies. If these global challenges are impacting you and your organization, then attending PDA's *Visual Inspection Forum* is a must!

The forum will showcase various technologies as it has done through its continuing series of meetings, which alternate between the United States and the European Union

each year. This year's event will again feature the medical impact of visible particulate matter which is highlighted by U.S. FDA presentations. The forum will also be followed by PDA's Training and Research Institute's Visual Inspection Forum course, “An Introduction to Visual Inspection, Session 2,” which has always received excellent acclaim from previous attendees. Prepare yourself for a comprehensive learning experience and speak with industry leaders in visual inspection technologies, philosophies and requirements. Please plan to join us for an enlightening two days with old and new friends and business acquaintances.

Hope to see you there! 🍷



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# The Future of Microbiology Comes to Maryland

**PDA 8<sup>th</sup> Global Conference on Pharmaceutical Microbiology • Bethesda, Md. • Oct. 21–25 •**

**[www.pda.org/microbiology2013](http://www.pda.org/microbiology2013)**

**Edward Tidswell, PhD, Baxter Healthcare and Program Committee Member**

The *PDA 8<sup>th</sup> Annual Global Conference on Pharmaceutical Microbiology* will take place this October in Bethesda, Md. As ever this event represents *the* venue for pharmaceutical microbiologists. The conference is now recognized as a tremendous opportunity to network with fellow microbiologists, experts in all areas of pharmaceutical microbiology, key vendors of microbiology testing equipment and supplies and worldwide regulatory and compliance professionals.

Extraordinary research in the field of microbiology and pharmaceutical microbiology continue to illuminate the microbiology of our environment, manufacturing environments, and our own microflora. Our vocation demands pro-

gressive refinement of processes, practices, controls, technology and standards reflecting best science in the provision of safe and efficacious therapies. This year's conference keynote speakers and agenda therefore, reflects new world knowledge, new technologies, best practices and changing regulations and standards.

The conference's first keynote describes the new microbiological knowledge derived from the Human Microbiome Project. This new data truly describes and defines the quantity and variety of microorganisms associated with the human body. Three courses will be offered after the conference by PDA's Training and Research Institute. The first course, "Investigating Microbial Data Devia-

tions," will be held on October 24 and will provide practical insights into both the regulatory and scientific considerations, which must be taken into consideration when investigating microbiological data deviations.

The second course, "Validation of Microbiological Test Methods," also offered on October 24, has been designed to assist those in quality assurance, regulatory compliance, quality control and validation function with the validation of microbiological test methods using a step-by-step procedure.

The third course, "Evaluation, Validation and Implementation of Alternative and Rapid Microbiological Testing Methods"

*Continued at middle of page 43*



**The Parenteral Drug Association presents the...**

## **2013 PDA/FDA Pharmaceutical Supply Chain Workshop**

*Pharmaceutical Supply Chain Integrity: The New Horizon*

**June 3-5, 2013 | Hyatt Regency Bethesda | Bethesda, Maryland**

The 2013 PDA/FDA Pharmaceutical Supply Chain Workshop will explore many critical aspects that drive a pharmaceutical supply chain including globalization, product stewardship and regulatory pressures. This unique event is designed to solicit participant's ideas on a variety of supply chain issues facing the pharmaceutical industry.

Registrants will gain insight from global regulatory experts and trade organizations including:

- **Huascar Batista**, Import Compliance Branch Chief, ODSIR, CDER, FDA
- **Brian Johnson**, Senior Director, Supply Chain Security Network Performance, Pfizer Global Supply
- **Anil Sawant**, PhD, Vice President, Compliance, Johnson & Johnson Consumer Companies, Inc.
- **Steven Wolfgang**, PhD, Acting Associate Director, ODSIR, CDER FDA

Following the 2013 PDA/FDA Pharmaceutical Supply Chain Workshop, PDA's Training and Research Institute will be hosting two courses to complement your learning on June 6.

- *Risk Management for Temperature Controlled Distribution*
- *Active Temperature Control Systems: Qualification Guidance*



**[www.pda.org/supplychain2013](http://www.pda.org/supplychain2013)**

**Exhibition: June 3-4 | Courses: June 6**





**11-12 July 2013**  
Dublin | Ireland

*The Parenteral Drug Association presents...*

## 2013 PDA Training Course

# An Introduction to Visual Inspection

## *A hands-on training course*

The training course covers the fundamentals of visual inspection methods and their application to injectable products. It will be a combination of lecture/discussion and hands-on laboratory exercises used to develop and practice practical inspection skills. The skills developed through this course may be applied to both manual human inspection and automated machine inspection.

Upon completion of this course you will be able to:

- Identify applicable international regulatory and compendial requirements for visual inspection
- Apply the critical parameters which must be controlled for reproducible inspection results
- Use appropriate statistical tools to assess and compare inspection methods
- Develop consistent validation strategies for visual inspection processes and equipment



TRAINING COURSE 11-12 JULY

<https://europe.pda.org/TCVisInsp2013>

## Link Up at the Next Supply Chain Event

### 2013 PDA/FDA Pharmaceutical Supply Chain Workshop

• Bethesda, Md. • June 3-6 •

[www.pda.org/supplychain2013](http://www.pda.org/supplychain2013)

**Mary E. F. Storch, Ben Venue Laboratories and Program Committee Member**

There is still time to make your reservation for the upcoming *PDA/FDA Pharmaceutical Supply Chain Workshop*. Attendees will be pleased to note that this workshop will be following the very effective format of combining lecture and breakout sessions.

No company is without their own challenges when it comes to supply chain management, especially as our industry grows ever more complex and globally diverse. All functions of an organization will have an opportunity to learn and gain valuable insight as the agenda has been developed to cover the full lifecycle of pharmaceutical products. Everything from raw materials and excipients through finished products manufactured by contract organizations will be addressed. The topics will also spark your interest by providing insight from the early stages of identification of potential partners through establishing the right metrics to monitor the performance of suppliers. The planning committee was careful not to recycle to same old information you have heard before, but put the emphasis on where these topics are trending for the future.

To make the most out your learning experience the workshop will kick off with a benchmarking session. Speakers from both industry and regulatory of non-pharmaceutical industries will set the stage with lessons they have learned in their own complex world of supply chain management. This could be your opportunity to learn something new.

No discussion on supply chain management would be complete without getting into the complex web of auditing all the players who contribute to your final product. During these sessions you will have the opportunity to hear about advances being made in the approach to auditing. Have you ever wondered who is managing who when it comes to your CMO? That is just one of the topics that will be addressed during a breakout working group. These valuable segments have been designed so that everyone has an opportunity to attend. Additionally, in these smaller groups you get the added benefit of always having both an industry and regulatory representative to help facilitate the conversation.

Immediately following the *2013 PDA/FDA Pharmaceutical Supply Chain Workshop*, PDA's Training and Research Institute will be hosting two new courses to complement your learning on June 6th. Visit [www.pda.org/supplychaincourses2013](http://www.pda.org/supplychaincourses2013) to learn more about the "Risk Management for Temperature Controlled Distribution" and "Active Temperature Control Systems: Qualification Guidance" courses.

*Continued at bottom of page 43*

## Protect Your Biologics From Viral Contamination

**PDA/FDA Advanced Technologies for Virus Detection in the Evaluation of Biologicals Conference • Bethesda, Md. • Nov. 12–14 • [www.pda.org/virusdetection2013](http://www.pda.org/virusdetection2013)**  
Program Planning Committee

The *PDA/FDA Advanced Technologies for Virus Detection in the Evaluation of Biologicals Conference: Applications and Challenges* will be held this November. Recent discoveries of virus contamination of biological materials used to manufacture biomedicinal products, and the challenges of addressing virus safety concerns in novel cell substrates, emphasize the need for sensitive, broad-spectrum assays to detect adventitious viruses and other microbial agents in biological products. This conference will provide a forum for discussing new molecular virus detection technologies.

On Nov. 12, prior to the conference, PDA's Training and Research Institute will hold two courses. The "Virus Contamination in Biomanufacturing: Risk Mitigation, Preparedness and Response" course will provide the necessary information and tools to enable companies and participants to understand and implement best practices to reduce the risk of viral contamination. The second course, "An Introduction to the Advanced Molecular Methods for Virus Detection," will provide an in-depth description of the advanced molecular methods for virus detection. 🌐

## Aseptic Returns to Chicago

**2013 PDA Aseptic Processing—Sterilization Conference • Chicago, Ill. • June 18–21 • [www.pda.org/aseptic2013](http://www.pda.org/aseptic2013)**  
Glenn E. Wright, Eli Lilly and Program Committee Member

It is hard to believe that PDA's *Aseptic Processing—Sterilization Conference* is just a little over a month away. With all of the recent issues that continue to make the network news and industry forums, this is a must attend conference for individuals working in the sterile products field. As well as the excellent content, the conference will offer great networking opportunities to talk with industry leaders, regulatory authorities, as well as attendees from a wide range of companies that are facing the same types of challenges.

To complement the conference, the PDA Training and Research Institute (TRI) will be offering several courses designed to help you further strengthen your sterile product manufacturing program.

We look forward seeing you this June in Chicago. 🌐



The Parenteral Drug Association presents...

**2013 PDA Europe**

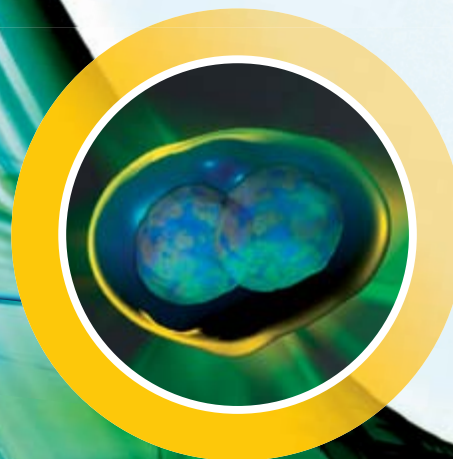
## Advanced Therapy Medicinal Products

The PDA Advanced Therapy Medicinal Products Conference will provide a unique interactive discussion forum and opportunity for exchange of information between the industry and regulators of different areas.

This should improve the understanding of ATMP development and the regulatory expectations in this new and emerging field of medicinal products.

**25–26 June 2013**

**Hilton Florence Metropole  
Florence | Italy**



**CONFERENCE | EXHIBITION**

<https://europe.pda.org/ATMP2013>



# Quality Systems Key to Improving Investigations

2013 PDA/FDA Improving Investigations Workshop • Washington, D.C. • Sept. 18–19 •

[www.pda.org/investigations2013](http://www.pda.org/investigations2013)

Program Committee Members Swroop Sahota, PhD, Catalent Pharma Solutions and Jennifer Magnani, Genentech

The joint *PDA/FDA Improving Investigations* workshop is designed to share current regulatory expectations, and deliver practical solutions to improve a crucial part of a CGMP-compliant quality system: the capability to do investigations of failures, complaints and deviations. Assuring a robust investigation program is crucial to all pharmaceutical companies, since “lack of adequate investigations” continues to be a top inspection observation globally. This workshop will be a unique opportunity for participants to engage directly with U.S. FDA and industry experts to ask questions and share best practices that will result in tangible, real-life solutions that can be immediately applied in your daily activities.

The FDA will provide an overview of the elements of a well-managed investigation, while an industry expert will discuss the business case for thorough investigations. Knowing how to establish a comprehensive investigation team, and determining the scope of an investigation effectively will be discussed. The technical aspects of an investigation, as well as how it is written, will also be covered. There isn't one “right” way to assess product impact and getting to the root cause, so speakers will provide examples of these different elements and the types of analysis tools and templates that can be used. Lastly, speakers will dive into CAPAs that avoid repeat issues and the value in assessing CAPA effectiveness af-

ter a period of time.

Throughout the workshop, participants will have an opportunity to practically apply new knowledge gained from the plenary sessions, and share their existing experience as they interactively work through each step of conducting a real-life industry investigation. While the FDA and industry experts facilitate these sessions, they will also share their ideas and experience.

Pharmaceutical industry professionals and regulators in the areas of quality, manufacturing, supply chain, internal/external audit, regulatory affairs, technical operations and R&D, or anyone involved with CGMPs, are invited to attend this workshop. 🌐



*The Parenteral Drug Association presents the...*

## 2013 PDA Aseptic Processing-Sterilization Conference

*Innovation and Best Practices in the Manufacture of Sterile Products*

**June 20-21, 2013** | Hyatt Chicago (Magnificent Mile) | Chicago, Illinois

The *PDA Aseptic Processing-Sterilization Conference* is proud to present some of the most highly qualified experts to share their experiences in the development, validation and ongoing control of aseptic processing and terminal sterilization programs. This conference provides the unique opportunity for participants to engage these experts in discussions on current trends and issues facing aseptic processing and terminal sterilization programs.

Some of the featured speakers on aseptic processing sterilization include:

- Hal Baseman, Chief Operations Officer, ValSource LLP
- Myran Civils, Validation Consultant, Eli Lilly & Company
- Barry Ressler, Chairman & CEO, Triton Thalassic Technologies, Inc.
- Michael Sadowski, Director, Sterile Manufacture Support, Baxter Healthcare Corporation
- Christopher Smalley, PhD, Director, Merck Sharp & Dohme
- Radhakrishna Tirumalai, PhD, Staff Liaison, Microbiology and Sterility Assurance, USP



[www.pda.org/aseptic2013](http://www.pda.org/aseptic2013)

**Courses: June 18-19 | Exhibition: June 20-21**

# Training Offers Advancement Opportunities

James Cooper, PharmD, Endotoxin Consulting Services

Twenty-five years ago I set out to make a “better mouse trap,” that is, a better LAL reagent. I had a solid nuclear background and several years of experience with **Ken Avis**, the parenteral pioneer from Tennessee. My confidence was only exceeded by my naiveté. As I began to prepare my biologics product and facility applications, I was stunned to discover how inadequately academics had prepared me for the world of parenteral manufacturing.

**Fred Carleton** identified some key PDA courses to help me build a working base of knowledge. My first course was led by **Dick Wood**, who taught depyrogenation and sterilization for PDA. He brought sound science and common sense to a subject often clouded by regulatory rumors and over-conservative advice. For example, he pointed out that F and D values were not applicable to depyrogenation and that endotoxin recovery studies were almost a moot point because the real goals of control were a qualified oven/tunnel and a robust heating cycle. After all, glass comes to us essentially endotoxin free. Subsequently, I found that our PDA faculty consistently brought that kind of expertise and objectivity to their courses.

Attending a PDA training course provides access to two enormous resources. First, PDA owns the most comprehensive information about parenteral technology in the form of its technical reports; each technical report is a thorough examination of a technology written by global experts. The second advantage is that a course is often led by one or more of the experts who created and wrote the technical report. The interaction with the course leader may lead to a future mentoring experience when you desperately need to communicate with an expert at a time of crisis.

PDA consistently schedules timely courses with the Annual Meeting to make most efficient use of time and resources. I identify strongly with words recently penned by **Anil Sawant**, PhD, of J&J: “The best advice I ever received is you have a lot to learn; learn one new thing every day!” My counsel to management is to make external education a major part of the budget process so that critical courses are identified for all, and funds are allocated to assure that training needs are not overlooked.

My advice to all who aspire to upward mobility is to develop a strategic plan for an increase in areas of expertise. An ability to perform your duties in exemplary fashion is dependent on your experience, training and time management. Hopefully, everyone has a dream of where they want to be professionally and has a plan to get there. With respect to mobility, I look for evidence of a zeal for continuing education when interviewing a job applicant. ➤

The Parenteral Drug Association presents...

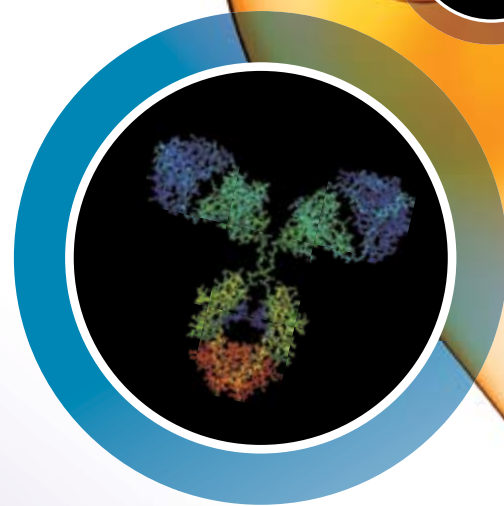


PDA Europe 6<sup>th</sup> Workshop on

# Monoclonal Antibodies

- Session 1:** Regulatory Guidelines Relevant to Monoclonal Antibodies
- Session 2:** The Relationship of Therapeutic Monoclonal Antibody Quality Attributes to Immunogenicity
- Session 3:** Analytical Requirements
- Session 4:** Implications of Immunogenicity on the Development of Biosimilars

**Register  
NOW and  
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**11-12 September 2013**

Ramada Plaza | Basel | Switzerland

**WORKSHOP | EXHIBITION**

<https://europe.pda.org/Monoclonal2013>



**4-8 November 2013**

**Congress Center  
Basel, Switzerland**

*The Parenteral Drug Association presents...*

# 2013 PDA Europe

## The Universe of Pre-filled Syringes and Injection Devices



**5 November 2013**

### SESSION 1:

**Advances in Health Care – Benefits for Patients and  
for Health Care Professionals**

### SESSION 2:

**Trends in Pharmaceutical Development and Manufac-  
turing of Pre-filled Syringes**

**Track 1: New Developments Related to Pre-filled  
Syringes/Parenteral Drug Delivery**

**Track 2: New Developments Related to Pre-filled  
Syringes as a Primary Container"**

**6 November 2013**

### BREAKFAST SESSION 1:

**The PFS User Perspective**

### BREAKFAST SESSION 2:

**Stoppers & Elastomeric Components for Drug Devices**

**Track 3: Formulation Challenges in the  
Development of Drug Devices**

**Track 4: Manufacturing – Process,  
Cost and Flexibility Aspects**

**Session 3: Regulatory & Compliance  
Trends for Drug Devices**



Workshop | Conference | Exhibition | Training Courses

<https://europe.pda.org/UPS2013>



My participation in the aseptic processing course is rewarded when I see that most participants are transformed in capability and confidence. They are eager to get back to the work place and apply what they have learned.

**[Editor's Note:** Dr. Cooper will be teaching the laboratory training course, "Validation of Dry Heat Processes Used for Depyrogenation and Sterilization," at TRI on August 13–15, 2013.]

### About the Author

**James Cooper**, PharmD, is an innovator of the bacterial endotoxins test (BET) for parenteral products. His publications span the history of LAL technology. He consults on depyrogenation, BET methods, endotoxin issues and root-cause investigations.



*The Future of Microbiology Comes to Maryland continued from page 38*

will be held from October 24–25. This new course is designed to provide attendees with an overview of the revised *PDA Technical Report No. 33, Evaluation, Validation and Implementation of Alternative and Rapid Microbiological Testing Methods*.

Look out for further updates as the conference agenda develops and book the dates in your calendar now.

*Link Up at the Next Supply Chain Event continued from page 39*

As a planning committee member I can tell you it has been very rewarding to have already collaborated with colleagues from the FDA in establishing the agenda topics. You can experience the benefit of hearing directly from the FDA on topics such as Import Compliance and key initiatives on the Asia Pacific Economic Cooperation (APEC). When it comes to the supply chain it's not just the FDA setting requirements. You will also hear from the California Board of Pharmacy on their E-Pedigree regulation which goes into effect in 2015. Threats to the pharmaceutical supply chain go beyond manufacturing and shipping risks. News worthy examples will be covered during the track and trace session.

Make your reservations today and come join us for this exciting and highly relevant topic. Be sure to spread the word in your organization as we have planned valuable topics for everyone along your supply chain.





Lisa Skeens, PhD, Hospira

## PDA's Volunteer Opportunities Help Make Members the Cornerstone of the Association

As a PDA board member, I am always pleased to hear PDA members tell me how volunteering through PDA has helped them achieve numerous career milestones in their paths to advancement and achievement. *People* remain one of the three pillars of our Strategic Plan along with Science and Regulation. After all, it is our members who support and work on our scientific and regulatory initiatives.

As someone who has personally benefited from my years of work with PDA (see the February 2013 issue of the *PDA Letter*, p. 30), I encourage members to consider volunteering with PDA. If you're not sure how you can get involved, we now have a Volunteer Interest form that you can complete on the PDA website. This will give our membership team an idea of where you might be able to help us. Once we receive the form, **Megan Kuhman**, our Volunteer Coordinator, will reach out to you with some suggestions for volunteering. She can also be reached at [volunteer@pda.org](mailto:volunteer@pda.org).

### Project-Based Volunteering—A Good Start

The easiest way to get involved is through project-based volunteering. Task forces work collaboratively to produce technical reports or technical positions. This is a great opportunity to influence and contribute to technical reports that are utilized by industry and regulators globally, as well as network with other task force members. In addition, the individuals involved in these task forces are often provided opportunities to become educational instructors for PDA's Training and Research Institute (TRI), or speakers at PDA conferences. We're always looking for potential speakers—experts in their field—to present on various topics of interest to our members. Being a poster presenter at a conference is another way you can volunteer for PDA. There are also opportunities to join planning committees that develop our conferences and workshops. At the local level, we have 23 chapters (and growing) around the world. These chapters focus on the issues unique to your region and offer opportunities for members to plan networking events and meetings on specific topics.

Are you someone who prefers to work on an individual-level? If so, don't let this stop you from volunteering! You can always write an article for the *PDA Journal of Pharmaceutical Science and Technology* or the *PDA Letter*.

In addition, volunteers help PDA develop comments in response to guidance and regulations from global regulatory bodies, support our advisory boards, and serve on our membership and education committees.

### Leadership-Level Volunteering—A Rewarding Commitment

Once you've made significant strides as a volunteer, there are great opportunities for leadership-level volunteer positions such as task force chairs, interest group leaders, planning committee chairs, advisory board members, chapter leadership and even the Board of Directors! This significant level of volunteer commitment is rewarding and a fantastic way to build relationships within the industry and make a difference serving the organization. Who knows, if you expand your involvement with PDA, maybe one day, you'll be writing a "Voices of the Board" column for PDA as a PDA board member!

I hope you will consider volunteering for PDA. Not only can you gain experience that can lead to further career advancement and opportunities, it allows to you to work closely with a diverse group of highly talented individuals in the pharmaceutical industry. Where else can you have the opportunity to impact both science and regulation and connect directly with regulators on the issues affecting you?

There is a reason why *People* is placed first in the PDA tagline "Connecting People, Science and Regulation". PDA volunteers are the cornerstone of our great member based association. I encourage you to take advantage of all the opportunities PDA has to offer, and to inquire about volunteer opportunities that match your style and interests, by visiting the Volunteer Opportunities portion of the website at [www.pda.org/volunteer](http://www.pda.org/volunteer) or by emailing Megan Kuhman at [volunteer@pda.org](mailto:volunteer@pda.org). 🌐



Register by **August 9th** and Save **\$400!**



*The Parenteral Drug Association presents the...*

# PDA 8th Annual Global Conference on Pharmaceutical Microbiology

**October 21-23, 2013**

Bethesda North Marriott Hotel | Bethesda, Maryland



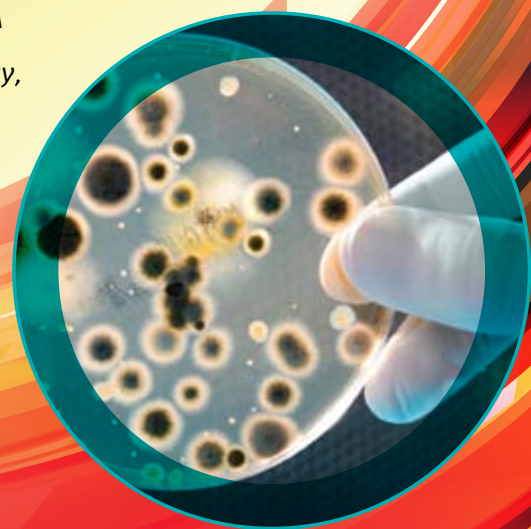
With the increased globalization of pharmaceutical manufacturing and regulatory demands, emerging technologies and the continued identification of new sources and types of contamination, it can be difficult to judge whether or not you are ahead or behind. Attending the *PDA 8th Annual Global Conference on Pharmaceutical Microbiology* conference will assist you with staying ahead of the curve and practicing proactive microbiology.

Registrants of the three-day conference will be able to participate in discussions and forums on the best practices of today and innovations of tomorrow and hear from:

- **Monica Caphart**, Branch Chief, Division of Medical Products and Tobacco Operations, ORA, *FDA*
- **Dennis Guilfoyle**, PhD, Microbiologist, Northeast Regional Laboratory, ORA, *FDA*
- **David Hussong**, PhD, Associate Director, New Drug Microbiology, CDER, *FDA*

Following *PDA's 8th Annual Global Conference on Pharmaceutical Microbiology*, PDA's Training and Research Institute will be hosting three courses to complement your learning on October 24-25, 2013.

- Investigating Microbial Data Deviations (October 24)
- Validation of Microbiological Test Methods (October 24)
- Evaluation, Validation and Implementation of Alternative and Rapid Microbiological Testing Methods (October 24-25)



**[www.pda.org/microbiology2013](http://www.pda.org/microbiology2013)**

**Exhibition: October 21-22 | Course: October 24-25**

## Responding to Member Needs: Career Development


At the 2012 PDA Annual Meeting, I met with chapter leaders and other PDA members to discuss publishing with PDA, and as part of those discussions, I asked about what they want to see in the *PDA Letter*. One resounding answer was “more information to help our career development.” We took that message to heart, and since then, have been working to infuse the Letter with more articles to help people manage their careers. Several years ago, we launched the “Tools for Success” series, but since last year, we have focused on getting members to talk more about their careers. All this work culminated in this issue, which includes three features on careers and career development.

Former *PDA Letter* Editorial Committee member **Winston Brown** jumped at the chance to write the cover story on career advancement. His sound advice comes from his own experiences which have been many and fulfilling. I learned a lot working on the article and hope our readers will too. The second feature on the state of employment in pharmaceutical manufacturing provides readers with a little insight into what this industry will have to offer them in years to come with respect to careers. Finally, the issue's Infographic provides a snapshot of the career trends in the industry over the last decade. The Training and Research Institute got into the career advancement spirit with an article by instructor **James Cooper** on the role of training. Indeed, participating in a PDA Task Force can help members expand their career opportunities, and the Letter's **Rebecca Stauffer** shares what she learned by discussing this aspect with a few PDA task force members in this issue's Science Snapshot.

What more can the *PDA Letter* do for you? We always want to hear your feedback. Let us know if this career-oriented issue provides you with useful information. You can always contact me or Rebecca with your comments ([morris@pda.org](mailto:morris@pda.org), [stauffer@pda.org](mailto:stauffer@pda.org)).

### Author's Wanted

The Letter always is looking for good articles from members. You can write commentaries, editorials, technical or regulatory articles for the Letter. We accept these for any issue. In addition, we are looking for feature-length articles on the following topics:

- Consent Decrees
- Outsourcing
- Disposable Systems
- Contact or send your article to [stauffer@pda.org](mailto:stauffer@pda.org). 

# PDA Letter

The PDA Letter is published 10 times per year, exclusively for PDA members.

Subscriptions are not available.

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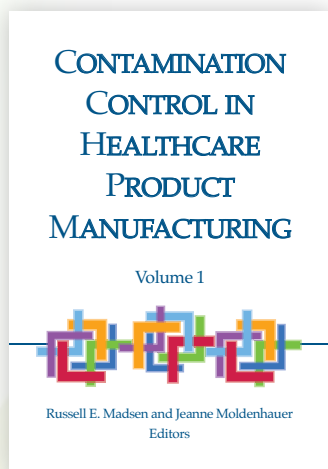
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## **Contamination Control in Healthcare Product Manufacturing, Volume 1**

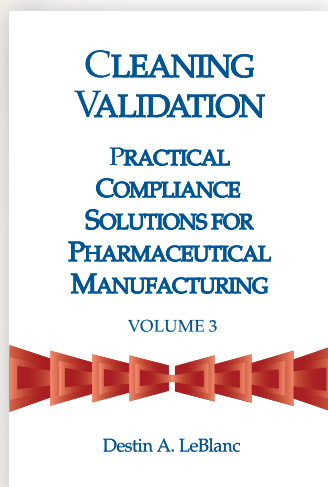
**Edited by Russell E. Madsen and  
Jeanne Moldenhauer**

*Contamination Control in Healthcare Product Manufacturing, Volume 1*, edited by **Russell E. Madsen** and **Jeanne Moldenhauer**, is primarily focused on microbiological contamination and the methods used to monitor and control it; a secondary focus looks at chemical contamination that may result from the use of cleaning and disinfecting agents.

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## **Cleaning Validation: Practical Compliance Solutions for Pharmaceutical Manufacturing, Volume 3**

**By Destin A. LeBlanc**

In **Destin LeBlanc's** *Cleaning Validation: Practical Compliance Solutions for Pharmaceutical Manufacturing, Vol. 3* pharmaceutical manufacturers and upper management are encouraged to meet the challenges of the science-based and risk-based approaches to cleaning validation.

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