Are you compliant with FDA requirements for process validation? Today’s regulators are applying more fine-grained specifications and demanding more sophisticated procedures for planning, executing, and documenting your processes throughout a drug product’s lifecycle. This two-day intensive summit brings together industry leaders to help you exceed regulatory thresholds and avoid costly FDA inspection findings.
### Critical Issues—Tech Transfer & Process Validation

**“Legacy Products” — A Journey from Retrospective to Prospective Process Verification**  
**Vishal Saxena, Ph.D., Senior Manager—Process Technology & Validation, Bayer HealthCare**

This presentation describes an approach utilized for adapting and aligning with FDA’s 2011 Process Validation Guidance, for Ongoing Process Verification, at a site with multiple commercial “Legacy Products.” A simple and logical approach was designed which includes retrospective evaluation and developing a path forward for prospective evaluation of existing manufacturing processes. To bridge the outcome of retrospective process verification to prospective process verification a risk based model was developed for classifying products into various categories, based on which the level of monitoring and process improvements were targeted. This approach does not only address the regulatory requirements, but was also time and cost efficient, especially when dealing with multiple manufacturing technologies.

---

### In-Depth Coverage on Biologics Validation

**BioPharma Lifecycle Validation: Beyond the Basics**

**Carmen Medina, MPH, Ph.D., Vice President, Technical, PAREXEL International**

Where to begin? How do we maintain commercial production when validating legacy products? What is really expected from the FDA? What is required for biological versus pharma products? These are all pressing questions facing today’s Bio-pharmaceutical industry. PAREXEL has developed a novel approach to successfully design, implement and sustain a BioPharma Process Validation Lifecycle Approach for new and legacy products. Come explore the key components necessary to design, monitor and improve your process validation platform, concept to commerce. Session will also present Biologics validation prerequisites; workflow considerations; small versus full-scale validation expectations, and documentation requirements.

I. Life Cycle Phases for New and Legacy Processes
   - Elements of Early Stage Process Design and Development
   - Scale-down Process Models
   - Process Performance Qualification Strategy

II. Risk Management
   - Raw Material Characterization
   - Univariate / Multivariate Experimentation
   - Design Space / Control Space Relationship (DoE)
   - Bioburden Mapping
   - Viral Clearance Studies
   - Resin Lifetime

III. BioPharma Limitations
   - Data related to CQAs and CPPs
   - Establishing Product & Process Comparability (Statistical Tools)
   - Theoretical Approach

IV. Monitor & Improve
   - Deepen process understanding batch-to-batch
   - Emphasize Continuous Process Verification

---

### Monday, October 5, 2015

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
</tr>
</thead>
<tbody>
<tr>
<td>8:00</td>
<td>Complimentary Breakfast</td>
</tr>
<tr>
<td>8:20</td>
<td>Chairperson’s Welcome and Opening Remarks</td>
</tr>
<tr>
<td>8:30</td>
<td><strong>BioPharma Lifecycle Validation: Beyond the Basics</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Carmen Medina, MPH, Ph.D., Vice President, Technical, PAREXEL International</strong></td>
</tr>
<tr>
<td></td>
<td>Where to begin? How do we maintain commercial production when validating legacy products? What is really expected from the FDA? What is required for biological versus pharma products? These are all pressing questions facing today’s Bio-pharmaceutical industry. PAREXEL has developed a novel approach to successfully design, implement and sustain a BioPharma Process Validation Lifecycle Approach for new and legacy products. Come explore the key components necessary to design, monitor and improve your process validation platform, concept to commerce. Session will also present Biologics validation prerequisites; workflow considerations; small versus full-scale validation expectations, and documentation requirements.</td>
</tr>
<tr>
<td>10:00</td>
<td>Mid-Morning Coffee and Networking Break</td>
</tr>
<tr>
<td>10:30</td>
<td><strong>The Trials and Tribulations of Continuous Process Validation</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Kirk Jozwiak, Pharma Quality Technology, Baxter Healthcare Corporation – Medical Products</strong></td>
</tr>
<tr>
<td></td>
<td>This presentation focuses on the design and implementation of methods for continuous process verification. Through continuous process verification one can demonstrate that a manufacturing process continues to operate in a predicted state of control. And in doing so, actively manage risks associated with the manufacturing process to strategically increase the overall health of the manufacturing process and thus increase the overall health of the product itself. The presentation describes a pragmatic approach that uses methods, techniques, and tools to achieve excellence. It will include real-world experiences, proven solutions, and lessons learned so that you can immediately apply what you have learned. Key discussion points include:</td>
</tr>
<tr>
<td></td>
<td>- Development of a control strategy based on risk</td>
</tr>
<tr>
<td></td>
<td>- Establishing appropriate listening systems to detect undesirable process variability</td>
</tr>
<tr>
<td></td>
<td>- Continuous assessment of risk controls to determine effectiveness</td>
</tr>
<tr>
<td></td>
<td>- Measurement of process performance and product performance</td>
</tr>
<tr>
<td>12:00</td>
<td>Complimentary Lunch</td>
</tr>
</tbody>
</table>
Regulatory Considerations

1:15 FDA Process Validation and Risk Management Approaches
Anita R. Michael, FDA ORA Pharmaceutical Specialist, FDA

This presentation will address Process Validation General Principles and Practices. We will review the statutory and regulatory requirements for validation studies. How industry can achieve Continued Process Verification and assure their process stay in a state of control. We will discuss how a successful process validation program consists of understanding sources of variation and product impact. Also, we will discuss how quality risk management and an integrated quality risk management system can build a strong foundation for regulatory operations, management of facilities and quality products. The presentation will address key Life Cycle approaches. In addition, we will review FDA cGMPs 21CFR parts 210, 211 including pertinent FDA 483 Inspectional Observations and deficiencies.

In-Depth Coverage on Continued Process Verification

2:15 Designing the Business of Continued Process Verification—It's More Than SPC!
Tara Scherder, Managing Director, Arlenda

Is Continued Process Verification as simple as a straightforward application of statistical process control methods? To improve the likelihood of a successful monitoring program, it is critical that manufacturers understand that it is more than a textbook case of control charts. This session presents several questions that must be answered in the design of the business process of ongoing process monitoring, including:

1) What criteria other than the statistical methods must be considered?
2) How do the characteristics of data from pharmaceutical manufacturing influence best practices?
3) Can a risk based approach be applied to determine monitoring frequency?
4) When and how should manufacturers respond to statistical signals?

3:00 Afternoon Networking Break

3:15 Continued Process Verification Approaches, Systems and Realization
Ronald D. Snee, PhD, President, Snee Associates, LLC

“Continued Process Verification” is the focus of Stage 3 of the 2011 FDA Process Validation Guidance. A system that addresses this need is presented. The system utilizes systems thinking and statistical engineering principles to integrate the tools needed to implement and operate such a system. Central to the approach are state-of-the-art Process Control, Process Capability Quality by Design and Design of Experiments concepts, methods and tools that are used to create the needed process understanding. The system integrates process control with process improvement and process design. These elements are described and the decision mechanisms for deciding how to move from one element to another are discussed. Pharma and biotech case studies are used throughout the presentation to illustrate how the various parts of the approach work together.

Benefits to Participants:

- How to design and implement continued process verification systems
- How to integrate process control, process and process design
- Awareness of QbD and its role in creating robust manufacturing processes
- How to sequence and link the QbD building blocks to create process understanding
- Guiding principles, tips and traps for the effective process verification systems

4:15 Implementing a Comprehensive Strategy for Process Validation: Stage 3, Continued Process Verification
Chris Watts, Principal Partner and Founder, VolPal

The last decade has seen a wide range of guidance/recommendations from Regulatory agencies (and ICH) that detail expectations for assuring, “by design”, quality of pharmaceutical products. From the FDA’s PAT guidance to the ICH Quality series (Q8, Q9, Q10, Q11) to recent guidance/guides on Process Validation, the focus on product/process quality is clear. However, these documents detail various tools and means for assuring product and process quality. This presentation will identify common themes in these documents, and detail an approach for integrating the recommendations into a comprehensive strategy for Process Validation, with a particular focus on Stage 3 – Continued Process Verification.

5:00 Panel Discussion

5:30 Raffle and Close of Day One

Register Now to Guarantee Your Space! Online: www.pharmaedresources.com • Phone: 217.721.5774
Finally, this presentation will explain the new guidance, • Ensure that root cause analysis, corrective and • Be able to develop a Process Validation plan that will • Understand what the various guidances call for, and on critical aspects rather than wasting time and money • Be able to develop a Process Validation plan that will • Ensure that root cause analysis, corrective and preventative actions, and continuous improvement become part of your compliance culture

Finally, this presentation will explain the new guidance, highlight what is different from the old standard (nearly everything!), and discuss the principles underlying the new CDER thinking.

Statistically Based Acceptance Criteria Methodologies

Statistically Based Process Validation Sampling Plans/Acceptance Criteria

James Bergum, President, BergumSTATS LLC

Withdrawal of the FDA draft guidance document for industry “Powder Blends and Finished Dosage Units – Stratified In-Process Dosage Unit Sampling and Assessment” in August, 2013, resulted in uncertainty for manufacturers that were currently applying it to approved products, as well as to those in development. The FDA’s primary concerns were insufficient blend uniformity testing and a lack of confidence that meeting the USP General Chapter <905> Uniformity of Dosage Units testing ensures content uniformity of the batch. FDA no longer supports approaches stated in the withdrawn guidance document, nor the use of USP <905> for batch release. This decision resulted in a gap for manufacturers and products that rely on traditional blend and dosage unit uniformity approaches for process validation and commercial batch release. The International Society for Pharmaceutical Engineering (ISPE) sponsored...
the Blend Uniformity and Content Uniformity Group, which was formed in August 2013 to discuss approaches to assess blend and content uniformity. Included in this presentation is a discussion of the recommendations from that group. Also included is a discussion of common sampling plans and two statistically based acceptance criteria methodologies. The first is ASTM E2709 referenced in the FDA guidance for process validation that provides the methodology and ASTM E2810 that applies the methodology specifically to content uniformity. The second is a tolerance interval method based on the percentage of content uniformity results falling between 85% - 115% Label Claim. Both methods can be used to provide a high degree of assurance that a batch will pass the USP UDU test. Several examples will be presented to show how each method can be applied to process validation content uniformity data.

12:00 Complimentary Lunch

1:00 Validation Master Plan—Plan for Success
Scott Collins, PMP—Director—Laboratory Operations and Compliance, QPharma, Inc.

Construction of an Effective Validation Master Plan (VMP)

I. General Information
   • Definition and purpose
   • Types of VMPs and scope

II. VMP Documentation Design
   • General format requirements
   • Content and template
   • Review and approval process
   • Deviation management (supplements)
   • VMP closure – Reporting and archiving

III. Benefits and Strategies
   • What to include – Value added activities
   • What to exclude – Non-value added activities

Participants are encouraged to bring examples of their own to discuss with their colleagues for new ways to address these changes.

Bonus Material
   • Example of a robust VMP
   • A summary of a comprehensive SOP for a VMP

1:45 Process Validation and Technology Transfer of Biologics & Vaccines
Dushyant Varshney Ph.D., Director, Manufacturing Assessment, MS&T Hospira, Inc.

In the past two decades, there has been a fast increase in the number of biologicals (e.g., therapeutic proteins, biosimilars) and novel vaccines developed by small and large biopharmaceutical companies. Development of such biologics is quite expensive and many companies lack in-house setup and capability to develop at commercial scale. In contrast, large companies, engaged in core or non-core business, have realized cost-saving by utilizing contract manufacturing organizations (CMOs) and improved productivity trends, as compared to investing in setting up and maintaining own facilities with required expert staff and regular updates. In such industry trends, technology transfer (TT) and validation of active pharmaceutical ingredients, analytical methods and drug products/process from development to market phase is becoming increasingly common and important to deliver safe and quality products. A successful TT ensures quality of product during the entire life-cycle of manufacture and validation, in accordance with cGMP, providing predictable and consistent operation of the processes.

The talk will focus on the current challenges and solutions in global technology transfer, subsequent process validation and commercial manufacturing. Specifically, external vs. internal manufacturing consideration, typical global TT roadmap, types of TT, regulatory/geographical challenges & risk management, process validation approaches for liquid/lyophilized biologics & vaccines products delivered by parenteral route will be discussed.

2:30 Afternoon Networking Break

2:45 Achieving the Business and Compliance Benefits of Quality by Design (QbD) and Continued Process Verification (CPV)
Justin O. Neway, Ph.D., Vice President and General Manager, Operations Intelligence
Senior Fellow, BIOVIA Science Council, BIOVIA, a division of Dassault Systèmes

The quality and process data collected on Paper Records and in electronic data systems like LIMS, LES, EBR, ELN, Historians, ERP, etc., is organized differently in each system to serve the needs of specialized users who focus on different portions of pharmaceutical and biologics production processes. This creates problems for Quality and Process users who need to perform monitoring, data analysis and reporting on the production process, to understand and improve the control of variability by implementing initiatives like QbD and CPV. These users need an automated way to access, aggregate and organize all types of process and quality data in a validated user environment for analysis and report-
ing without using labor intensive, error prone spreadsheet methods. This presentation will describe how new quality guidelines have been increasing pressure on pharmaceutical and biotech companies to improve quality, and how the industry-leading companies have been addressing these needs by using a software solution that provides a validated environment for self-service, on-demand access and automated organization of all process and quality data.

3:30  
**Changes And Introduction Of New And Modified API And Excipients Under The Most Recent FDA Process Validation Guideline**  
*Eran Oz, Director of Technical Operations, Apotex*

In today’s environment and under the new regulations, the level of expectations is elevated. The issue of cost effectiveness is somewhat addressed in the new guidelines, yet many questions remain. The constant changes in raw material either due to cost or due to supplier-driven change frequently trigger the need for an assessment, however, not always a full study. This presentation will share some of our experiences and open a discussion with regards to a potentially agreeable approach.

4:15  
**Process Validation Regulatory Expectations & Best Practices**  
*Alfredo Canhoto, Associate Director of Technical Solutions, ProPharma Group*

This session is based on a training given directly to a team of agents and auditors within the U.S. Food and Drug Administration’s headquarters in Maryland. This was originally a half-day interactive training session, and has been condensed into a 45-minute presentation. This session covers the expectations and best practices of the 2011 U.S. FDA guidance pertaining to Process Validation including all three (3) stages and what to do if a facility only has legacy products and processes. The speaker will cover how industry-leading companies have implemented the 2011 Guidance both prospectively and retrospectively, the successes and benefits of the new approach, and the required cross-functional teamwork both within industry and the Agency that have facilitated successful implementation.

5:00  
**Close of Conference**
Please Complete the Following

FIRST NAME: ____________________________
LAST NAME: ____________________________
TITLE: ____________________________
COMPANY: ____________________________
ADDRESS: ____________________________
ADDRESS: ____________________________
CITY: __________________ STATE: __________________
ZIP: _______ COUNTRY CODE: ____________
OFFICE PHONE: _________________________
MOBILE PHONE: __________________________
FAX: __________________
E-MAIL: __________________

Please register me for:
Process Validation 2015 Summit:

Standard registration: $1,695
Early bird: Register by June 15th and take $200 off!
Call for government or academic discount

PAYMENT METHOD

CREDIT CARD REGISTRATION:
☐ CREDIT CARD ☐ VISA ☐ MASTERCARD ☐ AMEX
NAME: ____________________________
CARD #: ____________________________
EXPIRATION: _____ / _____
SIGNATURE: ____________________________
BILLING ADDRESS: ____________________________

VENUE INFORMATION:

Dates: October 5-6, 2015
Venue: Sheraton La Jolla Venue
Venue Address: 3299 Holiday Court
La Jolla, CA 92037
Venue Phone: (858) 453-5500
Hotel Address: 3299 Holiday Court
La Jolla, CA 92037
Hotel Telephone: (858) 453-5500

CHECK REGISTRATION:
To pay by check, please provide a purchase order below. Please note that all payments must be received five (5) days prior to the conference to ensure space. Attendees will not be admitted to the conference without full payment.
PURCHASE ORDER #: ____________________________

PLEASE NOTE:
PharmaEd Resources does not offer refunds. However, if you cannot attend after registering, we are happy to apply your registration fee to another PharmaEd Resources event, or transfer your registration to a colleague. Notice of cancellation must be received at least 5 days prior to the event.