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IVT NETWORK
INSTITUTE OF VALIDATION TECHNOLOGY

25TH ANNUAL VALIDATION WEEK

OCTOBER 16-18, 2019 • HARRAH'S • LAS VEGAS, NV

After 25 Years of Designing Training on Validation and Quality, IVT Provides a Robust Opportunity to Learn What Matters Most NOW

- Considerations for Validation and Facility Design in Cell Therapy Manufacturing
- Leverage Data Integrity Audits to Eliminate 483s and Warning Letter Observations
- Integrate Quality-by-Design Lifecycle into Process Validation, Qualification and Quality Systems
- Take the Fear Out of Change Control in CSV & IT
- Explore Innovations in Continuous Manufacturing
- Human Error Reduction in Validation Activities — A CAPA Approach
- Pragmatic Approaches to Third-Party Risk Management and Validation Oversight
- Practical Approaches to Supply Chain Validation and Verification
- Assess Audit Requirements in Cloud Computing and Vendor-Hosted Applications

Validation Week Provides the Building Blocks for Successful Quality and Validation Programs

- Learn from Recent FDA Inspections
- FDA ORA Medical Devices Spotlight
- Global Regulatory Trends Impacting Quality Management
- Update on FDA Draft Guidance on Computer Software Assurance (CSA)
- Project Management and Leadership to Drive Quality and Innovation

IVT Certificate of Attendance
IVT
Earn GMP Training Hours

FEATURING

3rd Annual
Women in Validation Empowerment Summit

WWW.CBINET.COM/VALWEEK

Join Us Wednesday Morning for the
3RD ANNUAL WOMEN IN VALIDATION EMPOWERMENT SUMMIT

Hear from industry leaders who have paved the way for women's leadership in validation, quality and engineering. Back by popular demand, this summit features interactive table talks and a panel discussion on key themes, including opportunities for career advancement, achieving a fulfilling work-life balance, cultivating leadership skills and enhancing workplace diversity and inclusion. This summit is only open to attendees of the **25th Annual Validation Week** — don't miss out!

Benefit from Expert Insights from Industry Leaders, Including:

Gamal Amer,
Principal,
Premier Compliance Services

Crystal Booth, M.M.,
Regional Manager,
PSC Biotech

Raymond W. Brullo, M.D. DPM,
Compliance Officer, Office of Medical Devices and Radiological Health Operations Div. 3, Office of Regulatory Affairs (ORA),
U.S. Food and Drug Administration (USFDA) (Invited)

Javier Cardenas, Ph.D.,
Senior Consultant,
Azzur Group

Mauricio Chinchilla Romero,
Senior Quality Engineer,
Edwards Lifesciences

Parsa Famili, MSc,
President & CEO,
Novatek International

Katherine Giacoletti, M. Stat,
Partner,
SynoloStats LLC

Alan Golden,
Principal,
Design Quality Consultants LLC

Gerardo Gómez, Ph.D.,
Senior Manager Business Development, **PharmaLex**

Senthil Gurumoorthi,
Assistant Director,
Gilead

Connie Hetzler,
Global Validation Head,
Alcon Labs

Michelle Hickey,
Director, Validation,
Clovis Oncology

William Johnson,
Director Facilities & Validation,
Bellicum Pharmaceuticals

Praveen Kalluri, Director, Quality Assurance – Computer System Validation, **PTC Therapeutics**

Lou Killian, Director Customer Education & Success,
Kneat Software

Valerie King-Bailey,
CEO,
OnShore Technology Group

Khaled Moussally, Head Quality Management Systems & Managing Partner, **Compliance Group**

Paul L. Pluta, Ph.D. Editor-in-Chief,
Journal of Validation Technology and Journal of GXP Compliance, IVT and Informa Connect;
Managing Director, **Lifecycle Compliance Systems**

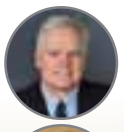
Lizzandra Rivera, Assistant Director Quality – Systems, Standards and Compliance, CSV Program Manager, **Alexion**

Ken Shitamoto,
Senior Director, IT,
Gilead

Willis Thomas, Ph.D., PMP, CPT,
Editorial Advisory Board Member,
Journal of Validation Technology and Journal of GXP Compliance

Kimberly A. Trautman, MS.,
Executive Vice President Medical Device International Services,
NSF Medical Devices

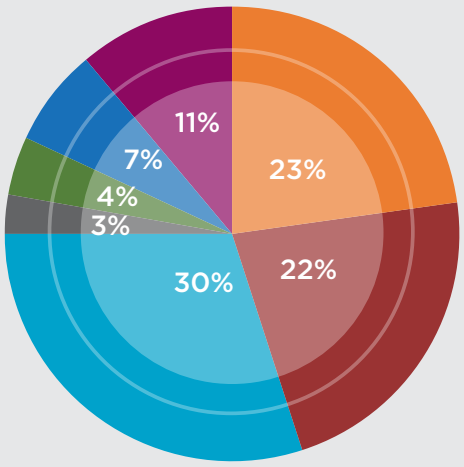
Judy Umlas, Senior Vice President, Author, Trainer, **International Institute for Learning, Inc.**



Chris Wubbolt,
Principal,
QAVC Consulting

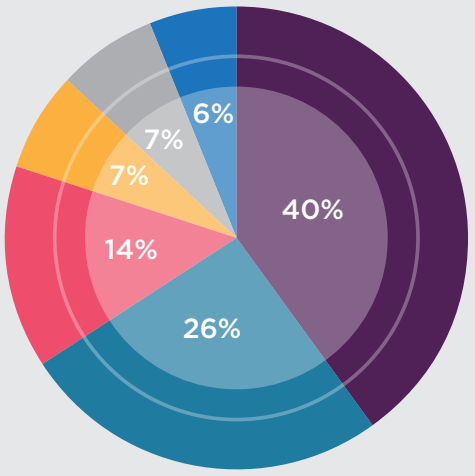
Joseph Zec, Associate Director, CSV and Compliance,
Takeda

2018 ATTENDEE PROFILE



Audience Function

- Validation
- QA/QC/Quality
- Engineer
- Other
- Systems/IT/IS
- Lab/Scientist/Chemist
- Regulatory Affairs



Company Type

- Bio/Pharmaceutical
- Medical Device/Diagnostic
- Service Provider
- CDMP/CMO
- Other
- Consumer Goods

PAVING THE WAY TO **VALIDATION EXCELLENCE**

IVT NETWORK
INSTITUTE OF VALIDATION TECHNOLOGY

IVT Network is the trusted source for life science validation and compliance professionals to access the most current and relevant industry and regulatory knowledge. Secure access to Validation Excellence with your membership to IVT Network. Members gain access to cutting edge content, industry research, lifelong learning and opportunities for networking on a global level.

As a member you will receive: Exclusive access to our peer-reviewed academic journals, over 300 content specific products including training videos, master validation plans, protocols, handbooks and special editions, as well as relevant regulatory and industry guidance materials.

As an attendee at 25th Annual Validation Week, enjoy a FREE 10-day trial and a limited-time, $500 discount on your membership!

MEET YOUR MARKET

IVT's 25th Annual Validation Week convenes the life sciences industry's leading experts responsible for implementing, managing and driving their organization's quality and validation programs. Capitalize on the opportunity to network, exchange ideas and share solutions throughout the conference. For more information, contact **Steve Markos** at **+1 339-298-2108** or email at **steven.markos@cbinet.com**.

CUSTOMIZE YOUR SPONSORSHIP EXPERIENCE

Cocktail Reception Host
Showcase your brand by hosting the prime networking event for all Validation Week participants. Sponsors create a custom experience on the show floor through entertainment, craft cocktails and exquisite menu planning.

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Continue to engage in conversation during scheduled programming breaks in the exhibit hall. Welcome attendees to a custom food and beverage station at your exhibit booth.

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EndPoint TECHNOLOGIES
From Inception to Solution

COMPLIANCE group

AGENDA AT A GLANCE

SESSION TOPIC KEY

Validation Essentials | Quality Control & Compliance | CSV & IT | Manufacturing & Production

DAY ONE WEDNESDAY, OCTOBER 16, 2019

3rd Annual **Women in Validation Empowerment Summit**

9:00	Summit Check-In and Welcome Refreshments
11:30	Close of Summit and Lunch for Summit Participants

MAIN CONFERENCE AGENDA

11:30	Main Conference Check-In
12:30	Chairperson's Welcome and Opening Remarks

U.S. FDA REGULATORY SHOWCASE

12:45	**FDA ORA Medical Devices Spotlight**
1:30	**Explore the Convergence of Global Regulatory Trends Impacting Quality Management**
2:15	**Game Changer! Update on FDA and Industry Collaboration on Computer Software Assurance (CSA)**
3:15	Networking and Refreshment Break
3:45	**Cell Therapy Manufacturing Facility Design, Construction and Validation**
4:30	**Advanced Therapy Medicinal Products (ATMPs) — A Journey into Uncharted Territory**
5:30	**Go Lean! Mastering the Principles and Best Practices of Lean Validation**
5:30	IVT Awards Ceremony
6:00	Close of Day One and **Networking Reception**

DAY TWO THURSDAY, OCTOBER 17, 2019

8:00	Continental Breakfast
8:30	**CHOOSE BETWEEN FOUR BREAKOUT SESSIONS (1-4)**

VALIDATION ESSENTIALS	QUALITY CONTROL & COMPLIANCE	CSV & IT	MANUFACTURING & PRODUCTION
SESSION 1 Drive Process Understanding through Optimized Process Validation and Qualification	SESSION 2 Leverage Data Integrity Audits to Eliminate 483s and Warning Letter Observations	SESSION 3 Pragmatic CSV — Risk-Based Testing and Documentation	SESSION 4 Develop a Strategic Plan for Facilities Design, Qualification and Validation

10:00	Networking and Refreshment Break
10:30	**CHOOSE BETWEEN FOUR BREAKOUT SESSIONS (5-8)**

VALIDATION ESSENTIALS	QUALITY CONTROL & COMPLIANCE	CSV & IT	MANUFACTURING & PRODUCTION
SESSION 5 Develop a Strategic Lifecycle Approach to Validation and Risk Management	SESSION 6 Integrate Quality-by-Design Lifecycle into Process Validation, Qualification and Quality Systems	SESSION 7 Take the Fear Out of Change Control in CSV & IT	SESSION 8 Mastering Automated Validation Testing — Principles and Best Practices

12:00	Networking Luncheon
1:15	**CHOOSE BETWEEN FOUR BREAKOUT SESSIONS (9-12)**

VALIDATION ESSENTIALS	QUALITY CONTROL & COMPLIANCE	CSV & IT	MANUFACTURING & PRODUCTION
SESSION 9 Validation Master Planning — A Risk-Based Approach	SESSION 10 Human Error Reduction in Validation Activities — A CAPA Approach	SESSION 11 Comprehensive Strategies for CSV — Tailoring the Process Made Easy	SESSION 12 Global Problems in Cleaning Validation — 2019

2:45	Networking and Refreshment Break
3:15	**CHOOSE BETWEEN FOUR BREAKOUT SESSIONS (13-16)**

VALIDATION ESSENTIALS	QUALITY CONTROL & COMPLIANCE	CSV & IT	MANUFACTURING & PRODUCTION
SESSION 13 Pragmatic Approaches to Third-Party Risk Management and Validation Oversight	SESSION 14 Achieve Outstanding Productivity Results in the QC Lab with an EVLMS Approach	SESSION 15 Bring Your Own Data Integrity Challenge	SESSION 16 Cleanrooms On-Demand, a Paradigm Shift in Early Phase Bio-Pharmaceutical Manufacturing

4:15	**CHOOSE BETWEEN FOUR BREAKOUT SESSIONS (17-20)**

VALIDATION ESSENTIALS	QUALITY CONTROL & COMPLIANCE	CSV & IT	MANUFACTURING & PRODUCTION
SESSION 17 Maintenance of the Validated State for Commercial Manufacturing Processes	SESSION 18 URS & Implementation of Risk-Based Cleaning Validation Management System	SESSION 19 Arrival of a New Era in Validation	SESSION 20 Practical Approaches to Supply Chain Validation and Verification

5:15	Close of Conference

DAY THREE FRIDAY, OCTOBER 18, 2019

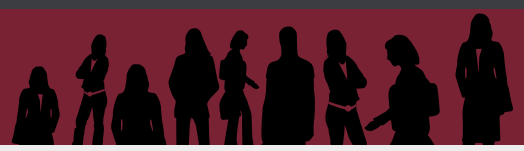
8:00	Continental Breakfast
8:30	**CHOOSE BETWEEN FOUR WORKSHOPS (A-D)**

WORKSHOP A	WORKSHOP B	WORKSHOP C	WORKSHOP D
Patient-Focused Statistics in Process Validation — Tips and Techniques for the Non-Statistician	Audit and Inspection Readiness Bootcamp	Design Control — Fundamentals, Requirements and Practice	Drive Quality and Employee Engagement Through Grateful Leadership and Acknowledgment

10:00	Networking and Refreshment Break for all Workshops
10:30	Workshops Resume
12:00	Close of Workshops and Networking Luncheon
1:00	**Identify Key Learnings and Common Roadblocks to Ensure Successful Audits**
2:00	**What's Next for Validation & Quality — Tangible Takeaways, Strategic Insights and Lessons Learned**
3:00	Close of Conference

DAY ONE WEDNESDAY, OCTOBER 16, 2019

3rd Annual
Women in Validation Empowerment Summit



9:00 *Summit Check-In and Welcome Refreshments*

9:30 **Paving the Way for Women in Validation and Quality**

PANEL

Gather with fellow life sciences professionals to discuss the challenges and experiences of women advancing their careers in quality and engineering. Hear compelling stories of personal career success, reflect on professional development paths, and learn how to capitalize on key career opportunities.

MODERATOR:
Connie Hetzler, Global Validation Head, **Alcon Labs**

PANELISTS:
Lizzandra Rivera, Assistant Director Quality – Systems, Standards and Compliance, CSV Program Manager, **Alexion**

Valerie King-Bailey, CEO, **OnShore Technology Group**

Kimberly A. Trautman, MS., Executive Vice President Medical Device International Services, **NSF Medical Devices**

Michelle Hickey, Director, Validation, **Clovis Oncology**

10:30 **TABLE TALKS**

11:30 *Close of Summit and Lunch for Summit Participants*

11:30 *Main Conference Registration*

12:30 *Conference Chair's Welcome and Opening Remarks*

Praveen Kalluri, Director, Quality Assurance – Computer System Validation, **PTC Therapeutics**

REGULATORY SHOWCASE

Insight from the FDA ORA Medical Devices and Pharmaceuticals — Learn from Recent Inspections to Increase Efficiencies and Decrease Violations

12:45 **FDA ORA Medical Devices Spotlight**

Raymond W. Brullo, M.D. DPM, Compliance Officer, Office of Medical Devices and Radiological Health Operations Div. 3, Office of Regulatory Affairs (ORA), **U.S. Food and Drug Administration (USFDA)** *(Invited)*

1:30 **Explore the Convergence of Global Regulatory Trends Impacting Quality Management**

The new and changed requirements for a risk management system according to the third edition ISO 14971:2019 and Regulation (EU) 2017/745 on medical devices will influence the technical documentation through the medical device lifecycle. Further, the clinical evaluation requirements according to the Regulation (EU) 2017/745 and the MEDDEV 2.7/1 rev. 4 is a substantial part of the technical documentation, which has significant influence on the approval and certification. The core of the clinical evaluation is based on pre-clinical and especially clinical data to support the safety, performance and clinical benefit of the medical device. Clinical data can be obtained from clinical investigations, scientific literature or clinical experience data. In addition, ISO 13485:2016 now has a specific requirement for Post Market Surveillance (PMS) as well as several new PMS requirements found in Regulation (EU) 2017/745. The correlation between risk management, clinical evaluation and other post market surveillance activities will call for some substantial changes within the Quality Management System in order to comply with new Global Regulatory expectations.

Kimberly A. Trautman, MS., Executive Vice President Medical Device International Services, **NSF Medical Devices**

2:15 **Game Changer! Update on FDA and Industry Collaboration on Computer Software Assurance (CSA)**

Although FDA Title 21 CFR Part 11 was introduced in 1997 to regulate the use of computerized systems, many Life Sciences companies still struggle with the complexities and cost to comply, and remain using paper-based, manual tools for documentation and quality management.

In an effort to harmonize with international standards, the FDA (CDRH) announced in their FY 2019 Proposed Guidance Development list to release a new draft guidance, ***"Computer Software Assurance for Manufacturing, Operations, and Quality System Software,"*** that aligns with the current quality systems regulation ISO 13485. Hear directly from members of the FDA/industry collaborative team on the scope of what this guidance may entail.

- Discuss industry recommendations for anticipated FDA draft guidance
- Hear success stories of implementing the guidance and the resulting benefits
- Analyze the challenges and solutions to automating non-product CSV

BONUS MATERIAL
- Examples and Case studies

Khaled Moussally, Head Quality Management Systems & Managing Partner, **Compliance Group**
Ken Shitamoto, Senior Director, IT, **Gilead**

3:15 *Networking and Refreshment Break*

3:45 **Cell Therapy Manufacturing Facility Design, Construction and Validation**

Learning Goals:

I. Learn Cleanroom design aspects for cell therapy manufacturing facilities
II. Learn how important the manufacturing process is to the overall facility
III. Learn Cleanroom Construction aspects for cell therapy manufacturing facilities
IV. Learn a case study of Bellicum's cleanroom for cell therapy manufacturing
V. Are there differences regarding validating a cell therapy vs. a traditional pharmaceutical facility?

William Johnson, Director Facilities & Validation, **Bellicum Pharmaceuticals**

4:30 **Advanced Therapy Medicinal Products (ATMPs) — A journey into Uncharted Territory**

This presentation will introduce the current state of advanced therapies, describe the challenges being faced both in industry as a whole and those specific to validation efforts for these specialized therapies, and discuss the influence from the regulatory bodies.

Javier Cardenas, Ph.D., Senior Consultant, **Azzur Group**

5:15 **Go Lean! Mastering the Principles and Best Practices of Lean Validation**

I. What Is Lean Validation
II. Game Change — Cloud Computing Systems and RPA
III. Lean Validation Principles and Best Practices
IV. Lean Validation Case Study
V. 10 Steps Towards Lean Validation Success

BONUS MATERIAL
- Lean Validation White Paper

Valarie King-Bailey, M.B.A., Chief Executive Officer, **OnShore Technology Group, Inc.**

6:00 *IVT Awards Ceremony*

6:30 *Close of Day One*

NETWORKING RECEPTION

DAY TWO THURSDAY, OCTOBER 17, 2019

8:00 *Continental Breakfast*

8:30 CHOOSE BETWEEN FOUR BREAKOUT SESSIONS (1-4)

VALIDATION ESSENTIALS

SESSION 1
Drive Process Understanding through Optimized Process Validation and Qualification

At the end of the 90-minute presentation, the participant will be able to:

I. **Review How the Product Lifecycle Links with the Most Recent Process Validation Lifecycle as Defined by the Main Regulatory Bodies**

II. **Demonstrate an Understanding of the Interactions Between Process Understanding and Process Validation**

III. **Case Study #1**
Process Understanding in a Bulk Biotech plant leading to a successful Process Validation

IV. **Case Study #2**
How a challenging Process Validation for a Biotechnology Drug Product influenced Process Understanding for subsequent products in the pipeline

V. **Interactive Activity**
The participants will identify Critical Process Parameters and the most likely Critical Quality Attributes being affected during the PPQ of a lyophilized drug product

Bonus Material
- Qualitative Tool for Process Understanding Article

Gerardo Gómez, Ph.D., Senior Manager Business Development, **PharmaLex**

QUALITY CONTROL & COMPLIANCE

SESSION 2
Leverage Data Integrity Audits to Eliminate 483s and Warning Letter Observations

Learning Goals:

I. **Review of Typical Data Integrity Related 483s and Warning Letters**

II. **Discuss Route Cause of these Observations**

III. **Incorporating Learnings into Data Integrity Program**

IV. **Conducting Data Integrity Audits/Assessments**

V. **Case Study — Conduct a Laboratory Data Integrity Assessment**

Bonus Material
- Data process flow example

Chris Wubbolt, Principal, **QACV BioPharma Group**

CSV & IT

SESSION 3
Pragmatic CSV — Risk-Based Testing and Documentation

I. **Background**
- Brief overview of current state of affairs
- Brief normalization on risk models

II. **Non-product Computer System Validation (NP CSV)**
- Overview of non-product CSV model
- Understanding basic assurance, unscripted testing, limited scripted testing and robust scripted testing
- Introduction of functional assurance
- Walk-through of empirical data derived from the application of the model to multiple systems

III. **System-level Risk (SLR)**
- Overview of the system-level risk model
- Detailed discussion, with examples, for each parameter of SLR, that is, what it is and how to calculate it
  1. Complexity score
  2. Distribution score
  3. Functionality score
  4. GxP record criticality
- How to calibrate SLR scores for your organization
- How to apply system level risk to determine deliverables/activities based on SLR

IV. **Interactive Exercise**
Applying SLR and NP CSV

V. **Leveraging Software Quality Assurance (SQA)**
- Overview of software quality assurance
- Discussion regarding the differences between, and advantages of, SQA over validation
- Process requirements for SQA (quality of deliverables, etc)
- Model for leveraging SLR and SQA in validation
- Automation and SQA and the impact to validation

VI. **Next Steps**

Bonus Material
- Reference tables for calculating SLR
- Reference tables for Non-Product CSV

Ken Shitamoto, Senior Director, IT, **Gilead**

Senthil Gurumoorthi, Assistant Director, **Gilead**

MANUFACTURING & PRODUCTION

SESSION 4
Develop a Strategic Plan for Facilities Design, Qualification and Validation

I. **Facilities Validations Overview**
- Learning the facility and utility lifecycle management
- Understanding impact of facility and utility systems in the final product
- Defining the risk level for the facility and utility systems
- Qualification stages

II. **Types of Facilities Validations**
- HVAC, cleanroom performance, compressed dry air, architectural finishes, etc.
- Outputs applicable per validation type

III. **Executing and Documenting Facilities Validations**
- Executing flawlessly a facilities validation
- Managing deviations and failures in facilities validations
- Maintaining the validated stated of the facilities and utility systems

IV. **Q&As and Lessons Learned**
Participants can ask questions regarding the presentation and develop an open discussion about lessons learned of completed validations.

Mauricio Chinchilla Romero, Senior Quality Engineer, **Edwards Lifesciences**

10:00 *Networking and Refreshment Break*

10:30 CHOOSE BETWEEN FOUR BREAKOUT SESSIONS (5-8)

VALIDATION ESSENTIALS

SESSION 5
Develop a Strategic Lifecycle Approach to Validation and Risk Management

I. Mapping the Lifecycle
- Understand where product and process validation fit in the lifecycle
- Identify the linkages throughout the lifecycle how they impact patients in the market
- Develop a strategy for managing the linkages from product design to process monitoring
- Establish an effective feedback loop for customer complaint data to complete the lifecycle management approach

II. Risk Identification in the Lifecycle
- Leveraging cross-functional input for comprehensive risk identification
- Risk categories for product and process
- How to better estimate and reduce risk in each category

III. Integrating Your Risk Management Program into a Meaningful Strategy
- How to present your program to executive leaders to increase support and resource allocation
- Preparing for audits with a lifecycle approach based on risk management

IV. Interactive Activity

We will have an interactive session to identify best practices and case studies for LCM.

Connie Hetzler, Global Validation Head, **Alcon Labs**

QUALITY CONTROL & COMPLIANCE

SESSION 6
Integrate Quality-by-Design Lifecycle into Process Validation, Qualification and Quality Systems

Learning Goals:

I. Outline, Definitions and Objectives

II. Define QbD and Lifecycle to Process Validation

III. Apply QbD/Lifecycle to Other Pharma Processes

IV. Analyze and Apply QbD/Lifecycle to Equipment and Other Qualification

V. Apply QbD/Lifecycle to Quality System Applications

Bonus Material

QbD/Lifecycle Approach Audit Questions

Paul L. Pluta, Ph.D. Editor-in-Chief, **Journal of Validation Technology and Journal of GXP Compliance, IVT and Informa Connect;** *Managing Director,* **Lifecycle Compliance Systems**

CSV & IT

SESSION 7
Take the Fear Out of Change Control in CSV & IT

Learning Goals:

I. Change Control — Why?: Understand Change Control and How to Ensure the Process Remains in Control

II. Understanding the Differences between Change Classification and Assessments

III. Navigate Application Changes and Security/Patch Updates

IV. Our Change Control vs. their Change Control — On Prem Systems vs. Cloud Solutions

V. Case Study — Evaluate Types of Changes One May Encounter and How to Deal with Them

Lizzandra Rivera, AD, Quality - Systems, Standards and Compliance, **Alexion Pharmaceuticals**

MANUFACTURING & PRODUCTION

SESSION 8
Mastering Automated Validation Testing — Principles and Best Practices

Learning Goals:

I. Test Automation Trends

II. Regulatory Considerations

III. IV&V Testing Principles and Best Practices

IV. Considerations for Automation — A Holistic vs. Tool Approach

V. Case Study — Applied Automated Validation Strategies for an ERP Project

Bonus Material
- IV&V Automation Testing White Paper

Valarie King-Bailey, M.B.A., Chief Executive Officer, **OnShore Technology Group, Inc.**

12:00 *Networking Luncheon*

1:15 CHOOSE BETWEEN FOUR BREAKOUT SESSIONS (9-12)

VALIDATION ESSENTIALS

SESSION 9
Validation Master Planning — A Risk-Based Approach

In this presentation, discuss the concepts associated with Quality Risk Management as outlined in ICH Q9 Guidance and learn to develop a Risk Priority Number (RPN) for real life situations. This knowledge will then be applied to decision-making in prioritizing and defining the extent of qualification necessary based on the concepts advanced in the FDA's Guidance on Process Validation issued in January 2011. This knowledge will then be used to help develop a Master Plan for Process Performance Qualification.

I. ICH Q9 and Quality Risk Management and The Risk Priority Number (RPN)
- Understand what risk is and the concepts of risk management
- What are the most risky operations in the pharmaceutical industry?
- How to define risk levels and risk level factors
- How to apply RPN to prioritize risk mitigation and the concept of x2

II. FDA's View of the Importance of Risk Management in GMP Compliance and Validation
- August 2002 FDA Initiative on Risk-Based Compliance for the 21st Century
- FDA's Process Validation Guidance and Risk Management

III. Applying Risk Management to the Validation Process and Developing a Master Plan
- Applying risk management techniques to prioritizing the qualification effort
- Qualification of facility and utilities
- Qualification of processing equipment
- Qualification of high-risk sub systems
- Process Performance Qualification (PPQ)

Gamal Amer, Principal, **Premier Compliance Services**

QUALITY CONTROL & COMPLIANCE

SESSION 10
Human Error Reduction in Validation Activities — A CAPA Approach

The cost of human error to the life sciences industry results in billions of dollars in lost revenue annually, in addition to products and services that never make it to market. Understanding the root causes of mistakes that people make through looking at the human performance model is one of the first steps that must be taken to address investigations and deviations that are associated with validation-related activities. Participants learn:

- Who should be involved in root cause analysis of human error in validation-related activities?
- What is human performance modeling?
- Where is the data and information that should be considered in root cause analysis?
- Why does it take so long to complete root cause analysis?
- How can the request for resources be justified for reducing human error?
- When is enough, enough in terms of root causes analysis associated with human error reduction?

Interactive Activity

- Case study review of findings and observations related to validation where human error could have been prevented through targeted training and development

Willis Thomas, Ph.D., PMP, CPT, Editorial Advisory Board Member, **Journal of Validation Technology** *and* **Journal of GXP Compliance**

CSV & IT

SESSION 11
Comprehensive Strategies for CSV — Tailoring the Process Made Easy

In today's world of complex and diverse methods for implementing computerized systems, it helps to have a validation strategy that is tailored to the situation. Attendees of this session will learn how to apply the correct CSV strategy for any given situation. The session will conclude with an interactive exercise where attendees will have the chance to discuss specific scenarios and how to tailor the validation process accordingly.

- Introduction
- The GAMP "V" Model
- Scenarios to Consider
  - On-premise vs. Hosted
  - Internally-developed vs. COTS
  - Cloud-based data storage
  - Agile Development
- Interactive Exercise — Apply the Strategy!

Joseph Zec, Associate Director, CSV and Compliance, **Takeda**

MANUFACTURING & PRODUCTION

SESSION 12
Global Problems in Cleaning Validation — 2019

Learning Goals:

I. Outline, Definitions and Objectives

II. Discuss API and Product-Related Problems

III. Describe Equipment-Related Cleaning Problems

IV. Analyze Cleaning Process Problems

V. Discuss and Describe Analytical Laboratory Problems

VI. Management and Staff Problems

Bonus Material

- Audit questions for cleaning validation programs.

Paul L. Pluta, Ph.D. Editor-in-Chief, **Journal of Validation Technology and Journal of GXP Compliance, IVT and Informa Connect;** *Managing Director,* **Lifecycle Compliance Systems**

2:45 *Networking and Refreshment Break*

3:15 CHOOSE BETWEEN FOUR EDUCATIONAL BREAKOUT SESSIONS (13-16)

VALIDATION ESSENTIALS

SESSION 13
Pragmatic Approaches to Third-Party Risk Management and Validation Oversight

I. What Are Quality Agreements?

- Define and explore quality agreements
- Regulations governing the use of Quality Agreements
- Review some regulatory observations

II. Developing a Quality Agreement

- Potential inclusions for the Quality Agreement
- Identify key risk areas in partnering with third-parties
- Working with vendors
- Set expectations between stakeholders to streamline validation activities and quality management
- Assigning responsibilities
- Review an example Quality Agreement

III. Interactive Exercise

- Using an interactive game, participants review the information and regulations

Crystal Booth, M.M., Regional Manager, **PSC Biotech**

QUALITY CONTROL & COMPLIANCE

SESSION 14
Achieve Outstanding Productivity Results in the QC Lab with an EVLMS Approach

Practical guide with case studies to implement an efficient and compliant e-validation EVLMS solution for lab asset lifecycle management.

Learning Goals:

- Interactive Knowledge Exchange — Attendees take part in a round-the-room discussion of company's lab asset management challenges and solution strategies
- Understand the challenges and pain points of the traditional lab asset management process
- Learn how to justify approval for the change and technology tool to enable the new process
- Understand the approach and benefits of the EVLMS lab asset management process
- Learn the "results-oriented" process to efficiently change to the new EVLMS process
- Review the "success story" case studies of Lab Asset Management implementations

Bonus Materials

- Published EVLMS Case Studies

Lou Killian, Director Customer Education & Success, **Kneat Software**

CSV & IT

SESSION 15
Bring Your Own Data Integrity Challenge

In recent years, data integrity has become a hot issue for regulators. The number of citations of data integrity lapses has increased worldwide as regulators focus in on this important practice. In this interactive session, attendees are encouraged to submit their own data integrity challenges, real issues they face on a regular basis in their work. Together, we will discuss these challenges and propose solutions that hopefully will help all in the vital effort of increasing data integrity levels in all areas of our profession.

Joseph Zec, Associate Director, Data Systems, R&D Quality, **Takeda Pharmaceuticals**

Lizzandra Rivera, Associate Director IT Quality, **Alexion**

MANUFACTURING & PRODUCTION

SESSION 16
Cleanrooms On-Demand, a Paradigm Shift in Early Phase Bio/Pharmaceutical Manufacturing

With increasing demands for manufacturing space and GMP capabilities, an alternate option to contract manufacturing and/or in-house manufacturing is now available to the bio/pharma and related industries. This talk details this new manufacturing option for pre-clinical or early phase clinical companies. The talk also provides Azzur's approach to qualification/ validation of this new manufacturing option.

Bonus Material
- Virtual Tour of Azzur Group's Cleanroom's on Demand

Ravi Samavedam, General Manager, **Azzur Group**

4:15 CHOOSE BETWEEN FOUR BREAKOUT SESSIONS (17-20)

VALIDATION ESSENTIALS

SESSION 17
Maintenance of the Validated State for Commercial Manufacturing Processes

Congratulations! You now have a validated, commercial manufacturing process. This session will explore the next phase of the process validation lifecycle, maintaining the validated state. The goal is to ensure you have a robust program in place, and the integrity of your initial hard work is not diminished.

Learning Goals:

I. Review Lifecycle Approach for Process Validation focused on Validation Maintenance and CPV

II. Identify Applicable Global Regulations and Guidance

III. Explore Approaches to Implementation of a Validation Maintenance Program

IV. Identify Best Practices and Challenges

V. Live Benchmarking Poll (results will be compiled and shared with participants)

Michelle Hickey, Director, Validation, **Clovis Oncology**

QUALITY CONTROL & COMPLIANCE

SESSION 18
URS & Implementation of Risk-Based Cleaning Validation Management System

Learning Goals:

I. Manual Systems vs. Computerized Systems

II. Benefits of Compliant Computerized Cleaning Validation Software System

III. Components of a Compliant Cleaning Validation System

IV. Cleaning Validation User Requirements Based on Inherent Risks

V. New FDA Draft Guideline "DATA Integrity"

VI. Supplier Qualification

VII. Implementation, Validation and Training

VIII. Q&A

Parsa Famili, MSc, President & CEO, **Novatek International**

CSV & IT

SESSION 19
Arrival of a New Era in Validation

Learning Goals:

I. Significance of Data Integrity

II. Risk Evaluation Strategies

III. Compliance Factors for Cloud Validation

IV. Embedded Systems in Equipment Validation

V. Importance of Periodic Reviews

VI. Clear Definition of Roles and Responsibilities

VII. Systems Audit Process

VIII. Interactive Discussion
- What are the currently followed risk evaluation methods? What are the pros and cons?
- What should be individual responsibility and what should be a collaborative effort in risk-based validation?

Praveen Kalluri, Director, Quality Assurance – Computer System Validation, **PTC Therapeutics**

MANUFACTURING & PRODUCTION

SESSION 20
Practical Approaches to Supply Chain Validation and Verification

The pharmaceutical supply chain represents an area of extreme vulnerability to the quality of the drugs and poses a high risk to the wellbeing of the public and the patient. The chain is where drugs can be stolen, counterfeited and unapproved/ un-approvable drugs introduced, contamination of drugs, and drugs can undergo major change or deterioration due to environmental conditions among other issues. This presentation will discuss:

I. Supply Chain Management
- What is supply chain management?
- Supply chain model
- Risks within a global supply chain that can affect the patient's wellbeing
- How to mitigate these risks
- Regulatory references

II. Verification of the Supply Chain
- Plan your supply chain and identify stakeholders
- Define the risks associated with the planned chain
- Audit suppliers and transporters
- Use Quality Agreements
- Ensure transparency of the chain — Track and trace
- Ensure your logistics suppliers are licensed
- Train and ensure your suppliers train their personnel involved in the chain

III. Validation of the Supply Chain
- Set the metrics
- Collect appropriate data
- Confirm the metrics are met by the planned supply chain

IV. The Future
What will it look like and what are the regulatory requirements that must be met by supply chain stakeholders over the coming years?

Gamal Amer, Principal, **Premier Compliance Services**

5:15 *Close of Day Two*

DAY THREE FRIDAY, OCTOBER 18, 2019

8:00 *Continental Breakfast*

8:30 CHOOSE BETWEEN FOUR WORKSHOPS (A-D)

A Patient-Focused Statistics in Process Validation — Tips and Techniques for the Non-Statistician

I. Statistics throughout the Process Validation Lifecycle — Overview

II. Optimal Sampling Plans to Demonstrate Performance in Stage 2 of Process Validation

III. Efficient Sampling Plans for Monitoring in Stage 3 of Process Validation

IV. Common Misconceptions about Statistics

V. The Power of Data Visualization

Katherine Giacoletti, M. Stat, Partner, **SynoloStats LLC**

B Audit and Inspection Readiness Bootcamp

PART 1 — Explore Audit Requirements in Cloud Computing and Vendor-Hosted Applications

In this session, benefit from audit-driven learnings on how to ensure robust documentation and validation oversight for cloud service providers.

- The responsibility of the Cloud Service Provider (CSP) in providing validation documentation (IQ/OQ/PQ/VQ) and validation summary report
- The responsibility of the CSP in supporting annual or biannual release upgrades and distinguishing the client's responsibility in related documentation, i.e., change control, performance qualification scripts, SOP updates, validation summary report
- The responsibility of the primary or secondary CSP in supporting 3 party connectivity, i.e., to HRMS or documentation management solutions

PART 2 — Mock Audit

Regulatory Inspections have become more confrontational as of late. Some countries train inspectors using police techniques and personnel are finding themselves becoming stressed and flustered. During these mock inspections, our team of experienced facilitators challenge the audience with typical validation inspection scenarios and you will have a chance to see if your approach and responses work well, as well as hearing tips from other practitioners as to how to do better.

Willis Thomas, Ph.D., PMP, CPT, Editorial Advisory Board Member, **Journal of Validation Technology and Journal of GXP Compliance**

C Design Control — Fundamentals, Requirements and Practice

This workshop will provide participants with a comprehensive overview of the principles and processes involved in design control. From conception to execution, benefit from expert insights to elevate your validation processes.

I. Introduction

II. Scope and Responsibilities

III. Design and Development Planning

IV. Design Input and Output

V. Design Reviews

VI. Design Verification and Validation

VII. Test Method, Process and Software Validation

VIII. Risk Management

IX. Design Transfer and Process Validation

X. Design History File

XI. Q&A

Alan Golden, Principal, **Design Quality Consultants LLC**

D Drive Quality and Employee Engagement Through Grateful Leadership and Acknowledgment

Learning Goals:

I. Identify the 7 principles of Acknowledgment

II. Outline the 5cs of Grateful Leadership

III. Discuss How Organizational Performance Is Linked to Leadership and Acknowledgment

IV. Learn about How People in Technical Roles Can Enhance their Leadership Presence and Acknowledge Peers to Improve Dynamics

V. Review Case Studies and Real-Life Examples of the Power of Grateful Leadership and Acknowledgment

VI. Participate in a Knock Your Socks Off Acknowledgment Interactive Exercise

VII. Provide a Path Forward with Tools and Resources to Enhance Your Grateful Leadership Skills

Judy Umlas, Senior Vice President, Author, Trainer, **International Institute for Learning, Inc.**

10:00 *Networking and Refreshment Break for all Workshops*

10:30 *Workshops Resume*

12:00 *Close of Workshops and Networking Luncheon*

1:00 **Identify Key Learnings and Common Roadblocks to Ensure Successful Audits**

This session will be highly interactive with audience members actively participating in an open discussion of their audit experience. Through discussion and examples, participants will gain an understanding of how to prepare for and audit, strategies to conduct a successful audit, and ways to respond to audit observations. The following topics will help guide the discussion:

I. **Preparing for a Third-Party Audit or Inspection**
- Assembly of an audit team
- Prestaging of documents and records
- Preparing "back room"

II. **Conducting the Audit**
- Required staff
- Opening meeting
- Tours
- Notes and communication

III. **Responding to Audit Findings**
- Response team
- How fast?
- Next steps

Alan Golden, Principal, **Design Quality Consultants LLC**

2:00 **INTERACTIVE DISCUSSION AND Q&A**

What's Next for Validation and Quality — Tangible Takeaways, Strategic Insights and Lessons Learned

In this session, benefit from expert insights from the 25th Validation Week speaking faculty as they reflect on the on-site conversations and share their perspectives on emerging trends and new developments.

Chris Wubbolt, Principal, **QAVC Consulting**

Willis Thomas, Ph.D., PMP, CPT, Editorial Advisory Board Member, **Journal of Validation Technology and Journal of GXP Compliance**

3:00 CLOSE OF CONFERENCE

PREMIER MEDIA PARTNER:

SUPPORTING MEDIA PARTNERS: