PharmaED RESOURCES, Inc.

Data Integrity & Pharmaceutical Quality Compliance Summit

October 3–4, 2019, Sheraton La Jolla, CA

Featured Speakers Include:

Ron Snee
Snee Associates

Dushyant Varshney
Jubilant Pharmaceuticals

Heather Longden
Waters

Raul Soto
Johnson & Johnson

Laurence O'Leary
ValidEire Consulting IVS

Jason Kelly
Lighthouse Worldwide Solutions

Kip Wolf
Tunnell Consulting

Gyorgy Vas
Intertek

Mike Fitch
Kelly@Takeda

Chris Wubbolt
QACV Consulting

Dipti Gulati
PJI Biotech LLC

John Avellanet
Cerulean Associates LLC

With Comprehensive Coverage On:

- Regulatory Guidance for Data Integrity
- A Regulatory Global View on Data Integrity and its Importance
- Examining FDA Integrity Guideline
- Creating Data Integrity Programs
- Data Integrity During Process Validation and Commercial Product Transfers
- CMOs and Data Integrity
- How to Detect the Lack of Data Integrity
- Data Integrity for Complex Analytical Systems. How to Deal Effectively with Vendor-Provided COTS Solutions?
- Data Integrity in cGMP Realized in Global Pharma Corporate Projects
- Performing a Risk Assessment for Data Deficiencies
- Data Lifecycle Management
- Process Validation and Technology Transfer of Biologics and Vaccines
- Software Validation Case Study: Validation of MES System
- MHRA and EMEA Guidance Highlights
- Considerations for Addressing Data Integrity in Quality Agreements
- Analytical and Statistical Methods for Detecting Data Problems
- And much more

With Representation From:

intertek Total Quality. Assured. · cerulean associates LLC · UNGER CONSULTING · STERIS · TUNNELL life sciences consulting · Waters THE SCIENCE OF WHAT'S POSSIBLE.™

QACV CONSULTING · JUBILANT PHARMA · Snee Associates LLC · Johnson & Johnson · VALIDEIRE · PJI Biotech · LIGHTHOUSE WORLDWIDE SOLUTIONS

PharmaEd Resources, Inc. • 2810 Robeson Park Drive • Champaign, IL 61822
tel. 217.721.5774 • *web.* www.pharmaedresources.com

Wednesday, October 3, 2019

7:30 *Complimentary Breakfast*

8:15 *Chairperson's Welcome and Opening Remarks*

In-Depth Coverage on Regulatory Considerations

8:30 CASE STUDY

Regulatory Guidance for Data Integrity

Kip Wolf, Principal, Tunnell Consulting, Inc.

The author/presenter will describe the various regulatory and guidance documents that exist related to data integrity in the life sciences industry and will provide examples of the current regulatory compliance landscape from contemporary inspection results. The author/presenter will also provide specific case study examples of compliance remediation related to data integrity.

Examples may include:

- Laboratory data and related systems
- Document/records management and related systems
- Conformance to file assessment

9:15

Understanding How the New Inspection Protocol Uncovers Data Integrity Issues

John Avellanet, Managing Director & Principal, Cerulean Associates LLC

Presented by one of the trainers for the US FDA, this presentation covers how the New Inspection Protocol (NIP) helps investigators more easily uncover data integrity issues. You'll learn why and how to start changing how you prepare for inspections, conduct your own quality audits, and train your personnel. Attendees will see an inspection case study from the initial pilot program when FDA first launched the NIP, learn the specific types of data integrity compliance proof to be prepared to share – to give you the best chance to avoid FDA-483s and EMA noncompliance observations on data integrity. As a bonus, attendees will also see the real-world dollar costs it took for the case study company to come into compliance so you can build your complete business case on how to prevent data integrity inspectional findings.

10:00 *Networking Break*

Examining FDA Warning Letters

10:20

A Regulatory Global View on Data Integrity and It's Importance

Laurence O'Leary, CEO/Founder, ValidEire Consulting IVS

Data Integrity has long been regarded as a must in many industries. The prevailment of GAMP and regulatory guidance addressing data integrity has verified the importance. Additionally, observations and warning letters are directly targeting the pharmaceutical industry, and this is significant, leading to costly remediations when neglected, both for the specific inspected site and subsequent sister sites in a global market. I will guide you with a few of the observations I made when studying FDA, MHRA and EMEAS guidelines. I will add to this by illustrating with appropriate observations and warning letters to drive the important message home. You cannot and must not ignore data integrity in the 21st century.

Points that will be presented:

- FDA guideline highlights
- MHRA guideline highlights
- EMEA guidance highlights
- Observations & WLs from corporate companies
- What the future holds in store for you with DI

11:05

Regulatory Requirement and Thinking Related to Data Integrity

Walid El Azab, Technical Service Manager, STERIS Corporation

The number of inspections findings related to data integrity has increased over the past few years. However, regulatory agencies have published many guidelines since 1963. Recently, several regulatory agencies and industry associations have released different guidelines for pharmaceutical manufacturers related to data integrity. The objective of this presentation is to share the different regulatory requirements and thinking. Also, the best practices to avoid breaches of data integrity in the pharmaceutical industry will be presented. Finally, several regulatory observations will be shared during the presentation.

11:50 *Complimentary Lunch*

12:50

Examining FDA Data Integrity Guideline

Raul Soto, Senior Principal Software Engineer, Johnson & Johnson

FDA's Draft Guidance on Data Integrity, Written in a Questions-and-Answers Format, Provides the Agency's Thinking on the Subject of Data Integrity.

1. What is data integrity?
2. The meaning of ALCOA
3. Static vs. dynamic data
4. Audit trails
    1. The various types
    2. Who should review them and how often
5. When does electronic data become an Electronic Record?
6. System security: FDA's view on group accounts
7. Backing up GXP data
8. Recommendations on how to manage data integrity issues

1:35 CASE STUDY

Data Integrity Validation and Site Inspections

Mike Fitch, QA CSV, Kelly@Takeda

Lessons learned from years of experience in Pharmaceutical and Medical Device Industries; defending CSV to 3rd party audits and FDA investigations; addressing CAPAs; seeing the beginnings of addressing Part 11; seeing the beginnings of addressing Data Integrity; moving from just beginning to realize we might need to validate some sys-

tems to having validations that we could confidently defend to the FDA.

1. Remember why you do what you do
2. Start out simple — getting simple process frameworks in place
3. Pay attention to what you are reviewing
4. Words matter
5. Recovering from failures
6. Focus on fundamentals

2:20 *Afternoon Networking Break*

Data Integrity Program & Culture

2:35 **Creating Data Integrity Programs**

Chris Wubbolt, Principal Consultant, QACV Consulting

This program will review the basic concepts of Data Governance Programs and how they are im-plemented and monitored from an enterprise-wide and site-wide perspective.

I. Data Governance Programs
   - Basic Elements of Data Governance Programs
   - Organizational Considerations – Data Governance Committees
   - Site-Wide vs Enterprise-Wide Data Governance Programs

II. Implementing Data Governance Programs
   - Data Governance Policies and Procedures
   - Procedures impacted by Data Integrity requirements
   - Training
   - Multi-site roll-out of Data Governance Programs
   - Monitoring Data Governance Programs

3:20 **Data Integrity During Process Validation and Commercial Product Transfers**

Dushyant B. Varshney, PhD, Vice President, Technical Services, Operations at Jubilant Pharmaceuticals

In the past two decades, there has been a fast increase in the number of biologicals, biosimilars and vaccines developed by small and large biopharmaceutical companies. Development of such biologics is quite expensive, and many companies lack the in-house setup and capability to develop at a 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, rather than investing in setting up and maintaining their own facilities with required expert staff and regular updates. In such industry trends, data integrity (DI) during technology transfer (TT) and validation of active pharmaceutical ingredients, analytical methods and drug products/processes from the development to the 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.

This talk will focus on the data-integrity considerations during global technology transfer, subsequent process validation and commercial manufacturing. Specifically, the roadmap to data integrity during external vs. internal manufacturing for biologics and vaccine products delivered by parenteral route will be discussed.

4:05 **Leveraging Vendor Expertise to Assess your Software**

Heather Longden, Senior Marketing Manager for Informatics Regulatory Compliance, Waters

Meeting regulatory requirements, (both part 11 as well as the relevant GxP regulations) in laboratories requires excellent knowledge of the tools deployed (software and instruments) supplied by outside vendors. As the compliance expert for a vendor of CDS and software (with over 400,000 users, mostly in regulated pharmaceutical laboratories) for over 25 years, I regularly receive questions from laboratories about the vendor's roles and responsibilities in that environment. Additionally regulated labs are leveraging other critical GxP services, such as Infrastructure or "compute" to outside service providers. Again, clearly defining how a company, such as a cloud services provider, can support a regulated company is critical. This presentation will highlight example questions that get asked of vendors and service providers and suggest possible answers or approaches to get the information needed to answer regulatory questions.

4:45 **Data Integrity: Challenges and Opportunities**

Dipti Gulati, President, PJI Biotech LLC

Data integrity has surfaced as a key issue in last five years during regulatory inspections of raw materials and drug suppliers overseas. Regulators around the globe have issued several guidance's on data integrity in last five years.

What is data integrity? In simple terms, data (paper or electronic) should be complete, consistent and accurate throughout data life cycle, i.e. from raw data generation and recording through use, migration, retention, archival and destruction. It is critical to ensure data integrity because data errors could make an adulterated drug batch to reach patient, thus impacting patient safety.

This talk will focus on systematically developing and implementing data integrity program, which includes 2 major steps: (A) Conduct a thorough assessment of current data integrity systems and identify if there are existing issues. Remediate the existing issues. (B) Develop and implement robust and sustainable data integrity systems and train employees. Establish the governance structure to provide oversight for management and continuous improvement of data integrity program.

5:30 *End of Day One*

Thursday, October 4, 2019

7:30 *Complimentary Breakfast*

8:15 *Chairperson's Remarks*

In-Depth Coverage on Analytical and Statistical methods for Detecting Data Problems

8:30 **How to Detect the Lack of Data Integrity**

Ronald D. Snee, PhD, President, Snee Associates, LLC

The interest in data integrity by the FDA and European agencies raises questions regarding how to assess data integrity and improve it. Lack of data integrity comes from purposeful manipulation of the data to deceive and inadvertent problems that occur in the production and analysis of data. Both types of issues affect decision-making and are addressed, including frameworks to identify data integrity problems, provide improvements and prevent the problems from reoccurring. Assessment of "data pedigree" puts focus on data integrity issues and analytical and statistical methods for detecting data problems. Discussion of methods for building an organizational culture that supports and sustains data integrity is also included. Illustrative pharma and biotech case studies are used throughout the presentation.

I. Today's Realities
   - FDA guidance and inspections
   - Effect of data integrity on cGMP Compliance
   - The usual recommendations—More is needed and more is possible

II. Assessing Data Integrity and Its Consequences
   - What is data integrity?
   - Lack of data integrity—Case studies
   - What is quality data?
   - What are the consequences of data integrity and quality issues?

III. What types of data triggers a concern about the integrity of the data?
   - Data pedigree - What is it? What Should We Look For?
   - How do I know that I have data integrity problems?
   - What to do—Problem identification, correction and prevention
   - How can you further investigate suspicious data?

IV. Assessing and Improving Data Integrity and Quality
   - Framework for improvement
   - Use of metadata, audits, and process flow mapping

V. Creating a Culture that Guides and Sustains Data Integrity
   - Roles and responsibilities of management and staff
   - Analyst Code of Conduct
   - Tips, traps, recommendations and guiding principles

10:00 **Data Integrity for Complex Analytical Systems. How to Deal Effectively with Vendor-Provided COTS Solutions?**

Gyorgy Vas, Ph.D., Scientific Liaison, Intertek Pharmaceutical Services

Data Integrity is a hot topic in the Pharmaceutical Industry. Besides the importance of the data integrity, the FDA has not yet published a final guidance to clearly indicate the expectations for data integrity. The complexity of the industry would require complex oversight for the problem, as different solutions are needed for a QC environment where less complex instrumentation is used for release of finished pharmaceutical products, and for R&D where more complex instrumentation is used, however data integrity and compliance is important than for both environments.

The instrument and the related software qualification and cGMP validation are essential parts of the data integrity package. If the vendor-provided software solution is not in compliance with the current regulations, the qualification will be very difficult or not even possible. It is important to highlight that establishing a fully compliant data-integrity solution is a complex workflow involving the vendor, the user and the quality control unit. Every step in the complex workflow must be in compliance with current regulations, guidances or Industry best practices.

This presentation will use case studies to focus on the following major areas:

- What to do before the instrument/software is purchased; what steps need to be completed?
- Roles of the vendor, the user and the quality unit
- Lessons learned during multiple computer software validations
- Common roadblocks for complex system validations; higher compliance with limited system performance or lower compliance with maximum system performance?

10:45 *Mid-Morning Networking Break*

Data Integrity in cGMP and Supply—Case Studies

11:05 **Data Integrity in cGMP realized in Global Pharma Corporate Projects**

CASE STUDY

Laurence O'Leary, CEO/Founder, ValidEire Consulting IVS

Manufacturing sites with huge continuous improvement budgets are facilitating data integrity and turning to implementing data-integrity training on a global scale as not seen before. After seeing this on two global sites, I ventured out and requested more information from other reliable sources. I see how it has impacted documentation, mindset and forward thinking. Reflecting on my observations and talking to global quality operations teams I can conclude that the pharma industry does realize this data integrity "mindset investment" has a high ROI.

Points that will be presented:

- Why industry has the big spend on DI
- ALCOA+: The real meaning behind this
- Typical documents and training methods
- Importance of understanding GAMP and GMP work together
- Case study of implementation of data-integrity training

11:50 *Complimentary Lunch*

12:50 **Cleanroom Environmental Monitoring Systems, Regulatory Compliance, Risk Mitigation and Data Integrity**

Jason Kelly, Vice President of Services, Lighthouse Worldwide Solutions

With the never ending shift towards continuous quality improvements within the manufacturing of pharmaceutical products it is worth looking at the current requirement of GMP and also 21CFR11 in the context of GAMP 5 requirements.

How a Company creates, maintains, retrieves, corrects and controls data can affect product quality. How a company reacts to out of tolerance conditions via continuous Environmental Monitoring Systems (EMS) alarm notification is crucial to the process operation and the product quality. Therefore the EMS becomes a critical process tool to ensure product quality and the supporting data. As far as electronic records are controlled, the FDA's main concern has remained the same since the introduction of 21CFR11 and that is "to safeguard record integrity in order to ensure product quality".

Record integrity and data integrity" is now a focus by the FDA during regulatory audits. So it makes sense to have a robust EMS that can be validated confirming it meets the requirements of regulatory compliance. This means that pharmaceutical manufacturing companies should be looking closer at their vendors to support them in the drive for these continuous process quality improvements.

More and more pharmaceutical companies are using risk mitigation practices in the selection of the right monitoring system and provider. Emphasis is on strong validation support and ongoing technical support to reduce down time and potential loss of production time. Which may lead to product shortages and loss of revenue.

Therefore selection of the right systems and vendor is critical as it may impact on business continuity.

This Presentation will cover the following:

- Particle collection technology – how particle counters detect particles
- ISO 21501-4 Calibration and how it relates to ISO 14644-1
- Design and implementation of a real time Monitoring System
- Sample Monitoring System schematic design – how everything connects
- Current GMP and GAMP requirements
- Risk Mitigation and the right system design
- Setting Appropriate Alarm limits that work for you not against you
- Data Integrity – ALCOA principals, what is it all about?
- FDA warning letters – Overview (Data Integrity issues)
- New data integrity technology built into today's particle counters
- Business Continuity and following Annex 11 GMP requirements
- 21CFR11 Compliance and testing
- EMS Process flow from concept to delivery
- Monitoring System Validation requirements
- System handover, PQ and Change Control and vendor support (SLA's)

1:35 **Data Lifecycle Management**

Chris Wubbolt, Principal Consultant, QACV Consulting

This program will reviews typical data lifecycle processes and inherent risks to data integrity.

I. Data life cycle phases
   - Review of each stage of the data lifecycle.
   - Review risks associated with each phase.
   - Discuss appropriate risk mitigation measures.

Technology Transfer—Case Study

2:20 **Process Validation and Technology Transfer of Biologics and Vaccines**

Dushyant B. Varshney, PhD, Vice President, Technical Services, Operations at Jubilant Pharmaceuticals

In recent decades, there has been a rapid rise 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, typi-

cal 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.

3:05 *Afternoon Networking Break*

3:50 **Software Validation Case Study: Validation of MES System**

Raul Soto, Senior Principal Software Engineer, Johnson & Johnson

In 2015, Johnson & Johnson Vision Care's MES upgrade project was awarded the Siemens Manufacturing Star Award. Mr. Soto was the Quality & Validation Lead for this project.

1. A Systems Development Lifecycle Approach to MES validation
    1. What are the benefits of an MES?
    2. ANSI/ISA-95 Control Hierarchy Levels
    3. Medical Devices: how MES can help you maintain your Device History Record
    4. Defining your project scope: Hardware and Software components of an MES
    5. What is an SLDC? Phases
2. Validation and Project Deliverables
    1. Which assessments do you need before validation?
    2. Software Validation Deliverables
    3. Hardware & Infrastructure Validation Deliverables
    4. Interfaces
    5. Electronic Records & Signatures
    6. From Workflows to Use Cases, to Test Scripts
    7. Testing: a risk-based approach
3. Going Live
    1. System governance: procedures and processes
    2. Change control
    3. What is "Hypercare"?

4:35 *Close of Program*

Data Integrity & Pharmaceutical Quality Compliance Summit 2019 Sponsored By:

PharmaED RESOURCES, Inc.

PharmaEd Resources, Inc. • 2810 Robeson Park Drive • Champaign, IL 61822

About your conference destination:

The Sheraton La Jolla is located just minutes from spectacular beaches, tide pools, Torrey Pines Golf Course, romantic La Jolla Cove, and shopping in La Jolla's elegant boutiques. Relax in the peaceful surroundings of our spacious guest rooms featuring our signature Sheraton Sweet Sleeper™ bed. A refrigerator, microwave, flat screen TV and in-room Starbucks Coffee® will ensure your stay has all the comforts of home. Guests have access to our beautiful outdoor pool and hot tub.

Registration Information

Register for the conference using one of three options:
Online: www.pharmaedresources.com **Phone:** (217) 721-5774
Mail: 2810 Robeson Park Drive, Champaign, IL 61822

Please Complete the Following

FIRST NAME: _____

LAST NAME: _____

TITLE: _____

COMPANY: _____

ADDRESS: _____

ADDRESS: _____

CITY: _____ **STATE:** _____

ZIP: _____ **COUNTRY CODE:** _____

OFFICE PHONE: _____

MOBILE PHONE: _____

FAX: _____

E-MAIL: _____

VENUE INFORMATION:

Dates:	October 3–4, 2019
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

Please register me for:

2019 Data Integrity & Pharmaceutical Quality Compliance Summit

Standard Registration: $2295
Early Bird Special: Register by: July 1st and save $300 (off of standard pricing)
Call for government or academic pricing

PAYMENT METHOD

CREDIT CARD REGISTRATION:

☐ CREDIT CARD ☐ VISA ☐ MASTERCARD ☐ AMEX

NAME: _____

CARD #: _____

EXPIRATION: ____ / ____

SIGNATURE: _____

BILLING ADDRESS: _____

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.