PharmaED RESOURCES, Inc.

Data Integrity & Pharmaceutical Quality Compliance Summit

March 4–5, 2019, Metro Meeting Center, Boston, MA

Featured Speakers Include:

Ron Snee
Snee Associates

Dushyant Varshney
Pfizer

Barbara Unger
Unger Consulting

Raul Soto
Johnson & Johnson

Laurence O'Leary
ValidEire Consulting IVS

Kip Wolf
Tunnell Consulting

Gyorgy Vas
Intertek

Mike Fitch
Kelly@Takeda

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 Commerical 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 STRONGER PERFORMANCE AHEAD · QACV CONSULTING · Pfizer · Snee Associates LLC · Johnson & Johnson · VALIDAIRE

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Monday, March 4, 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

10:00 *Networking Break*

Examining FDS Warning Lettes

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 Azib, 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

This case study presents, from the point of view of CSV and CSV QA team members, how we got through the process of beginning remediation—site inspection including CSV that resulted in a site under consent decree, third party certification and finally FDA Inspection. Initially, there was some degree of recognition that we needed some level of remediation in the CSV space. A small team, consisting of a manager and three members, was put together to spearhead the efforts. We had templates for everything and procedures for nothing. We started with assessments and tried to get things moving with what we had. We established a high-level SOP. Then the FDA showed up at a site. CSV in the IT Space was not, in our opinion, a primary source of dissatisfaction, but it was yet another area where we failed under inspection. We quickly went from a mostly insignificant team to being very critical to the success of the entire organization—if we did not get the IT right, the division would never ship products. They also had the option to go back to paper, which they did in some cases. By the time the first third-party inspection hit us, we were feeling OK. We had all the basic elements of validation covered. At least we thought we did. We failed miserably. We licked our wounds and tried to figure out what went wrong.

The second inspection also failed, although not quite as miserably. Our third try started seeing some systems that

were considered validated! Facing the FDA was new for most of the IT folks, but we had the chance for a new experience. We learned a lot from the entire effort and, at the end, were confident that our systems were sufficiently validated to pass a rigorous inspection.

2:20 *Afternoon Networking Break*

Data Integrity Program & Culture

2:35 **Creating Data Integrity Programs**

Chris Wubbolt, Principal Consultant, QACV Consulting

ABSTRACT IN PROGRESS

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

Dushyant B. Varshney, PhD, Head of MSAT, Pfizer

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 **CMOs and Data Integrity**

Barbara Unger, President, Unger Consulting, Inc.

This presentation will address how sponsors can ensure confidence in data integrity at their contract development and manufacturing organizations (CDMOs), contract laboratories and suppliers of critical raw materials including excipients. This presentation will identify some of the actions that a sponsor can take to ensure they have confidence in the data provided by CDMOs and suppliers. Among the topics we'll address are:

- Unique challenges posed by CDMOs and suppliers
- Regulator's focus in this area
- How to address the due diligence selection process
- How to address routine GMP audits and oversight
- Considerations for addressing data integrity in Quality Agreements
- How to make the most effective use of limited time for on-site audits

4:50 *End of Day One*

Tuesday, March 5, 2019

7:30 *Complimentary Breakfast*

8:15 *Chairperson's Remarks*

In-Depth Coverage on Analyrical 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 **Performing a Risk Assessment for Data Deficiencies**

Barbara Unger, President, Unger Consulting, Inc.

Performing a gap assessment and identifying risk levels for data integrity/data governance within the GMP area often seems like a daunting undertaking. Where to begin? And what to do with the completed evaluation? This presentation will address key components of a gap assessment, how the risk posed by identified gaps should be evaluated, and initiation of corrective actions. The presentation will include:

- How to structure a gap assessment—what do we need to consider?
- The regulations and guidance to consider in gap assessments
- How to assign risk level to gaps
- How to identify, prioritize and track corrective actions
- Where does data governance fit in remediation efforts?

1:35 **Data Lifecycle Management**

Chris Wubbolt, Principal Consultant, QACV Consulting

ABSTRACT IN PROGRESS

Technology Transfer—Case Study

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

Dushyant B. Varshney, PhD, Head of MSAT, Pfizer

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, 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.

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*

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