Day 1

Tuesday, March 30, 2021

10:00 AM **Welcome, Verification of Attendee Workshop Tools, Session Overview**

10:00 AM – 10:30 AM EDT

- Review of connectivity and interactive tools
- Session agenda overview
- What to do in case of connectivity issues

10:30 AM **GMP and QSR Data Integrity – Requirements and Realities**

10:30 AM - 11:30 AM EDT

- Core regulatory requirements – regulatory health agencies
- Practical elements of data integrity characteristics (ALCOA+) – how this looks in the "real-world" of raw materials/component intake, manufacturing, quality control sampling, and finished product distribution
- Overlooked guidance documents that can help define expectations (including what FDA and EMA inspect for and why)
- *Interactive Q&A on this section* - Attendees have the chance to ask questions and have them answered by the instructor

11:30 AM **Morning Break** *(offline)*

11:30 AM - 12:00 PM EDT

12:00 PM **Post-Market and Complaint Handling Data Integrity Requirements**
12:00 PM - 12:30 PM EDT

- Core regulatory requirements – regulatory health agencies
- Practical elements of data integrity characteristics (ALCOA+) – how this looks in the "real-world" of complaint handling, post-market reporting, recall handling and reporting, and product complaint trending
- *Interactive Q&A on this section* - Attendees have the chance to ask questions and have them answered by the instructor

12:30 PM **Lunch** *(offline)*
12:30 PM - 1:30 PM EDT

1:30 PM **Suppliers and Data Integrity**
1:30 PM - 2:30 PM EDT

- Accountability v. responsibility (the legal view)
- Data integrity chain-of-custody from raw material/component suppliers through your finished product distribution chain
- Digital data record keeping challenges for manufacturing and post-market/complaint handling data
- Typical supply chain red flags for data integrity that FDA and other regulatory health agencies look for
- Dealing with critical suppliers who collect, handle and store manufacturing and post-market/complaint digital data who are NOT regulated themselves
- Qualifying record/archival storage vendors (e.g., Iron Mountain, et al)
- *Interactive Q&A on this section* - Attendees have the chance to ask questions and have them answered by the instructor

2:30 PM **Afternoon Break** *(offline)*
2:30 PM - 3:00 PM EDT

3:00 PM **Risk-Based Data Integrity Controls**

3:00 PM - 4:00 PM EDT

- Basics of computerized system assurance as a risk-based approach
- Eight practical elements of data integrity (ALCOA+ in practice)
- How to narrow the scope to avoid doing too much
- Policies and SOPs to consider
- Site data integrity master plan
- *Interactive Q&A on this section* - Attendees have the chance to ask questions and have them answered by the instructor

4:00 PM **Wrap Up and Review**

4:00 PM - 4:30 PM EDT

4:30 PM **Adjournment of Day One**

Day 2

Thursday, April 1, 2021

10:00 AM **Welcome, Verification of Attendee Workshop Tools. Session Overview**

10:00 AM – 10:30 AM EDT

- Review of connectivity and interactive tools
- Session agenda overview
- What to do in case of connectivity issues

10:30 AM **GMP and QSR Data Integrity Enforcement**

10:30 AM – 11:00 AM EDT

- Examples and statistics from regulatory agencies
- Recent, relevant enforcement examples
- *Interactive Q&A on this section* - Attendees have the chance to ask questions and have them answered by the instructor

11:00 AM **Morning Break** *(offline)*

11:00 AM – 11:30 AM EDT

11:30 AM **Digital Data Integrity Inspectional Tactics – Onsite v Remote**

11:30 AM – 12:30 PM EDT

- Differences and similarities between the NIPP and remote inspection methodologies
- Example regulatory agency inspection questions to prepare for
- Example regulatory agency tactics during manufacturing and post-market/complaint handling inspections
- *Interactive Q&A on this section* - Attendees have the chance to ask questions and have them answered by the instructor

12:30 PM **Lunch** *(offline)*

12:30 PM – 1:30 PM EDT

1:30 PM **Modern, Risk-Based Validation Techniques**
1:30 PM – 2:30 PM EDT

- Validation by risk level – it's all about the data
- Sampling and test cases – FDA's view
- FDA's view of supplier-provided validations
- Taking advantage of the traditional DQ\IQ\OQ\PQ format
- Example FDA-"approved" test cases for data integrity-based validation
- *Interactive Q&A on this section* - Attendees have the chance to ask questions and have them answered by the instructor

2:30 PM **Afternoon Break** *(offline)*
2:30 PM – 3:00 PM EDT

3:00 PM **Data Integrity, Recordkeeping and Long-Term Archival Controls**
3:00 PM – 3:30 PM EDT

- Records to retain to prove good data integrity controls
- Basics of bit rot and other risks to archived data
- Incorporating quality audits and sampling techniques
- Developing a media migration strategy
- Qualifying record/archival storage vendors
- *Interactive Q&A on this section* - Attendees have the chance to ask questions and have them answered by the instructor

3:30 PM **True and Certified Copies with Digital Records – Risks and Realities**
3:30 PM – 4:00 PM EDT

- Basics of the true/certified copy and legal admissibility
- True copy requirements from submission guidances
- Putting together a true-copy scanning process for manufacturing records
- *Interactive Q&A on this section* - Attendees have the chance to ask questions and have them answered by the instructor

4:00 PM **Wrap Up and Review**
4:00 PM – 4:30 PM EDT

Attendees have time to ask any final questions for the day

4:30 PM **Adjournment of Day Two**