AGENDA

Day 1

8:30 a.m. – 9:00 a.m. **Registration and Continental Breakfast**

9:00 a.m. – 9:15 a.m. **Introduction and Welcome**

9:15 a.m. – 10:45 a.m. **Data Integrity: What's Really Required?**

- Core regulatory requirements — FDA, EMA, Health Canada and more
- Overlooked guidances — what you don't know will hurt you
- How to quickly parse warning letters for data integrity expectations
- FDA investigator tactics and questions about your data integrity
- **Interactive Hands-On Exercise:** Attendees act as FDA investigators in different company types to find the data integrity controls FDA expects during an inspection

10:45 a.m. – 11:00 a.m. **Break**

11:00 a.m. – 12:00 p.m. **Suppliers and Data Integrity: Who's Actually Accountable?**

- FDA's view — accountability versus responsibility
- Dealing with your regulated data at critical suppliers
- Contractual components to address data integrity risks
- Handling SaaS providers, hosted IT systems and cloud computing
- Managing data integrity with CROs and outsourced clinical sites
- Overseeing data integrity at your CMO and contracted services
- Addressing data from suppliers of raw materials
- **Interactive Hands-On Exercise**: Attendees act as FDA investigators to review the data integrity controls from several case study companies have in place over their suppliers — should the sponsor/purchaser get a warning letter?

12:00 p.m. – 1:00 p.m. **Lunch**

1:00 p.m. – 2:15 p.m. **Practical Realities: The Business Costs of Poor Data Integrity**

- Real world business costs of poor data integrity
- Legal pitfalls for senior management from poor data integrity
- Practical quality costs of poor data integrity
- **Interactive Hands-On Exercise**: Attendees review several case studies to determine costs and dangers of poor data integrity

2:15 p.m. – 2:30 p.m. **Break**

2:30 p.m. – 4:30 p.m. **Critical Data Integrity Elements to Prove Compliance**

- Eight practical elements of data integrity (ALCOA+ in practice)
- Narrowing the scope
- Risk-based data integrity controls — a simplified approach
- Verifying data integrity controls at suppliers
- Qualifying personnel — from CV to training
- Defining roles and responsibilities
- Conducting quality audits of data integrity — what to look for and why
- Monitoring, metrics and communication
- Policies and SOPs to consider
- Scanning, true copies and source data
- **Interactive Hands-On Exercise**: Using case studies, attendees identify likely risks and select the most appropriate controls for each situation

4:30 p.m. – 5:00 p.m. **Day One Wrap Up and Review**

- **Interactive Hands-On Exercise**: Attendees identify 3 compelling reasons for their own company to adopt data integrity controls now

Day 2

8:30 a.m. – 9:00 a.m. **Continental Breakfast**

9:00 a.m. – 9:15 a.m. **Day Two Welcome and Quick Learning Recap**

9:15 a.m. – 10:30 a.m. **Modern Validation Protocol**

- 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 Hands-On Exercise**: Attendees review case study validation tests to see if data integrity is actually being verified

10:30 a.m. – 10:45 a.m. **Break**

10:45 a.m. – 12:00 p.m. **Mapping Your Data Chain-of-Custody**

- Data mapping defined
- Steps to map your data flow across the data lifecycle
- Benefits to mapping your chain-of-custody — business and the FDA
- **Interactive Hands-On Exercise**: Work in teams to data map a sample data flow from several case studies (one cGCP and one cGMP)

12:00 p.m. – 1:00 p.m. Lunch

1:00 p.m. – 2:15 p.m. **Advanced Tactics to Cut Costs and Reduce Your Workload**

- Change management — from preapproved to emergency
- Containing costs with cross-functionality
- Incorporating data integrity compliance into the day-to-day operations of departments and supervisors
- Creating a site master data integrity compliance plan
- Data integrity governance
- **Interactive Hands-On Exercise**: Draft a communication to be sent out by your senior team to all company employees about good data integrity that will actually lower your workload and encourage self-compliance

2:15 p.m. – 2:30 p.m. Break

2:30 p.m. – 3:30 p.m. **Data Integrity, Recordkeeping and Archival Controls**

- Records to retain to prove good data integrity controls
- Basics of bit rot and other risks to archived data
- Developing a media migration strategy
- Qualifying record/archival storage vendors
- **Interactive Hands-On Exercise**: Attendees work in teams to outline a sample set of data integrity controls and auditing plans for several case study companies

3:30 p.m. – 4:00 p.m. **Building Your Business Case for Defensible Data Integrity**

- Quick tips for talking to senior management about data integrity
- A sample data integrity action plan — nine brainstorming questions
- **Interactive Hands-On Exercise**: Attendees work with the expert instructor to draft their own personal, business case and prioritized plan for implementing a data integrity control framework at their company

4:00 p.m. – 4:30 p.m. **Wrap Up and Final Questions**

4:30 p.m. **Adjournment**