Considerations for a Corporate
Data Integrity Program
(What's So Funny 'Bout) Part 11 and Data Integrity

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Helpful Reference Materials

available for download (until June 20th) at www.ceruleanllc.com/ISPE
Postmarket Adverse Event Data

From § 314.80(i) Recordkeeping

“The applicant shall maintain for a period of 10 years records of all adverse drug experiences known to the applicant, including raw data and any correspondence relating to adverse drug experiences.”
**ALCOA+** controls across data lifespan

- **EMA**: 29+ years (active market authorization + 10yrs)
- **Health Canada**: 25 years (AE+25yrs)
- **FDA**: 10 years (AE+10yrs)

Translation:

Data integrity controls cover the **life of the data** not the **life of any one system**
Data Integrity Lifecycle

What are your ALCOA+ controls for 10, 25, 29+ Years?

Ex: what are your data chain-of-custody controls across vendors, sites, etc. for 10, 25, 29+ years?
Eight Step Process

1. assemble a core team
2. educate the team
3. develop overall strategy
4. data map to define controls
5. verify vendor compliance
6. prioritize and implement
7. monitor, measure and audit
8. re-evaluate and revise

Assemble a Core Team

- quality
- IT
- records management
- legal (or corporate compliance)
- functional representatives (mfg., clinical, etc.)

and maybe...
- regulatory affairs
- validation
- vendor management
- audit
Example: Senior Management

- Show them recent, sample enforcement actions that have humiliated other firms
- Explain how data integrity simply asks “Can the agency trust our data?”
- Discuss how a data lifecycle-focus can help limit the scope and cost (and avoid Part 11 mistakes of the past)
- Review the costs of poor data integrity
  - 3rd most common reason for a delayed or rejected submission
  - untrustworthy product release records lead to public recall
  - 5th most common warning letter – and attendant loss of revenue

Educate the Team

- In-person workshops
- Webinars
- Consider combining with a data integrity gap analysis
  - discuss results in workshop (or use workshop to lay the groundwork for expected audit results)
  - make sure gap analysis covers all four data lifecycle stages!
Develop Overall Strategy

- Overall principles
- Roadmap
- Roadmap deliverables
- Progress to date
- Leveraged resources
- Team roles
- Financials
- Metrics for success

Example: Leverage Your RRS

<table>
<thead>
<tr>
<th>Record Category</th>
<th>Record Type / Description (Examples)</th>
<th>Minimum Retention Period</th>
<th>Retention Review Date</th>
<th>Regulatory Reference</th>
</tr>
</thead>
<tbody>
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Other considerations:
- data “owner” or steward
- process or equipment that produces the data
- if data is created/held on your behalf by a vendor
Data Map to Define Controls

Example: Data Archival

**sticky-shed syndrome**
(moisture or oxide shedding)

**rodents**
(physical damage)

**software-rot**
(dormant v. active)

**bit-rot**
(data degradation)

**disc-rot**
(chemical degradation)
Verify Vendor Compliance

- conduct audits
- look for undocumented data “review” points, etc.
- incorporate controls into contracts and quality/technical agreements
- ALWAYS verify what will happen to your data at vendor after transfer to your possession

Prioritize and Implement

- Use risk assessment techniques to prioritize
- Consider using risk to define control depths
- Track progress on a site-by-site basis
Monitor, Measure & Audit

- verify departmental compliance with policies (annually)
- verify vendor compliance rates
- conduct periodic fire drills of DR backups and long-term archives
- combine with internal quality audits
- rigorous sampling ($c=0$)
- review NARA sampling standard (36 CFR § 1234.30) for e-media

Example: Calibrate Benefits

32\% reduction in product liability litigation costs

save up to $438,000 per year

lower validation costs by 30\%

Sources:
The Information Management Journal, March/April 2013
Norton Rose Fulbright LLP's Litigation Trends Survey, October 2011
Biopharmaceuticals: Biochemistry and Biotechnology, Gary Walsh, 2003
Re-Evaluate and Revise

- Quality Systems Management Review (QSMR)
- Annual Product Review (APR)
- End of a clinical trial (or end of each phase)
- After an independent data integrity audit

Key Point Review

- Integrity risks are persistent thru data lifecycle
- ALCOA+ runs from data creation to disposition
- Core team must be cross-functional
- Educate the team – do not assume knowledge
- Use the simplified 8-step process to start
- Mix automated, procedural, vendor controls
- Leverage your corporate RRS to narrow scope
- Continuously audit and revise to improve
Kick-Start Your Data Integrity

1. Download the helpful reference material at www.ceruleanllc.com/ISPE (until June 20th)
   • Checklist: Departmental Steps Taken to Maintain Data Integrity
   • Article: 21 CFR 11 Enforcement – Where is the FDA Headed?
   • Article: Electronic Archiving – a 100 Year Experiment

2. Identify four functional leaders in your organization who work in the data lifespan and invite them to your core team

3. Review the key points covered in this presentation with your core team

4. Talk through the helpful reference material with your team

5. Verify your organization has a (relatively) recent RRS

About Your Presenter

John Avellanet gives practical, compliance solutions to simplify and streamline compliance for clients around the world. Winner of the 2009 & 2011 Best of Business Services award by the Small Business Commerce Association, Mr. Avellanet has earned international acclaim for his business-savvy, pragmatic FDA compliance and data integrity advice.

His latest book, Get to Market Now! Turn FDA Compliance into a Competitive Edge, was featured at BIO 2011 and has garnered multiple five-star reviews from industry publications, blogs, Amazon.com readers, and former FDA officials.

He has a breadth of experience designing, implementing, and being accountable for quality systems and compliance programs for FDA, DEA, ICH, BIS, GHTF, and ISO. For more than 15 years, John was directly accountable for regulatory compliance, records management, and information technology, most recently as a C-level executive for a Fortune 50 combination device subsidiary.

In 2006, Mr. Avellanet founded his independent lean compliance consulting and training firm, Cerulean Associates LLC.
About Your Presenter

Recent Resume Highlights
- Lead author of 2 certification courses for US RAPS
- IRO for Dr. Comfort Corporate Integrity Agreement
- Member, ISPE GAMP Data Integrity Working Group
- 2010 and 2011 Top 10 FDA Compliance Blog
- 2010 Top 50 Pharma/Biotech Blog
- 2009 and 2011 US Best of Business Services Award
- 2008-2012 Guest Lecturer at NIH
- 2006 Lifetime Achievement Award – Who’s Who of Biopharma & Device Executives

FDA Lean Compliance Services
- Streamline SOPs and policies
- Simplify Part 11 and data integrity compliance
- Perform audits for compliance and cost-effectiveness
- Develop FDA recordkeeping policies
- Conduct private training and corporate workshops
- Serve as consent decree IRO and litigation support

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