Device Supplier Controls
Does the FDA's Next 483 Have Your Name on It?

Your office, Feb. 26, 2014

Agenda

10:00 a.m. – 10:15 a.m. **Introduction to the Virtual Conference**
John Avellanet, Managing Director, Principal Consultant, Cerulean Associates

10:15 a.m. – 11:05 a.m. **Opening Keynote: Supplier Controls — FDA Medical Device Requirements**
The FDA has been actively focusing on the protection and integrity of contract manufacturers and suppliers for medical devices. Understanding the FDA's approach is essential to ensuring compliance and avoiding compliance problems. In this session William MacFarland will take you through the latest FDA policies and processes.

Attendees will learn:

- Common contract manufacturer and supplier issues the FDA uncovers in medical device inspections and how can firms avoid them
- How suppliers, contractors and consultants should meet the requirements established by the finished device manufacturer
- After the initial assessment or evaluation, tips for determining the combination of assessment methods, and how to include third-party or product certification

William MacFarland, Director, Division of Enforcement, Office of Compliance, CDRH, FDA *(invited)*

11:05 a.m. – 11:55 a.m. **Regulatory Requirements Affecting Supplier Quality Management**
Recent changes in the regulatory landscape of medical device supplier quality management have medical device manufacturers actively looking for additional information on how to best align suppliers with enhanced regulatory guidelines. Increased supplier monitoring standards, additional registration requirements, and quality systems alignment are all capacities in which the FDA has increased regulatory attention. Defining the evolution in the

expectations of manufacturers as well as the FDA's enforcement policies on such have manifested a concern in the medical device industry.

Attendees will learn:

- Expectations in supplier and sub-tier supplier monitoring
- Outlook on global supplier monitoring requirements
- Noncompliance issues triggering an audit
- Registration and reporting requirements
- The future of FDA regulatory requirements

Mike Heyl, Partner, Hogan Lovell *(invited)*

11:55 a.m. – 12:10 p.m. Break

12:10 p.m. – 1:00 p.m. **Recent FDA Supplier Control Inspection and Enforcement Trends**

Review FDA 483s and warning letters over the past 16 months citing poor supplier management and noncompliance with 21 CFR 820.50 Purchasing Controls to determine lessons learned before the FDA investigator arrives. Examine typical questions that FDA investigators ask about supplier qualification and supplier management. Identify the inspection pathways that FDA investigators take to subtly judge just how well you are managing your suppliers against how well you think you're controlling your suppliers.

Attendees will learn how to:

- Test your SOPs against the most commonly cited sections of 21 CFR 820.50
- Verify your supplier dossiers contain the records that FDA investigators will ask to see
- Review key warning letters to find the hidden problems that tripped others up
- Identify several key documents to have ready to print out and produce at a moment's notice

John Avellanet, Principal Consultant, Cerulean Associates

1:00 p.m. – 2:00 p.m. Lunch

2:00 p.m. – 2:50 p.m. **Assessment Tool for Choosing the Right Subcontractor or Supplier**

Choosing the right CMO or subcontractor to partner with will set the

stage for your compliance and business relationship. Many partners are chosen based on filling out a questionnaire and a quote. Learn a new strategy using a quantitative risk assessment tool to help you make the right choice for your company's business and compliance needs.

Attendees will:

- Learn the areas of competency you should be assessing your suppliers on
- Determine how to implement the assessment tool in more than one way in your organization
- See the tool in action through an actual case study

Jackie Torfin, Vice President of Quality, Heraeus Medical Components

2:50 p.m. – 3:40 p.m. **Lessons from Veteran Supplier Manager: Understanding How to Manage Suppliers Whether You're a Big or Small Company**
Supplier controls are critical to reliability, compliance, and production continuity. Whether you are a Fortune 500 device manufacturer or a 50 headcount start-up, understanding how to manage your suppliers is crucial. Both the large and small companies need to play by the same rules (sec. 820.50) but the approach they take may differ significantly. Understanding how to manage suppliers if you're a big or small company can make or break your operation.

Attendees will learn:

- Best practices for prioritizing your supplier control approach that will work if your company is large or small
- Managing your supplier controls over the long haul to create good business relationships and assure FDA compliance
- What motivates a supplier to do business with you

David Parkin, Supplier Development Manager, Boston Scientific

3:40 p.m. – 4:00 p.m. **Closing Comments and Adjournment**