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

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 problems. This session 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 firms can 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

Maria Isabel Tejero del Rio, MD, PhD, Lead Consumer Safety Officer, Division of Manufacturing and Quality, Office of Compliance, CDRH, FDA

11:05 a.m. – 11:55 a.m. **Legal and Regulatory Issues to Consider Relating to Quality Agreements: Why it is Important to Have a Strong Quality Agreement**
A quality agreement is a written contract that helps to delegate the responsibilities for compliance with current cGMP requirements or QSRs, describe any particular requirements regarding the product or service provided through specifications, and establish the responsibilities and procedures applicable to the parties' respective RA/QA groups Call them a safeguard, call them CYA, call them a

smart business practice, but don't make the mistake of not having a quality agreement in place or ignoring one. And don't bother looking for the definition of a quality agreement in FDA's implementing regulations. You won't find one. That puts all the more pressure on you to develop a defensible program. In this session, you'll learn the value and necessity of a quality agreement, and understand why more and more of your colleagues and competitors are benefitting from doing them right the first time.

Attendees will learn:

- Why quality agreements are important
- FDA enforcement action trends
- Who is ultimately responsible for maintaining compliance
- Tips and tools to develop quality agreements
- How to determine a clear delineation of roles and responsibilities

Alan Minsk, Partner and Leader, Food and Drug Practice Team, Arnall Golden Gregory LLP

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**