Live webinar Tougher Supplier Controls â€“ Avoid Unwanted Changes

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Event URL : http://www.BostonEventsList.com/events/live-webinar-tougher-supplier-controls-â€“-avoid-unwanted-changes-apr-2018

Organizer : conference Manager

Venue : online

Location : WCS Consulting Inc.3190 Stirling Rd, Unit K4 ,Hollywood, FL 33021,
Hollywood, FL, US, ZIP: 33021
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Ticket Price: $179 One Dial-in One Attendee | Corporate Live Recorded $279 One Dial In - Max 10 attendees |Group $399 Multiple locations upto 5 dial in | Recorded $249

There has been a major shift in the emphasis of U.S. FDA requirements for supplier CGMP compliance. The FDA has implemented major global initiatives. Companies are required to tightly manage their entire supply chain. The infrastructure behind the COA / COC is being challenged. Such changes in focus have a major impact on individual compliance objectives, efforts and measurements of success. The Agency has come under increasing negative publicity due to major publicized product failures / recalls, leading to public concern over insufficient oversight of the entire medical product supply chain, including global outsourcing. Of both raw materials, components, as well as services. "Better science" requirement impacts suppliers as well. All this is affecting the Agency's approach to audits and their expectations for companies. These areas of change will be evaluated to see how to better prepare address supplier chain management and vendor audits. And the company on the label is responsible for compliance.

Why should you attend

This webinar will provide valuable assistance to all regulated companies in evaluating their existing supply chain control / ccompliance and vendor audits in light of changing FDA's CGMP supplier management requirements and enforcement. Once recognizing the danger and likely locations of potential problem areas, a company can evaluate / perform a gap analysis, and then

put in place the necessary fixes to ensure continuing compliance. This information applies to personnel / companies in the Pharmaceutical, Medical Device, Diagnostic, Neutraceutical and Biologics fields.

Areas Covered

- The Globalization of the Supply Chain and What That Means
- Avoid complacency from past "good" FDA / ISO audits
- Supplier Ranking Models
- Mandated Supplier Controls; Change Controls
- COAs / COCs
- The Tiered Risk-Based Audit Approach
- "Entropy"; Maintain "the Edge" / "State of Control"

Who will Benefit

- Senior management
- R&D
- Engineering
- Software engineers
- Marketing
- Purchasing
- Consultants
- All others tasked with product development, acquisition and production

Speaker Profile

John E. Lincoln is Principal of J. E. Lincoln and Associates LLC, a consulting company, with over 32 years experience in U.S. FDA-regulated industries, 18 of which as a full time independent FDA-regulated industry consultant. Mr. Lincoln has worked with companies from start-up to Fortune 100, in the U.S., Mexico, Canada, France, Germany, Sweden, China and Taiwan. He specializes in quality assurance, regulatory affairs, QMS / CGMP audits and problem remediation and FDA responses, new / changed product 510(k)s, process / product / equipment including QMS and software validations, ISO 14971 product risk management files / reports, Design Control / Design History Files, Technical Files. He’s held positions in Manufacturing Engineering, QA, QAE, Regulatory Affairs, to the level of Director and VP (R&D).

Event Categories :