Quality Metrics and Risk Based Inspections; FDA's New July 2015 "Request for Quality Metrics Guidance for Industry" & Safety and Innovation Act (FDASIA) - Recorded Webinar

Description: The FDA Safety and Innovation Act (FDASIA) of 2012 provides a firm legal basis for setting clearer standards for collecting data to assess manufacturing operations. Section 705 of FDASIA requires FDA to establish a risk based schedule for inspecting drug manufacturing sites, and requires access to more detailed information on facilities and quality controls. Section 706 authorizes the Agency to obtain information on drug production sites and operations in advance of an inspection. Together, these two Sections support FDA's strategy for improving how it assesses the ability of a manufacturing site to consistently produce medicines fit for intended use.

FDA understands that establishments involved in the manufacture, preparation, propagation, or processing of human drugs, including oversight to ensure quality, currently use quality metrics as part of the process validation lifecycle and pharmaceutical quality system (PQS) assessment. This new, proposed guidance outlines FDA's authority to require owners and operators of such establishments to provide upon request records and information that FDA may inspect under section 704 of the Federal Food, Drug, and Cosmetic Act (FD&C Act, or the Act), and describes an initial set of requests the Agency intends to make to certain owners and operators. FDA intends to make its requests at the time this guidance is finalized, and to provide notice in the Federal Register.

Why Should you Attend:

Quality Metrics and Risk Based Inspections is a topic often "tossed around". But what does it mean to the manufacturer within the pharmaceutical/biotechnology arena? Each year the FDA and CDER, in particular, issue a variety of the most frequent Observations that they encounter and summarize them according to their frequency. Interestingly, even though Industry can readily view this list and various members of the CDER organization speak about them at numerous conferences, seminars and on-line, the list continues to exist, and the numbers of Observation occurrences is not diminished. When asked why the list does not "go away", comments such as 'the list does not apply to our Company" to "we don't understand the Observations" are often heard. These flippant comments from various Companies only perpetuate additional Observations.

This webinar will discuss the just issued (July 2015) DRAFT Guidance for Industry on "Request for Quality Metrics" along with how FDASIA is pushing it forward, review the most common Citations issued during the past several years, dissect each resultant Observation, explain the rationale behind them and present actual examples of Form FDA 483s and Warning Letters that include that particular Observation. A total of approximately 15 sections within CDER's CFRs from each year will be examined in detail and their frequency compared against previous years.

This webinar is valuable to not only those within the Quality area of your Company, but also within other Departments to include Incoming Raw Materials, Manufacturing and Facilities. Because of the sensitivity and importance of understanding Quality Metrics, this training is a MUST for anyone in your organization that is involved in the management or recipients of Regulatory actions.

Who can Benefit:

- Quality Assurance Personnel
- Quality Control Personnel
- Research & Development
- Manufacturing
- Regulatory Affairs Professionals
- Facilities (Those that use contract manufacturing and contract testing facilities)

Objectives of the Presentation:
-Learn about the new proposed "Request for Quality Metrics" and its Relationship to FDASIA
-Understand the Requirements of the FDA's Request to Industry
-Determine how the Draft Relates to Most Frequent Citations from 21 CFR 210/211
-Learn of the Most Frequent Citations from within the 21 CFR 210/211 (Code of Federal Regulations (CFR))
-Review of the Past Several Years' Overall Major Citations and how They may Impact your Organization
-Hear the Rationale Behind an Observation and why the Underlying "Citation" was cited
-Comparison of Citations against Observations within Warning Letters
-Interpretation of the Results
-Review of Pertinent Form FDA 483s and Warning Letters

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