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### Current FDA audit trends and most common cited drug GMP deficiencies

The audit approaches of the FDA have changed over the years based on the findings within industry during inspections. These changes have also been the result of attempts to streamline the audit procedure and to help achieve efficiencies in trying to audit the ever increasing number of new companies on top of those existing. Preparation is still the main factor to help assure a successful audit result, and by knowing what the most common deficiencies have been, companies have an opportunity to compare their own practices and correct them where applicable. This presentation will review current and past audit approaches by the FDA, the four types of inspections performed, the regulatory forms associated with all FDA audits, what data sources are used by the FDA in preparing for their audits, common areas of focus, issues associated with data integrity, five proposed categories of "operator error" that are looked at when reviewing investigations that cite operator error as the probable cause and the top 10 most common cited drug GMP deficiencies for the last three years (2012-2014). Attendees will have the opportunity to ask questions and actual case studies will be used to highlight various points discussed.

### Biography

Kenneth Christie has over 30 years of sterile manufacturing and regulatory GMP consulting experience in the areas of Quality Assurance and Validation Management in the pharmaceutical and biotechnology industries. Specifically, his responsibilities include quality system auditing, GMP training, and serving as a subject matter expert for aseptic manufacturing processes, equipment and utilities, medical devices, and solid dosage processes on a global basis. He also performs vendor audits, site pre-approval inspections and assists clients with addressing and correcting regulatory observations. He was the Validation Manager at Parke-Davis' Sterile Products Facility where he was involved in the review and approval of all facilities, equipment, and system commissioning/qualification activities. He had routine interaction with the FDA and European inspectors (EMA), corporate management and third party contract-manufacturing representatives.

He is a speaker and trainer for several professional organizations in the US, Canada, Europe, and Asia and is a published author of several articles dealing with the challenges of aseptic processing. Additionally, he has served as a member of the ISPE's Professional Certification (PCC) Commission as an Examination Development Committee (EDC) member.

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