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Compounding. Compliance. COVID. The impact of temporary FDA guidance now, and in the future.

By **Eric Kastango**

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On this episode of Voices in Validation we welcome Eric Kastango to the show.

Eric has dedicated his life's work to patient safety through better sterile compounding, aseptic manufacturing, lean production, and robust quality management practices. has practiced pharmacy in hospital, community, and homecare settings in a variety of roles. He was previously Corporate Vice President of Pharmacy Services for Coram Healthcare and also managed a cGMP outsource manufacturing operation for Baxter Healthcare. In addition to his consulting role, Eric continues to serve as a sterile compounding, 503B outsourcing, and patient safety subject matter expert for his clients, the American Society of Health-System Pharmacists, State Boards of Pharmacy, and was one of the key US Department of Justice expert witnesses during the New England Compounding Center trials from 2017-2019.

Stacey and Eric discuss the FDA's implementation of temporary guidainces and how compounders can mitigate their risks to consumers and clinical sites. Included in the discussion are thoughts on pre and post-COVID guidances, the unique abilities of both 503A and 503B compounding facilities, the drug shortages during the pandemic and the specific requirements during these uncertain times, as well as, navigating the PPE shortage and what impact the proposed MOU may have on the compounding industry. This and much more...