

Addressing the Root Cause, Not the Symptoms: Root Cause Investigations for CAPA.



James Vesper

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This Week on VIV

In this episode, Jim and Stacey speak about the reasoning for such an emphasis on investigations and corrective actions, highlight the current guidance on CAPA investigations, cover the best tools for investigations beyond the “5 Whys” and Fishbone diagram, dispelling the “rule of three” that many companies count on, while defining what constitutes an acceptable root cause, “human error,” “training” and “revise the procedure” over used in corrective actions, and much more.

For step by step investigation advise, and tips on drilling down into the root cause for CAPA planning and analysis our listeners can review Jim’s latest book: [Root Cause Investigations for CAPA: Clear and Simple](#) by visiting the PDA Bookstore.

About Our Guest

James Vesper has worked in the pharmaceutical industry for more than 35 years, starting out at Eli Lilly and Company where his last position was leading the GMP training initiative. For 24 years, he was President of Learning Plus, a training consultancy and, in 2017, he joined ValSource as Director of Learning Services. Dr. Vesper has authored numerous books, book chapters, articles, and also speaks and teaches at international conferences and workshops, as well as consults for the World Health Organization (WHO). He received his PH.D. in education from Murdoch University, Perth, Australia.

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