Reader Q&A: Questions 21-24

May 26, 2013 1:47 pm EDT

Several respondents have recommended current expectations for validated processes as a topic for further discussion. Some of the discussion points suggested by respondents have included: What is really meant by validation? What is really needed to demonstrate a reliable and consistent process? Why isn't the usual "three lot" approach to validation sufficient? What does FDA mean when they say that "three lots" doesn't tell the whole story on validation? Why is the validation group always asking for more—supporting documents, reports, rationales, justifications, plans, and so on? These points...