IVT NETWORK
INSTITUTE OF VALIDATION TECHNOLOGY | an informa business
Unlimited Validation Knowledge Awaits...
Published on *IVT Network* (http://www.ivtnetwork.com)

GXP Talk: Questions 73 & 74

Jerry Lanese

Timothy J. Fields

By ,

Mar 23, 2016 7:00 am EDT

Getty Images

Question 73 In the US Food and Drug Administration 2011 Guidance on Process Validation and during discussions at meetings on the topic of process validation, we are told that that we can no longer assume that three batches constitutes process validation. How many batches will be required for process validation? Answer This is an excellent question, and one that many validation professionals are asking. Unfortunately, there is no good answer at this time. The regulation; specifically, Code of Federal Regulations Title 21 Part 211.100(a) (1), which is the FDA's justification for requiring...