

Workshop Announcement

Strategies for Setting Defensible Significant Loss Thresholds (SLTs)

Presented by
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Title 21 CFR Part 203 requires pharmaceutical companies to have policies and procedures in place to identify “significant loss” of drug products, yet the Food and Drug Administration (FDA) does not specify what amount of loss should be considered “significant.”

Instead, the FDA has indicated that the threshold level of what constitutes a significant loss will necessarily vary depending on such factors as the size of a company and the value of its total inventory, the accuracy of a manufacturer’s or distributor’s system for tracking sample distribution, and the circumstances surrounding the loss.

Mark Faloon and Paul Hamby are two excellent presenters, well-experienced in the pharmaceutical industry, and knowledgeable on what you need to know in setting SLTs. This workshop has been designed to examine the various factors that should be considered when setting SLTs for a pharmaceutical company’s various drug products. Statistical techniques, risk-based approaches, analysis of past sampling behavior, corporate thresholds vs. SLTs, recommendations on frequency of reviewing and “resetting” SLTs, and other factors will all be discussed and examined in this interactive workshop.

Audience participation will be encouraged to facilitate dialogue of “best practices” and “lessons learned” by attendees.

Already registered?

Pass this email along to a colleague or friend. And don't forget when three people from the same pharmaceutical, medical device or biotech company attend, one more may attend for **FREE**.

Email: mail@sharingalliance.org for details.

Meet Paul and other members of the IQVIA Team (Booth #5/6) during the “Meet and Greet” in the Exhibit Hall on Monday (Oct. 15) immediately following the OIG Keynote Address at 5:15pm.

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