

Significant Loss Threshold Assurance

The Porzio Confidence Level

Under the Prescription Drug Marketing Act, life sciences companies are required to report a “significant loss” of prescription drug samples to the U.S. Food and Drug Administration.

While the PDMA sets timelines for the reporting and investigation of losses, it neither defines what is “significant,” nor provides specific factors for consideration in creating significant loss thresholds. Life sciences manufacturers and distributors are tasked with delineating consequential losses of their products based on their unique business models.

Without governmental specifications as to what constitutes a significant loss, many organizations have assigned arbitrary percentages or dollar amounts as loss thresholds. For example, some companies have set loss thresholds of 10% of the quantity distributed, or 5% of the cost of the product. Unfortunately, quantitative calculations do not account for the nature of products in determining appropriate significant loss thresholds. To avoid improper over or under reporting of sample losses, life sciences companies must consider qualitative factors, such as the potential for product abuse or diversion in their threshold calculation.

Porzio Life Sciences has created **Significant Loss Threshold Assurance**, a customized, formula-based approach to sample accountability. After years of working

alongside industry leaders to create compliance programs and manage sample distribution, we have identified 16 key variables for successful significant loss threshold determination. Using **Significant Loss Threshold Assurance**, we can provide your company with tailored thresholds for each product you distribute. Our proprietary formula determines significant thresholds that account for your organization’s individual distribution model, historical sample loss records, and full product portfolio.

Significant Loss Threshold Assurance incorporates critical sample distribution factors, including:

- Product safety information
- Loss history
- Shipment and distribution volume
- Risk of diversion

Significant Loss Threshold Assurance is a thorough and efficient approach to establishing appropriate sample loss thresholds for your organization. As your company’s distribution model or product portfolio evolves, we can promptly reassess your sample data to ensure continued compliance.

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