

CASE STUDY: Strategic Compliance Enhancement: Tailoring Sample Loss Thresholds in Pharmaceutical Marketing

Background:

The Client, a mid-size pharmaceutical manufacturer actively promoting and sampling multiple products, engaged QPharma to ensure compliance with the Prescription Drug Marketing Act (PDMA). This included mandatory reporting of significant losses of drug samples to the FDA, a requirement under 21 CFR §203.34(c). The initiative was driven by increased regulatory scrutiny under §6004 of the Affordable Care Act and the company's transition to QPharma's services, recognizing the need for a well-documented rationale and robust compliance procedures.

Challenge:

- The Client had a numerical value assigned for reporting a significant loss and it was applied to all products
- Products being sampled have varying degrees of associated risk such as black market and recreational value, thus increasing the likelihood of diversion
- Neither the Client nor the former vendor partner could produce documented rationale regarding how the numerical threshold was determined

The client required a tailored, risk-based framework to establish compliant and justified drug sample loss thresholds for various products.

QPharma's Solution:

- **Risk Assessment Framework:** QPharma implemented a proprietary matrix to create a risk profile for each sampled product, setting lower loss tolerances for higher-risk products.
- **Factors Considered for Loss Tolerance:** Key factors influencing the Significant Loss Threshold (SLT) included market status, public health impact, distribution packaging, sampling volumes, black market potential, and production costs.
- **Flexible Loss Metrics:** The methodology allowed the client to adopt specific loss metrics – either as a percentage, a numerical quantity, or a combination of both – tailored to each product's risk profile.

Titanium® Results:

The Client was able to provide appropriate SLT rationale documentation for each product sampled with its higher risk products having a lower loss tolerance. The adjusted loss thresholds not only satisfied the Client's compliance concerns, but also allowed the business to more closely monitor its higher cost samples and adjust its marketing strategies accordingly.