

**“Counterfeit Drug Prevention and Serialization System for
Glitz Pharma”**



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ABSTRACT

The project presents a working solution to ensure that Glitz Pharma has a low-risk method of implementing a serialization and track-and-trace system, which can help to prevent potential diversion of prescription medications and counterfeits from manufacturing through to storage in warehouses, to pharmacies. The project identifies the specific areas of the pharmaceutical supply chain where unit-level identification, event tracking and authentication may have been compromised. The project will employ a mixed-methodology strategy utilizing a qualitative case study to describe the current operating processes at Glitz Pharma; identify areas of risk; reach a consensus among key stakeholders as to how they verify their products; and develop the measurement criteria for determining if the proposed new process is successful. The qualitative methodology will use operational and quality data collected over a two-to-three year timeframe to measure the success of the proposed new process by assessing the effectiveness of the new process in identifying counterfeit products, verifying the legitimacy of returned products, expediting the recall of potentially tainted products, increasing the frequency of distributor and pharmacy inspections and improving customer service levels. The recommended plan will incorporate accepted standards for product identification, product aggregation, product event messaging and integrating the proposed plan with existing systems. In addition to the previously described items, the plan will include a detailed step-by-step pilot program allowing Glitz Pharma to demonstrate the feasibility of the proposed plan; to facilitate the transition and implementation of the proposed plan into its operational environment; and to gain the support of its partners. The ultimate objective of the project is to develop a roadmap to implement a track- and-trace system for Glitz Pharma that targets high-risk products and channels of delivery, identifies the parameters for managing data, and establishes measurable criteria to determine the success of the proposed system upon implementation.

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