

PDMA Audit and Inventory Management Services



A mid-size pharmaceutical company partners with Knipper to remain FDA and PDMA compliant through a hostile termination situation.

BACKGROUND

A mid-size pharmaceutical company was struggling with a terminated Sales Representative who was unresponsive. The samples managed by the Sales Representative were unaccounted for, and as a result, the company was at risk of a potential FDA reportable situation and PDMA violation. A timely reconciliation was critical.

CHALLENGE

Client wanted to remain FDA and PDMA compliant through a hostile termination situation. In addition, the Sales Representative was completely unreachable with a large amount of samples in a storage unit. Company needed to gain access to the storage unit to collect company assets, including the samples within the required reporting timelines.



SOLUTION

Within the required compliance timeline, a team of Knipper Security and Audit experts were able to design a solution which permitted the company to account for the samples as quickly as possible without the Sales Representative present. Knipper was able to document all the communication attempts to the terminated representative for the Pharmaceutical Company's Human Resources Department. By leveraging Knipper's existing partnership with WarehouseAnywhere*, the UB Account Manager provided Knipper Inventory Specialists limited access to the storage unit electronically. To increase security and compliance, Knipper Security and Audits department coordinated with two Inventory Specialists to ensure double count verification at the time of the closeout at the storage location. Access was granted for the day of the closeout and then the Inventory Specialist names were removed immediately following the closeout.



RESULTS

Within a short timeframe, the pharmaceutical company was able to account for all samples in the terminated Sales Representatives storage unit. Utilizing Knipper's Field Audit and Inventory Services the company was able to avoid any FDA reportable situations and remain PDMA compliant.



**Through its partnership with WarehouseAnywhere, Knipper now provides integrated field storage solutions for its pharmaceutical, biotech, and medical device customers nation-wide.*



Contact Center & Direct Marketing

Experienced, integrated, healthcare focused solutions to engage physicians, pharmacists and patients and to increase market share through education, awareness and world class customer service.

- Understanding how best to reach your audience (when, where, and how) and **get them engaged**.
- Ensuring engagement is in lock-step with all of your sales and marketing initiatives both **personal and non-personal**.
- **Eliminating gaps** in communications which result in fewer scripts, pharmacy switching, and reduced market share.
- **Unparalleled experience** providing all of these essential and highly dependent services under one roof.



Sample Fulfillment & Distribution

State of the art FDA and DEA licensed distribution centers with rigorous security protocols, impeccable regulatory records, and a "Quality First" philosophy driving excellence throughout every phase of operations.

- A **highly controlled environment** providing full audit capability from dock to stock through packaging and delivery.
- Fast, efficient, provider with the maturity and technology to **meet customer's most challenging SLAs**.
- **Unparalleled reliability** with federal, state, and local regulatory requirements.
- All activities executed with the highest degree of quality for the end-user, **quality is paramount**.



Sample Management Services

Highly experienced integrated service partner providing a single source for comprehensive data management, sample reconciliation, field inventory, and reporting services.

- A **proactive** team of **experienced SA experts** dedicated to increasing efficiency and eliminating reportable incidents.
- **Integrated HCP Validation**, SDF Management, HCP Signature Audits as well as Random and For-Cause Audits.
- Nationwide Field Audit and Inventory Services that are **prompt, reliable, accurate**, and fully integrated.
- Comprehensive **online access** to all of your PDMA compliance data as well as state and federal reports.



Healthcare Provider Data Services

Accurate and complete healthcare provider data that decreases compliance risk and supports marketing and sampling proficiencies.

- Online access and inline integration to **over 13 million U.S. healthcare provider records**.
- Attributes including specialty, state license & DEA status, and **state & federal sanctions**.
- Seamless integration with CRM, MDM, and EMS solutions.
- Advanced notice of critical factors which help to mitigate issues **before they become a problem**.



Patient Services

Knipper's Patient Services help companies and their brands cultivate and nurture patient relationships and increase brand loyalty through innovative programs and leading technologies.

- Providing product and disease state education as well as lifestyle information from **a true patient perspective**.
- Highly efficient Patient Assistance Programs with **white-glove** qualification and approval processes.
- Integrating communications with existing HCP and Pharmacy based programs to provide **superior value**.
- Helping to identify each patient's unique barriers to adherence and recognize **how those challenges evolve**.

Knipper has multiple facilities totaling over 800,000 square feet, with 20,000 of that refrigerated and 12,500 for controlled substances.



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