

## CASE STUDY

### European based multi-national pharmaceutical organization improves PDMA compliance with automated processes and reduced administrative burden

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#### *Business Challenge*

The US business unit of a global pharmaceutical manufacturer faced some increased compliance and operational challenges in its sample accountability area. Sample accountability was already working at capacity, but a new product was being scheduled for release that would further increase workloads.

At the same time, the existing sample management system was difficult to maintain and was expensive to change. The existing sample slowed the business down and could not be modified rapidly enough to support the pace of change from new initiatives driven by the field.

Management identified that the majority of sample analyst time was being spent on reviewing and closing inventory counts that did not have discrepancies, and therefore posed little compliance risk. These administrative review tasks were not adding value, and were taking away time from identifying and investigating real compliance issues. In addition to spending time on low value tasks, the workload of the department was skewed heavily to the beginning of the month by the end of month count process. This was a reactive process – the user counts inventory, it is reconciled and then a reaction to the result takes place.

Ideally workload should be spread by identifying potential issues during the month, so that investigations can begin immediately while events are still fresh in the mind, and before any end of month rush reduces the time available to research the issue. Because the current software offered limited reporting and no analytics, the task of reviewing, evaluating and analyzing historical data was difficult.

After an exhaustive search which included evaluating upgrade paths for the then existing system, the company selected a new sample accountability solution using the following criteria:

- Automation: time must be saved using automated business processes to conduct routine processes.
- Proactive processes: the proposed solution should proactively analyze inventory transactions and highlight potential problems immediately for research.

- Usability: users must be presented with information in an actionable way.
- Analytics: users and managers must be able to report and analyze the enormous amount of data in the system to identify potential problems.
- Complete: the proposed solution must be a complete sample accountability solution, and include important compliance features such as infraction and case management.
- Validation: the proposed solution must be validated and must come from a vendor with a proven quality system and history of building validated systems.
- Data integration: the proposed solution must receive data from a number of other systems including the ERP system, SFA systems, data warehouse and 3rd party vendors.
- Flexibility: the proposed solution must be based on flexible technologies, and allow for business rule changes within the validation framework.

#### *Solution*

After conducting an extensive search and selection process, StayinFront Sample Inventory Management System (SIMS) was selected as it met the evaluation criteria, and showed an ability to add value to the sample teams processes and objectives.

StayinFront SIMS would be implemented with focus in the following areas:

- Leverage the StayinFront Workflow Engine to automate processes, reducing the administrative burden, and allowing administrators to focus on compliance issues.
  - Utilize StayinFront Analytics and Workflow to conduct a nightly 'Trial Balance' on every inventory, allowing proactive identification of potential problems.
  - Adopt StayinFront Analytics Dashboards to bring summaries of all necessary information to user specific dashboards, allowing connections and patterns in disparate data to be identified.
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- Utilize StayinFront SIMS to provide a complete set of functionality for the accountability, audit and compliance aspects of the sample management function, including usual reconciliation.
- Capitalize on StayinFront SIMS flexible architecture to implement business specific rules and processes, ensuring that the solution will fit existing business processes where appropriate.
- Use StayinFront Workflow and integration to pull data from different sources for integration into the system.

Implementation of the solution began with an extensive User Requirements and Functional Requirements gathering process. The sample accountability team had been using an electronic solution to assist them for over 10 years, ensuring that there was significant input into business process design and the user interface. Managers were particularly interested in configuring dashboards that would deliver specific information to specific users based on configurable rules. The dashboards proved to be popular with users for their ability to provide summarized and aggregated data on the dashboard while providing links through to the detailed data underneath. Users can review the summary, and click through to the detail instantly.

Improved data analysis and reporting were important system requirements that were met by StayinFront Analytics. The three areas of reporting functionality – Quick Reports, StayinFront Reports and Analytics, allow the Sample Accountability team to meet their regulatory reporting requirements, while the flexible analytics model allows users to dive deeper into the data.

- Quick reports provided the ability to select and filter, group and sort lists for quick export to HTML or Excel.
- The StayinFront Reporting function provided advanced static report building features. In a regulated environment these static and 'validated' reports are critical to reporting for compliance purposes, because the reports are secured against changes.
- StayinFront Analytics provided flexible 'drag, drop and drill' analysis. This allowed the Sample Accountability team to provide important value-add information to the business like sample burn rates, geographic sampling rates and physician profiling based sample analysis.

### Challenges

One of the challenges faced in the implementation was the

migration of the existing dataset through to the StayinFront SIMS database. StayinFront's Data Quality Team implemented meaningful 'repairs' to the existing data during the migration process. The importance of ensuring the quality of the data is highlighted by StayinFront Analytics, where managers can conduct extensive analysis of the data – and therefore missing or incorrect data is highlighted.

What could have been a major hurdle in the project resulted in an opportunity to further leverage the tools and services available to further derive benefit from the system.

In this case the StayinFront Data Quality Team, using their DataFlux data quality toolset was able to profile and repair the data. Starting a new system with data quality issues would have clouded the overall success of the project, and continued the compliance and operational difficulties presented by the existing system.

### Validation

A team of experts from the clients quality and compliance department were assembled to design and supervise the validation of the system, which included a complete validation of the data migration process to ensure that the data migrated and corrected from the previous system was loaded correctly into StayinFront SIMS. The reports from StayinFront SIMS were relied upon for federal and state regulatory reporting purposes, including the FDA, and therefore the underlying data was identified as a critical component of the new solution.

### Results

StayinFront SIMS was rolled out to the user team following the completion of validation, and immediately the software made an impact on the sample accountability team.

Less time is spent on review of 'clean' inventory counts (counts that do not show discrepancies), and less time is spent matching transactions together (such as the shipment notice from the ERP system and the shipment) acknowledgement from the SFA system) as the StayinFront workflow engine executes many of these routine tasks.

The user interface, including user specific dashboards, is easier to navigate and gives the user the ability to see information from different systems (such as the ERP and SFA systems) together on a single dashboard. Nightly trial balances are highlighting potential problems before the end of the month rush, enabling more efficient use of time.

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The combination of these benefits allows the sample accountability team to concentrate on investigating compliance issues, and protecting the organization from potentially significant regulatory breaches. Management now has a firmer grip on the processes and workloads, and can more effectively focus and manage their teams. These changes have resulted in a significant positive impact on the management of compliance tasks and activities.

### About StayinFront

*For over 20 years, StayinFront has been a global leader in the development, delivery and support of leading CRM and decision support tools. From new products such as Edge and Web Detailing to the full suite of online and offline solutions, StayinFront's innovative technology helps increase sales force effectiveness while delivering robust performance and flexibility. On-demand or on-premise, StayinFront provides the rich functionality, fast deployment and easy to use tools that your teams need to sell more and manage better.*

*StayinFront has been chosen globally as a strategic partner by many of the world's top life sciences, consumer goods, financial services and business-to-business companies and StayinFront solutions have been implemented in over 65 countries in 25 languages.*

*Headquartered in Fairfield, New Jersey, StayinFront has offices in Illinois, the United Kingdom, Ireland, India, Australia, Singapore and New Zealand. For more information, visit [www.stayinfront.com](http://www.stayinfront.com).*

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