Business Benefits of an IQ Program

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bioMérieux - The Company

$1 billion global organization with subsidiaries and production plants throughout the world.

Specializes in the *in vitro* diagnostics sector.

Designs, develops, produces and markets diagnosis systems for medical or industrial applications.

Operates in an FDA regulated environment.

The Regulation

Operating within the FDA regulated industry requires that manufacturers abide by the Code of Federal Regulations, Part 820, Quality System Regulation. The following referenced sections are specific to this presentation.

Section 820.198 requires that each manufacturer shall establish and maintain procedures for receiving, reviewing, and evaluating complaints. Section 820.100 (1) expands to require the procedures to address the analysis of processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems. Appropriate statistical methodology shall be employed where necessary to detect recurring quality problems.

Failure to follow up on complaints about medical devices is among the most frequently cited observations on FDA-483s and Warning letters. Negative customer feedback about a medical device's performance or safety is a strong indicator of whether a firm's manufacturing process is in control.

The Challenge

bioMérieux has 3 discrete databases that organize and maintain complaint data. These servers are located in France, North America and the Netherlands.

These databases are non-interactive; users can only access data within their local system. To achieve a global representation of complaint information data must be exported from each discrete database and then combined into a single file.

The pooling of information from the 3 data sets is challenging, data export routines do not have a common definition, data formats are inconsistent, required fields are not similar and data export files exceed the size limitations of the desktop applications being utilized causing data to drop off and be lost.

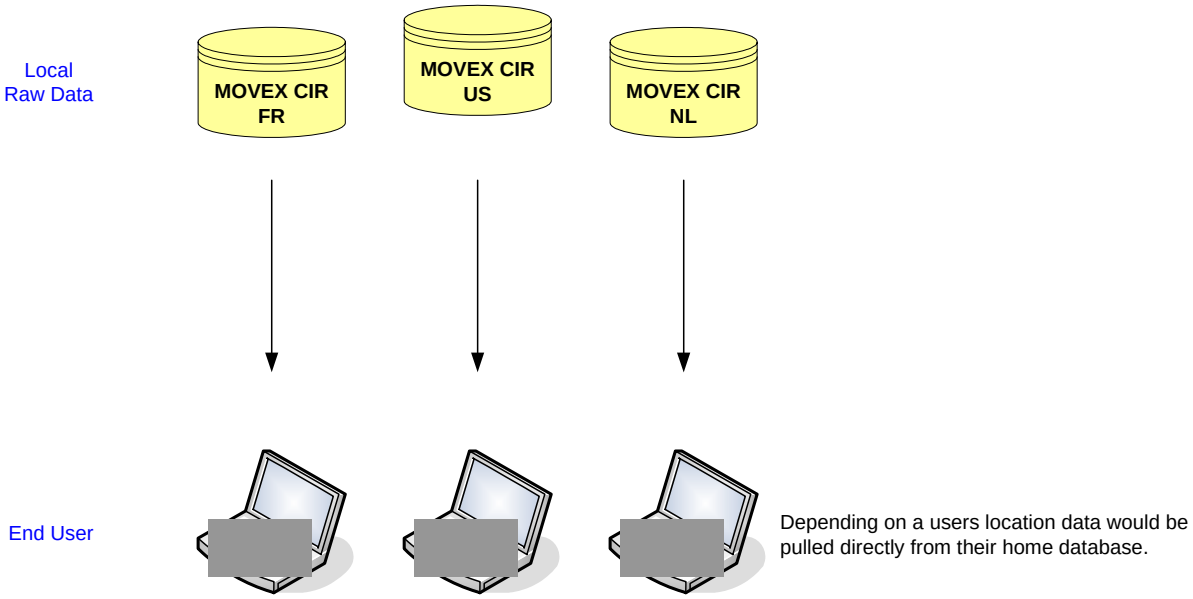
Data is not readily available, data extraction requires skilled personnel with an advanced understanding of the system. Data only available to personnel utilizing the system.

The process cycle time and personnel required is excessive and yields inaccurate information.

The risk of non-compliance is high, trending and root cause analysis using statistical methodology is not accomplished in a consistent and accurate manner.

Initial Process

Trending Data directly from AS 400 (Movex)



Depending on a users location data would be pulled directly from their home database.

Solution

A system that combines complaint data in like format into a single data warehouse and provides the user with the ability to trend on worldwide complaint data. The data should be in a data repository or DB facility that allows for the overlaying of business intelligence tools to be used to visually trend on the data ie…charts and graphs. The DB should be maintained in a way that applies data standards and interacts with the methods best suited for the business intelligence tool. The database should be maintained at a global level in a central location.

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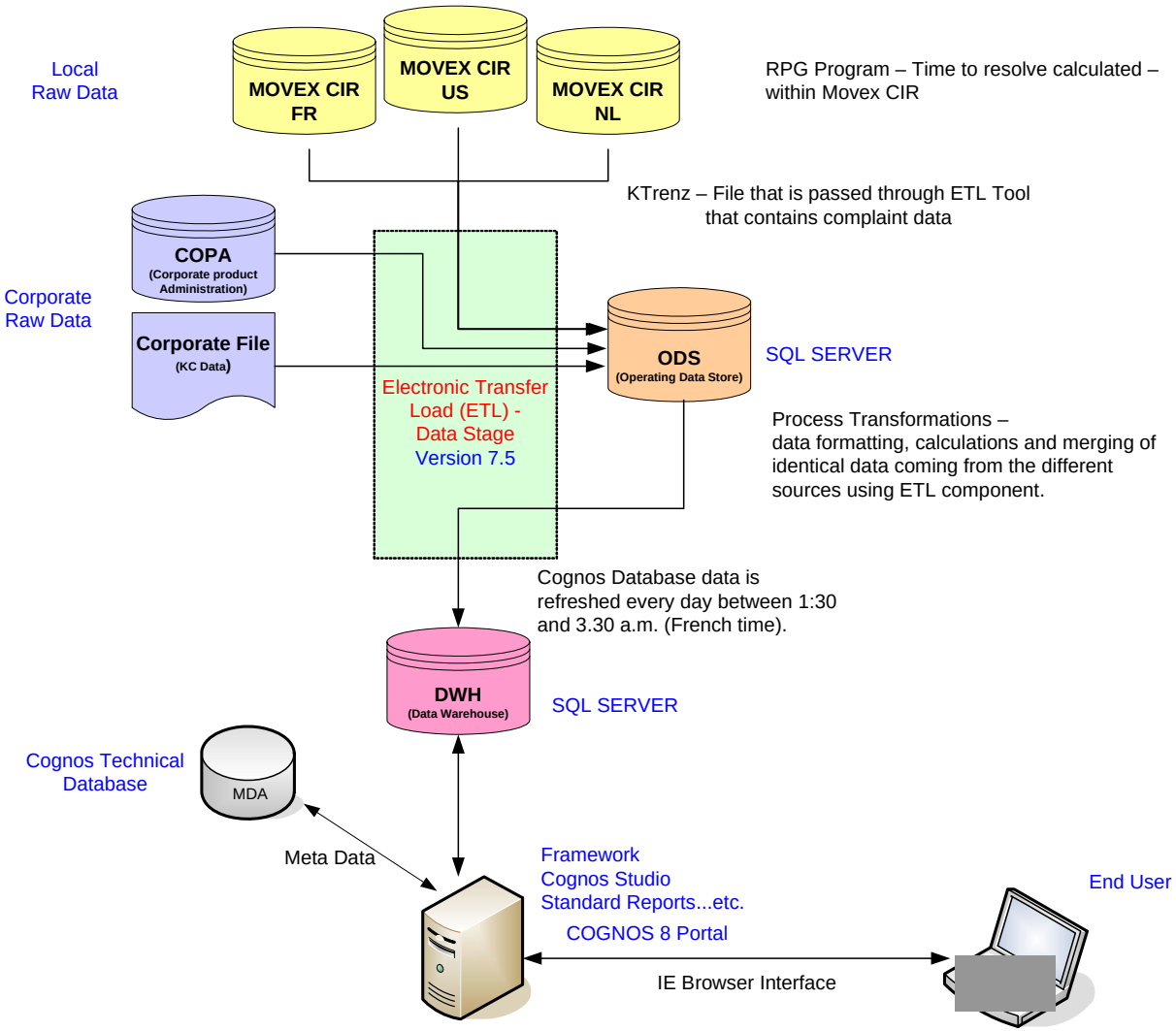
Final Process

Worldwide Complaints Trending Process



Benefits

The complaint trending database provides ready access for bioMérieux employees with network access and password authorization the ability to trend complaint data. This solution provides the business a tool, when utilized, will satisfy regulatory requirements and mitigate the potential for regulatory action. This database is validated and maintained within a controlled environment.

In addition, the database has delivered hard costs savings buy reducing the process cycle time associated with producing reports and is currently being utilized by Process Improvement Projects.

Annual HDCT savings	$140,000
Six Sigma Time to Resolve	$200,000
Six Sigma pH	$170,000
Total	**$510,000**

*** Mitigated Compliance Action measured but not presented.**