Improving the organizational efficiency and quality compliance by Data modernization and automation in Pharmaceutical R&D quality

The McKinsey Global Institute[1] estimates that applying big-data strategies to better inform decision making could generate up to $100 billion in value annually across the US health-care system, by optimizing innovation, improving the efficiency of research and clinical trials, and building new tools for physicians, consumers, insurers, and regulators to meet the promise of more individualized approaches.

Intuceo® team partnered with a fortune 100 big pharma client to modernize the quality and compliance data environment with a goal to improve organizational productivity, data quality and enable self -service analytics. Having data that is consistent, reliable, and well linked was one of the biggest challenges facing customer and resulted in time consuming and manual quality compliance operations. The key business goals are to enable cross sector (Pharmaceutical, Consumer & Medical Devices) reporting and analytics and proactively identify potential audit findings, Inspections, Observations & CAPA while reducing the risk for future inspections.

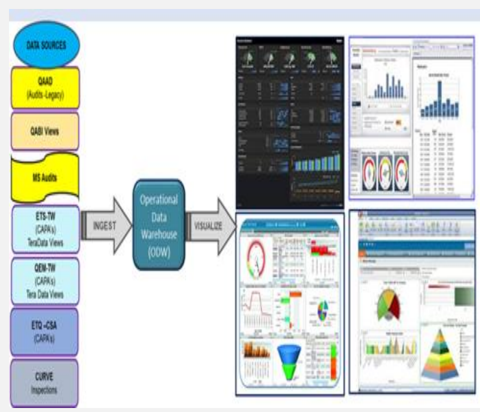
Intuceo® team of experts with proven Big Data reference models, frameworks, intellectual property and valued-added Auto ML tools partnered with the client and implemented a modernized Quality Analytics and Reporting data eco system. The key features include:

1. Integrating data maintained in multiple instances of six quality systems for across the three sectors – Pharmaceutical, Consumer & Medical Devices.

2. By creating comprehensive mastered data, business rules and applying machine learning, automatically establish the linkages, data manipulation and transformation and eliminating/ reducing error rates.

3. Near real time data ingestion and analysis capability to respond to changing regulatory and business requirements.

4. Self Service reporting and analytics framework to
    a. Exploratory Querying
    b. Non-complex Reporting
    c. Monthly Reporting
    d. PSMF Reporting
    e. Adhoc Analytics



Investing in an integrated data & analytics platform enabled business with self-service, on-demand and real time reporting capabilities of quality data, expedited the investigations & compliance reporting, **while reducing 95% in cycle time**.