CASE STUDY

Novo Nordisk harmonization of quality management and management of change

Key facts:

Company:
Novo Nordisk

Industry:
Biopharmaceuticals

Country: Denmark

Octave product used:
Reliance
(formerly ETQ Reliance)

Key benefits:

- Harmonized change management globally by replacing manual paper-based system with automated solution
- Integrated with SAP and other business systems to seamlessly connect production, HR and regulatory data
- Achieved inspection readiness with real-time reporting and single global point of reference for all change requests

Novo Nordisk is a worldwide biopharmaceutical organization with over 35,000 employees in 74 countries, with production spanning multiple global facilities.

The business need

Given its global footprint and strict regulatory compliance imperatives, Novo Nordisk sought to harmonize and standardize their Quality Management System (QMS) in order to reap greater process speed and efficiency, specifically with regard to management of change. Previously, the company used a largely paper-based system for change management. This manual systems created several challenges, so Novo Nordisk decided to implement an automated QMS solution in order to reduce errors, eliminate redundancy and maximize the efficiency of the QMS.

Novo Nordisk completed an exhaustive and comprehensive selection process for a solution, and ultimately chose ETQ for the flexibility of the compliance platform, and the ability to harmonize the solution across their global operation.

Quality journey

Manual → **Change management** → **Automate, harmonize and integrate quality and change control**

Filling the gap

Through ETQ, Novo Nordisk was able to harmonize their Change Management process through capturing all data online, avoiding any data loss from manual systems, and improving data quality. They were able to configure ETQ's solution to meet their business needs exactly, and through intelligent business rules automation, they were able to ensure their management of change is streamlined and they are able to respond to changes quickly.

Furthermore, Novo Nordisk's Change Management process is connected to other business solutions, and ETQ serves as a "hub" for all compliance related events. Using ETQ's integration management tools, Novo Nordisk is able to integrate with their SAP solution and other business systems to ensure production and employee data is seamlessly pulled in, and regulatory information is transferred from ETQ to their various business systems. Through this integration, they are able to connect production data, human resource data, and regulatory data through the process to the systems that need it.

Meeting the need

Through the implementation of ETQ, Novo Nordisk was able to meet their business needs in harmonizing the solution globally, and automating the process of Change Management and Quality Assurance. They have gone from a manual, paper-based system, to an automated system that uses dynamic business rules and seamless integration to connect groups and users to their compliance process. Ultimately, ETQ's system helps Novo to achieve its corporate-wide goals.

Ensuring a future state of compliance and inpsection readiness

ETQ helps to provide Novo Nordisk with a rapid response when challenged by inspectors and in daily operations.

Reducing lead time and increasing efficiency

ETQ has been able to streamline the process from manual to automated, eliminating any handwritten signatures or paper-based distribution, resulting in better data collection and increased implementation and completion of change requests.

Increasing transparency

ETQ's solution is now Novo Nordisk's single, global point of reference for all change request information. ETQ's real-time reporting and access to compliance data helps to create visibility and provides easier, more reliable search and trending.

As a result of implementing ETQ, Novo Nordisk has been able to harmonize their quality processes, automate their change control processes, and integrate with their various business systems to ensure compliance is met throughout their organization.

About Octave

Octave is a leader in enterprise software, turning data into decisive action and intelligence into your edge. Our software solves for and simplifies complexity, from the design and build to operations and protection of people, property and assets – for any scope, at any scale. For decades, we've partnered with customers to sharpen performance, elevate efficiency and amplify results. From factory floors to entire cities, our solutions are tuned to scale up what's possible from day one onward.

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