

Novo Nordisk harmonization of quality management and management of change

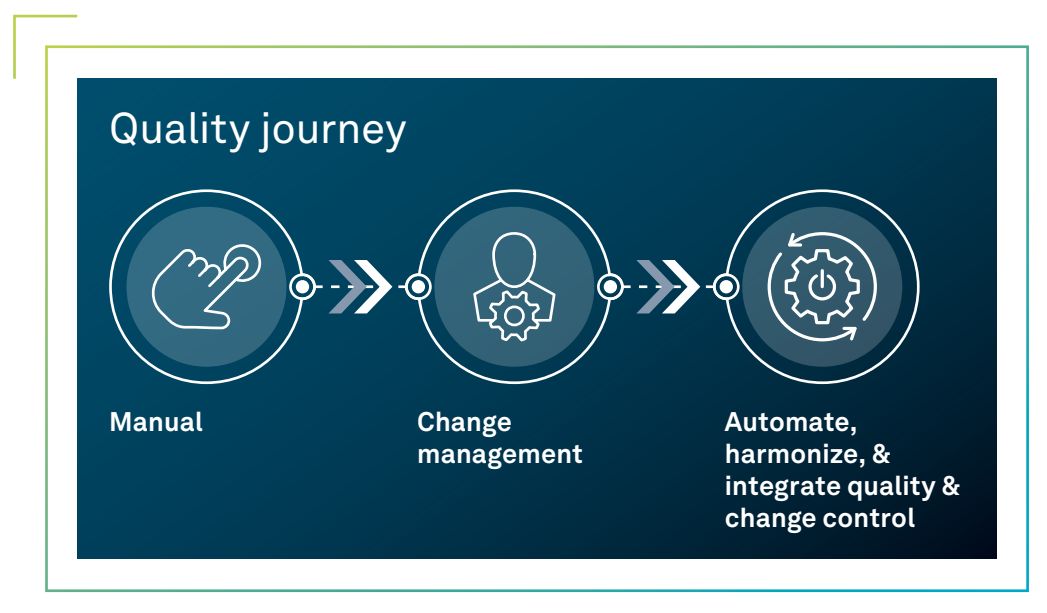


Novo Nordisk is a worldwide biopharmaceutical organization with over 35,000 employees in 74 countries, with production spanning multiple global facilities.

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 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.





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 inspection 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 hand written 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.



ETQ, part of Hexagon, is a global leader in integrated quality management, health, safety, and environmental solutions for manufacturers. Learn more at etq.com.

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