CASE STUDY

Ventilator Manufacturer Scales with AssurX to Maximize Patient Safety and Build a Strong Brand

NIHON KOHDEN

Nihon Kohden OrangeMed, Inc.

AssurX

Proactively taking control of quality management and regulatory compliance with powerful workflow processes that form a connected, single source of truth.

Nihon Kohden OrangeMed, Inc., located in Orange County, California, focuses on design, development, and manufacture of state-of-the-art innovative respiratory products. Nihon Kohden OrangeMed is part of Nihon Kohden Corporation, headquartered in Tokyo, Japan. Nihon Kohden is a world leader in medical device design and manufacturing, delivering medical technology innovations and high-quality medical products worldwide. Nihon Kohden's products range from bedside monitors, central monitors, defibrillators, AEDs, physiological measuring equipment, in vitro diagnostic equipment, and mechanical ventilators.

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Sheryl Higgins
Director, Regulatory Affairs & Quality Assurance
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QUALITY PROCESS AUTOMATION FROM THE START

Nihon Kohden OrangeMed began as a true start-up in 2015. Nihon Kohden wanted to add a new ventilator to its product portfolio that would be designed from scratch. The company hired a small, highly experienced engineering team that began R&D out of an office in Irvine, CA.

In 2016, Sheryl Higgins joined the team as Director, Regulatory Affairs & Quality Assurance. At the time, R&D was using a basic paper-based document control system that consisted of pre-production drawings. "As a start-up, there was no better time to implement a digital system to control documentation," explained Higgins.

Nihon Kohden OrangeMed was fully receptive and gave Higgins permission to implement an automated system to better manage documentation, training management, and subsequent process additions and enhancements. The system was required to securely contain all necessary records for regulatory compliance for FDA, and ISO certification.

"We wanted a single source of truth with a relational database and the entire quality system in one platform," explained Higgins. She evaluated a few automated QMS solutions, and ultimately selected AssurX. "AssurX had the greatest ability to integrate and connect processes, meet our configuration requirements, and scale without limitation."

IMPLEMENTING THE ASSURX QUALITY MANAGEMENT SYSTEM

Nihon Kohden OrangeMed highly customized its configuration, as is often the case for life-sustaining devices. AssurX Professional Services worked closely to build out the document management system to meet the company's specific needs.

The implementation and validation took approximately 7 months. To validate the system, Nihon Kohden OrangeMed ran its processes in parallel for three months. This included validating 65 DCNs that encompassed over 300 document revision changes – with no errors.

AssurX electronically links postmarket complaints to MDR reports, which makes the system very favorable to auditors.

"[AssurX Professional Services] empowered us with knowledge to manage system administration tasks we were capable of, and continue to support system enhancements that require expertise outside of our scope."

Sheryl Higgins
Director, Regulatory Affairs & Quality Assurance
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"Since we were relatively small at that time, we brought in all our historical data from the outset," said Higgins. "AssurX Professional Services helped our technical users learn 'how to fish' to use the import tool. They empowered us with knowledge to manage system administration tasks we were capable of, and continue to support system enhancements that require expertise outside of our scope."

After the success of the document management implementation, Nihon Kohden OrangeMed continued integrating workflow processes including training management, supplier quality management and calibrations.

Nihon Kohden OrangeMed continued to grow, leased a manufacturing site, and received its first 510k approval. At that point the company brought on an additional technical staff member charged with AssurX administration, adding automation to error-proof processes, further enhance usability of existing modules and continue to build out new modules such as complaints and FDA MDR.

ASSURX HELPS RAPID PRODUCTION SCALE DURING THE PANDEMIC

The real test of the system came in 2020. When the Coronavirus pandemic hit, the company had just released their first ventilator. Based on the market demand, Nihon Kohden OrangeMed was asked to significantly increase production. The company needed to scale – fast.

AssurX's ease-of-use helped enable the scale-up in a systematic and compliant manner. Employees were trained on the processes and procedures applicable to their roles. Those required to work within the AssurX system came up to speed in a brief period of time.

All SOPs, and other documentation was available through the AssurX system for reference and re-training as required. Access to Design Files such as drawings, specifications, Device History Record forms, Inspection and Testing Forms were also readily available through AssurX.

FURTHER ENHANCEMENTS TO THE ASSURX SYSTEM

In the beginning, Nihon Kohden OrangeMed rolled out document management, training management, and calibration management. They were the most critical in terms of forming a bedrock for the quality system.

Utilizing onsite resources and support as needed from AssurX Professional Services, additional processes were integrated into the platform.

Due to the critical nature of the ventilator during the COVID pandemic, Nihon Kohden OrangeMed has been audited several times. Audits from the FDA and other global bodies have been highly favorable.

"There are virtually no limits to what we can do with AssurX."

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Today, Nihon Kohden OrangeMed's quality management system connects the following processes:

- Document Management
- Training Management
- Equipment Management (Calibration and Maintenance)
- Nonconformances/Investigations
- CAPA Management
- Supplier Quality Management and Supplier Corrective Action Requests (SCARS)
- Complaint Management with Integration for MDR Submission (via AS2 account with FDA ESG)

Nihon Kohden OrangeMed is planning additional integrations and enhancements to continue to leverage AssurX scalability and breadth of quality solutions. "There are virtually no limits to what we can do with AssurX," said Higgins.

ADDITIONAL BENEFITS OF ASSURX

- Postmarket complaints are electronically linked to MDR reports, which makes it very favorable to auditors. Furthermore, reminders and escalations keep all reporting within regulatory guidelines.
- Nihon Kohden OrangeMed utilizes the FDA and EU reportability checklists within AssurX. The checklist criteria are translated to matrices that prove that all complaints are being reported according to regulations.
- Due to the critical nature of the device during the pandemic, Nihon Kohden OrangeMed has been audited several times. Audits from FDA, EU Notified Body, Ukraine, Brazil, Korea, and other global bodies have been highly favorable.
- Calibrations never exceed past due based on system reminders, minimizing down time from equipment issues.

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