nexdigm

Case Study

A Leading Medical Devices and Technology Company

Service(s) offered: **Program Management**

Sector/Industry: **Healthcare**

Program Management Support for Product Launch, Migration, Testing, and Implementation of Medical Products

A leading global medical devices and technology company was planning various enterprise-wide initiatives to stay industry-relevant. From navigating regulatory frameworks to ensuring the implementation of rigorous quality management systems (QMS), each step demanded meticulous planning and execution.

Challenge

As a specialized manufacturer of medical technology and devices, they detected gaps in their current resources to carry out a comprehensive project management program. They lacked dedicated SMEs appropriately qualified to initiate the project. Additionally, the organization sought a designated point of contact to facilitate effective coordination between the organization and its third-party vendors.

They engaged Nexdigm to establish a clear communication channel, effectively manage change management, and supervise the project.

The project deliverable for this particular client entailed:

- Support for testing and implementation at a sterilization facility.
- Monitor the Quality Management System (QMS).
- Migration of medical devices in 30 countries.
- Discontinuation and replacement of product line globally.
- Launch a new packaging configuration in 14 countries.

Case Highlights

- Successful migration of 33% of products across Europe.
- No business disruption with minimal patient loss (~8%).
- Discontinuation completed in 3 countries.
- Upgradation of >95% antimicrobial dressings.
- Launch of new packaging configuration in 14 countries.
- Successfully completed testing for single and double exposure cycles.
- Remediation & submission completed for 2 DHFs.

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Solution

As a part of the support, Nexdigm provided a comprehensive solution to the client through our start-to-end project management initiative. We began by understanding the unique requirements of each initiative and preparing a project execution plan, ensuring meticulous tracking of progress at every stage. Nexdigm effectively coordinated between cross-functional teams and stakeholders, facilitating seamless collaboration throughout the project. Continuously monitoring milestones and progress, we proactively communicated any risks or delays to keep all parties informed. Moreover, Nexdigm maintained clear and effective communication throughout the project delivery, ensuring smooth and successful implementation of the client's objectives.

Support for Testing and Implementation of Sterilization Facility

- The primary requirement of the initiative was to establish a well-managed communication network. In order to bring about transparency in the single and double exposure cycles between the high management and ancillary teams.
- Set up internal meetings to ensure necessary documents for Change Control Requests were updated.

Monitor the Quality Management System (QMS)

- In the task of monitoring the client’s QMS, they sought Nexdigm to update the Delete History File (DHF) to the QMS, making it ready for Medical Devices Regulation alongside to carry out Remediation of Process Failure Mode Effect and Criticality Analysis (PFMECA).
- We ensured that the PFMECAs are remediated and updated into a new template.

Nexdigm’s team of experts acted as the point of contact between the Remediation Project Manager and PFMECA team as a part of Risk Identification and Communication Management initiatives.

Migration of Medical Devices in 30 countries

- To ensure the successful migration of the product to 30 countries, we supported the execution and the timely discontinuation of legacy products in different markets as per their phase-in and phase-out timelines.
- Further, we coordinated with cross-functional teams like Supply Chain, Demand Planning, Regulatory, etc., to remove silos from the organization.
- Regularly coordinated with commercial leads to monitor the migration to major markets like Italy, Nordics, France, and Belgium.

Discontinuation & replacement of product line globally

- In order to discontinue and replace the product line globally, we first identified SKUs to be discontinued based on sales and prepared a project execution plan.
- Efforts by team resulted in creating benchmarks in regions to discontinue and consolidate selected SKUs.
- Planned the communication of discontinuation of the firstborn Hydrocolloid dressings with end dates globally alongside alternative suggestions.

Launch of new packaging configuration in 14 countries

- To launch the new packaging in 14 countries, including Nordics, MENA, Baltics, Australia, Taiwan, Croatia, and the Czech Republic, we initiated the process with validation of data with the market.
- This process was followed by calculating forecasts and creating the Market Engagement Plan (MEP)
- We supported the client in analyzing and calculating the margins and coordinated with third-party manufacturers for Lead time for manufacturing and shipping and with the regulatory team for registration timeline for all regions.

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Impact

By leveraging our deep industry knowledge, operational insights, and comprehensive suite of services, Nexdigm supported the client in enhancing their operational capabilities, optimizing regulatory compliance, streamlining processes, and achieving their business goals efficiently.

As a result of an organization-wide initiative, Nexdigm delivered a series of significant impacts. We acted as the execution partner to the clients. Through our first initiative, we successfully completed testing for single and double exposure cycles, ensuring the safety and efficacy of their sterilization facility. Additionally, we accomplished the remediation and submission of Delete History Files (DHF), reinforcing the client’s commitment to regulatory compliance. The successful migration of 33% of the client's new products across Europe demonstrated Nexdigm's ability to handle operations in new markets effectively. Nexdigm takes pride in the fact that our initiative resulted in no business disruption, with minimal patient loss at approximately 8%.

This achievement reflects our dedication to maintaining seamless operations while prioritizing patient care. Moreover, we successfully completed the discontinuation process in three countries, streamlining the client's product portfolio and optimizing their resources. To further enhance patient outcomes, we overlooked the upgradation of over 95% of the antimicrobial dressings, ensuring that the products are at the forefront of medical advancements. Lastly, our initiative included the launch of a new packaging configuration in 14 countries, catering to diverse market demands and improving product accessibility.

These achievements exemplify Nexdigm's commitment to excellence and innovation, as well as to deliver exceptional solutions to our customers and stakeholders.

For more information on this case study, please write to us at:

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You can also visit our website to know how our services resulted in tangible business benefits:

www.nexdigm.com