Medical device manufacturing case study

Change drives digital transformation

Medical device manufacturer evolves record protection processes under a tight deadline

The challenge

In 2018, the parent corporation identified global best practices for managing physical vital records. The effort was part of a larger vision to digitise data, apply artificial intelligence/machine learning (AI/ML) analysis, and improve their overall security profile. Each subsidiary was given approximately 24 months to comply.

The task force assembled to address the corporate requirement felt the pressure almost immediately. Vital record designations had expanded to include many document types that had not previously received special handling. An estimated 60% of existing paper artifacts could be affected by the expansion, making the physical challenge daunting. Additionally, the disparate, departmental records and information tracking systems were mostly paper-based and could not scale without increased staff.

The solution

The corporate information governance team arranged meetings with the medical manufacturer's task force and Iron Mountain to form a plan of attack using Digital Solutions.

A comprehensive records management and storage program was designed to:

- 1 Securely scan each document and ensure high fidelity reproduction
- 3 Release electronic copies to secure digital storage and microfilm processing facilities
- 2 Preserve the original physical record in approved off-site locations
- 4 Automatically update the corporate vital records database

The results

The solution rollout was completed to the satisfaction of the corporate office. Automating tasks helped resolved inconsistencies and reduced the workloads for department record coordinators. The success of the vital records process update also opened possibilities for redeploying part-time record coordinators to full time manufacturing roles, expanding management automation to other areas of the business, and advancing AI/ML data analysis projects.



The situation

- Each functional department had its own, home-grown, largely manual process for tracking records
- More than 50 part-time coordinators were involved
- Records classification change affected 60% of paper-based records
- > The task force was overwhelmed due to tight timelines, budget worries

Our solution

Iron Mountain Digital Solutions

Key benefits

- > Potential audit and litigation exposure is reduced
- > Standardised vital records processes enterprise-wide
- > The manufacturer is positioned to seamlessly support future corporate AI/ML initiatives



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