

INDUSTRY

Healthcare

CHALLENGE

Digitisation of batch records to improve data access

SOLUTION

Document scanning and off-site records management

VALUE

- Access to vital files in seconds rather than days
- Improved operational efficiency
- Simplified and accelerated compliance processes

CASE STUDY

MENTOR MEDICAL

SCANNING VITAL PRODUCTION FILES ASSURES COMPLIANCE

MAINTAINING EXEMPLARY QUALITY STANDARDS

Part of Johnson & Johnson, Mentor Medical is a world leader in breast implant manufacturing, research and testing. It has an enviable reputation, consistently recognised by medical professionals for outstanding product integrity.

Mentor Medical has its European manufacturing centre at the Leiden Bio Science Park in the Netherlands. Products made there are of the highest quality, with strict standards of design and testing. Every step of the manufacturing process is tightly controlled and documented, with records retained for up to 125 years.

"We keep meticulous records to assure full traceability and batch identity," says Sjaco Baas, Site Records Manager at Mentor Medical. For example, source data of raw materials, silicon chemical analysis results, time-stamped oven temperature graphs and equipment maintenance schedules. Records are validated and signed by qualified persons, for sound evidence should an investigation ever be required.

"Our batch records have traditionally been kept in paper form, stored off-site by Iron Mountain®," continues Sjaco. "Although this arrangement has served us well we need to continually enhance our procedures for greater efficiency."

SPEEDING EVIDENCE FOR EXTERNAL AUDITS

The Mentor Medical manufacturing process is subject to audit checks from customers and global regulatory bodies. Auditors often ask to see evidence of manufacturing controls, requiring documents to be retrieved from the off-site archive. "Digitising our batch records would speed up access," says Sjaco Baas. "That would help us get audit activity concluded much faster."

In considering file scanning it was natural for Mentor Medical to turn to Iron Mountain as custodian of its batch files.

"HAVING OUR BATCH RECORDS AVAILABLE IN DIGITAL FORM MEANS WE HAVE ACCESS TO WORKING COPIES OF VITAL RECORDS IN SECONDS RATHER THAN DAYS."

Sjaco Baas
Site Records Manager
Mentor Medical



With the assistance of Iron Mountain's Project Governance Specialist, Mentor Medical created a statement of work to define project activities, timelines and deliverables. That led to an initial pilot to scan 20 boxes of production files. Sjaco Baas confirms; "We learned a lot during that pilot and from it we were able to develop a comprehensive 35-page work instruction."

A second pilot exercise followed. The successful scanning of 50,000 pages of files validated that work instruction. As part of the agreement to proceed, Mentor Medical conducted an audit of the Iron Mountain scanning centre.

"The site visit helped us visualise the process as well as confirm Iron Mountain safety and security provisions at first hand," says Sjaco Baas.

MOVING TO FULL-SCALE DIGITISATION

With the process proven and file structure defined, Iron Mountain embarked on full-scale digitisation of the Mentor Medical records archive. Over the next months Iron Mountain created more than 1.6 million PDF images, made available via a secure portal for download into the Mentor Medical document management system.

Now the back-catalogue has been fully digitised, new batch records are routinely collated and sent for scanning. Each month Iron Mountain collects and scans around 20 boxes of files, creating around 50,000 PDF images for download within a 10-day timeframe. Once scanned the original paper files are archived, to remain available if ever required; for example, in the unlikely event of a legal enquiry.

"Having our batch records available in digital form means we have access to working copies of vital records in seconds rather than days," says Sjaco Baas. "It's just a far more effective and efficient way to work."

DEVELOPING A STRONG BUSINESS REALATIONSHIP

The association between Mentor Medical and Iron Mountain continues to evolve. For example, Iron Mountain recently supported the company following the closure of a manufacturing facility in Mauritius; cataloguing and transporting around 33,000 boxes of records for archive in the Netherlands.

"Iron Mountain does a fine job and we have a great relationship," concludes Sjaco Baas. "Scan quality and accuracy is excellent. The project is a great example of us developing our business relationship."

The Mentor Medical goal is to make life more beautiful; helping patients maintain, enhance, and restore self-esteem and quality of life. In helping the company attain the highest quality standards, Iron Mountain can be proud to be part of that.

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ABOUT IRON MOUNTAIN

Iron Mountain operates in major markets worldwide, serving thousands of customers throughout the UK, Europe, US, Canada, Asia Pacific and Latin America. For more information, visit our website at www.ironmountain.co.uk or at www.ironmountain.ie

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Ref:EN-cs-95-0517-en