

# Otto Bock HealthCare Products GmbH

## SAP material file at the push of a button

Otto Bock HealthCare Products GmbH in Austria has modernized and expanded its existing SAP material file with solutions from EASY SOFTWARE AG. This makes all important data and documents available even more quickly and easily at all process levels. In addition, the straightforward, structured, and transparent representation of all information is ensured, for instance in case of audits.

Providing information and important documents quickly is a daily challenge faced by employees in many companies. The integrity and traceability of processes for the aspect of legal certainty plays a central role. Proof of consistent filing and the fast accessibility of documents are of particular importance in case of external audits.

Otto Bock HealthCare Products wanted to put an end to elaborate searching between departments and divisions, and in various filing systems (including paper-based filing). A new document management system was intended to provide optimum support for the pending audit by the FDA (Food and Drug Administration). In cooperation with SYCOR GmbH, the existing system was transferred to a

new material file on the basis of SAP and EASY with the goal of providing all information relevant for the FDA electronically "at the push of a button". Secure, faster and thus more cost-effective audits are therefore ensured.

### Central data and document storage

Otto Bock HealthCare Products has to comply with strict legal documentation requirements for the US market and the Food and Drug Administration (FDA). Compliance with all regulations has to be proven in the course of regular audits. In the worst-case scenario, a negative audit would mean that certain products could no longer be sold in the USA.



We give IT a face.



Accordingly the consistent documentation of individual processes to support the FDA audit is essential for the company. "Our previous system was reaching its limits and no longer provided adequate support for audits. A lot had to be done in paper form – which is a protracted, complicated and expensive process," says Manfred Schmid, Business Solutions Manager at Ottobock, describing the initial situation. "It was important for us that the system can be used by both SAP and non-SAP users. We wanted a solution that makes the documents from both worlds available in a file structure with access control," Schmid continues.

### New requirements

In the project, Sycor was responsible for the analysis, conceptual design and configuration of the solution and for setting up the software environment in Ottobock's data center. Project coordination, implementation, specific adaptations, training, documentation and the migration of legacy data to the new system were included in the scope of performance as well. Sycor also assumed responsibility for software maintenance and system operation after the conclusion of the project. Stephan Sturzenbecher, Head of Corporate IT Operations at Ottobock, has this to say in retrospect: "We were under time pressure since the audit was coming up soon. The Sycor team with its professional approach to the solution completed the project quickly and successfully. Cooperation was consistently pleasant and goal-oriented."

New FDA requirements such as the Device Master Record (DMR) and Device History Records (DHR) made the project even more complex. DMR refers to a comprehensive record of all processes and instructions for the production of medical devices. A DHR documents compliance with all procedures and processes described in the DMR for all manufactured products. "We were able to meet these two documentation requirements with the implementation of the DHR-EBUTTON," explains Kathrin Ullrich, Sycor Project Manager. "Ottobock previously introduced a batch management requirement for materials in SAP, also with Sycor's support."

"The new solution has already proven itself. We were able to access all necessary and relevant information quickly during the audit. We are facing the next review much more calmly," says Schmid in conclusion.

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### Otto Bock HealthCare Products GmbH

#### Headquarters

Vienna, Austria

#### Industry

Medical Devices/Healthcare

#### Products

Prosthetics, Orthotics, Mobility Solutions

#### Web

[www.ottobock.at](http://www.ottobock.at)

#### The Project

Electronic material file implementation based on SAP and EASY

#### Benefits

- Cost reduction in the IT organization
- Central digital storage
- Easier and faster navigation of file structures

#### Your contact



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