



CASE STUDY | Biologische Heilmittel Heel GmbH

Heel implements electronic documentation processes

Pharmaceuticals manufacturer Heel has had a positive experience in converting to electronic processes on the basis of Microsoft Office Sharepoint and EMC Documentum.

Optimised Administration and Coordination Processes

To convert to a standard electronic workflow, the first step was to simplify administration and coordination processes and set up a new documentation structure with defined hierarchies. The directory structures in SAP and in the central documentation system (EMC Documentum) were also adjusted. In parallel to this, suitable IT support was sought for the administration of testing and procedure documentation. Prior to the introduction of a suitable electronic administration tool, the optimized process flows were tested initially over the course of a year.

Switching Over to an Electronic Workflow

»Up until now, the documentation process has been paper-based and thus more time-consuming and less efficient than electronic processes. Furthermore, we have used the

opportunity to optimize the processes and bring the internal processes into line with the external ones. This allowed us to implement important efficiency benefits«, says Monika Gartner, Team Leader of Processes and Projects in the Supply Chain section at Heel – which served as the point of origin for the introduction of an electronic workflow.

For the preparation of an electronic workflow, specialists in document-based processes were brought on-board from fme AG in Braunschweig. Upon analysis of the initial situation at Heel, a suitable electronic process and platform were selected. In accordance with the requirements specifications of Heel and those of fme, Microsoft Office Sharepoint Server was ultimately selected for the electronic administration of the testing and process documentation. One of the specifications was the close interlinking of Sharepoint with the 'Regulatory Document Management System' of EMC Documentum. The new process workflows, which have already been tested, were implemented as a process chain in Sharepoint – including all document tests, releases and presentations to the authorization department through to handover to the approval authorities.

Name	Status	SAP Reference No.	SAP Reference Text	Valid from	Created	UJ/ChangeBy	Modified
CTD-10-01	APP	000504	ANTHROPALUM COMP 080505 BLAU APP	12/12/2008	12/12/2008 8:03 PM	Gartner, Monika	12/28/2008 4:33 PM
CTD-10-01	APP	000505	ANTHROPALUM COMP 080505 BLAU APP	12/12/2008	12/22/2008 4:33 PM	Gartner, Monika	12/28/2008 9:29 AM
CTD-10-06	APP	000506	CACTUS COMP 080506 BLAU APP	12/12/2008	12/15/2008 2:41 PM	Gartner, Monika	12/28/2008 9:28 AM
CTD-10-06	APP	000509	CAUSTEUM COMP 080509 BLAU APP	12/12/2008	12/28/2008 1:45 PM	Gartner, Monika	11/10/2008 5:23 PM
CTD-10-02	APP	000510	CAUSTEUM COMP 080510 BLAU APP	12/12/2008	12/28/2008 1:45 PM	Gartner, Monika	12/28/2008 4:33 PM
CTD-10-02	APP	000511	ICHTHYERUM COMP. BLAU APP. DE	12/12/2008	12/28/2008 11:06 AM	CTD_Buher	12/28/2008 12:28 PM
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CTD-10-02	DEL	024262	SALPUR OHA DEL	12/24/2008	12/24/2008 12:52 PM	Sabine, Heide	12/28/2008 1:11 PM
CTD-10-01	DEL	000543	ANAMBITA COCCALUS FRUCTUS	12/12/2008	11/27/2008 8:55 AM	Heide, Sabine	12/24/2008 5:44 PM
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CTD-10-01	DEL	022062	ANAMBITA COCCALUS DEL	12/12/2008	12/20/2008 10:52 AM	Heide, Sabine	12/20/2008 11:12 AM

Overview of the manufacturing documents depending on their status

Advantages of Electronic Workflow

Sharepoint has considerably simplified the administration process for users. Another plus for Sharepoint is the fact that it uses the familiar user interface of the office programs. Documents can be moved with a simple click of the mouse and the processing status with all deadlines is a lot more transparent. Operations can be directly processed and completed. According to Monika Gartner, an important advantage is that analysis reports can now be generated at any time. Users can immediately see which documents were created, when this was done and their processing status. It is easier to monitor process- and validity deadlines and coordinate the filing of approval documentation. Moreover, the close interlinking with the 'Regulatory Document Management System' of EMC Documentum generates time-savings.

Conclusion: Saving Time and Costs

»The introduction of Sharepoint and conversion to electronic testing and process documentation went smoothly, not least thanks to the excellent cooperation with fme. The entire process is now considerably more transparent and more efficient and we were able to implement concrete savings with respect to time and costs«, Monika Gartner summarizes the results. As a result of this positive experience, a follow-on project has been agreed on for internal manufacturer's instructions, which are to be created using a similar workflow.



A must in homeopathy: the potentization of pharmaceuticals.

Technology

- Microsoft Windows Server 2003 SP2
- Microsoft Office SharePoint Server 2007 Enterprise
- Microsoft .NET Framework 3.5
- Web Services Enhancements (WSE) 3.0
- Adlib (Express Server und Exponent-Produkte)
- Documentum Content Server 5.2.5
- Documentum WebTop 5.2.5