



WELEDA AG RELIES ON SCHEMA

SCHEMA ST4 ensures integrated process safety at Weleda AG in Schwäbisch Gmünd. For creating their various pharmaceutical packaging, Weleda has been using the XML editing and content management system SCHEMA ST4 since late 2008. This manufacturer of pharmaceutical products is thus able to control processes systematically and create a central data store with all packaging texts, images, barcodes and layouts. Rolebased permissions ensure that tasks are assigned to the respective team and control the release process.



WELEDA



HOLISTIC APPROACH - USING ONE SYSTEM FROM CREATION TO PUBLICATION OF PHARMACEUTICAL PRODUCT INFORMATION

Weleda is one of the leading manufacturers of medicinal products for alternative medicine and holistic body care. When creating their pharmaceutical product information, the company pays the utmost attention to legal requirements such as those specified by German pharmaceutical law and EU policies.

All information must be kept up to date reliably and consistent on all packaging of the pharmaceutical products. If there are changes to a drug's dossier, e.g. through discovery of new information about the side effects of an active ingredient, these must be inserted reliably into all pharmaceutical product information in which this ingredient is mentioned. The relevant text must be updated for all drugs containing the ingredient, no matter the dosage, delivery format, or language. The obligation of pharmaceutical companies to label their drugs in compliance with the law and to adhere to regulations regarding changes, tracking, or archiving, make processes for the creation and management of packaging information particularly complex and cost-intensive.

To implement requirements more efficiently and systematically, Weleda decided in 2005 to reorganize the creation of print templates for labels, tubes, folded boxes and package inserts, as well as the content (text modules) for the pharmaceutical directory. The possibility to coordinate data was one of the main things missing in the individual legacy software solutions. Redundant data storage required significant coordination effort. Safety and quality aspects made it necessary to replace the legacy systems by a central solution which could serve as data storage

for all pharmaceutical product information and packaging (folded boxes, package inserts, labels and tubes), as well as providing workflow-based creation of content. All departments and responsible team members involved were to be directly integrated into the process.

After an extensive evaluation phase, the decision was made for the XML editing and content management system ST4 from SCHEMA. The solution was convincing for its flexibility and good price performance ratio.

"The standard solution SCHEMA ST4 already covered a number of our requirements for creating packaging and pharmaceutical product information," says Anja Walliser, project manager at Weleda AG. "SCHEMA's prior experience with other pharma companies was important. In the requirements analysis workshops, we felt that we and our processes were correctly understood."

Central Management of Pharmaceutical Product Information and Master Copies

First, Weleda decided to use SCHEMA ST4 in their business unit for pharmaceutical products to create boxes, labels and package inserts. In SCHEMA ST4, text and content are saved as media-independent information units in XML in order to generate from them various formats and target publications. Weleda's central data pool is being built up bit by bit. For new products or changes to existing drug dossiers, information is created with SCHEMA ST4.

"The complete migration of all the heterogeneous data sources would have meant too much effort," Anja Walliser says, explaining their method. "This would have included the cleanup as well as the consolidation of the data. At least



we transferred a major portion of the existing pharmaceutical product information and master data into SCHEMA ST4, as well as the content of thousands of labels which we already had as text modules." Apart from product descriptions and information, the print templates, images, or PDF files are also stored and managed in SCHEMA ST4. Data from other systems, such as those used to manage related texts or a product catalog, can also be stored.

Ensuring Quality Processes Across Departments

At the same time, SCHEMA ST4 makes possible the comprehensive representation of processes and changes to packaging and allows companies to document the necessary tracking and release steps in a legally secure manner and to store all pharmaceutical and packaging information in a central database. The entire process for creating pharmaceutical product information is initiated and controlled in SCHEMA ST4; starting with text creation, via editing and release of the content, to creating the layout for the packaging, and checking and releasing the master copies for printing. "With the individual workflow steps, different teams and departments are integrated," says the project manager. "This meant we needed a sophisticated set of permissions to control who is allowed to do what at what time." At Weleda, the following departments and responsible team members are directly integrated into the workflows for creating packaging with SCHEMA ST4: the product manager, packaging management, the information officer (a special post according to the pharmaceutical law), the printer, the packaging department, and quality control. "Today, the entire process is system-based," says Anja Walliser. "Instead of communicating by email, which required a high degree of coordination effort, responsibilities are now clearly defined. All involved see in their Task Viewlet what they should do next. The individual workflow steps are connected to different release statuses."

Simplified Layout Creation

The templates and master copies for the packaging materials for various pharmaceutical forms, dosages and product sizes of medicinal products are created with the layout program Adobe InDesign® and controlled in SCHEMA ST4.

PROJEKT- HIGHLIGHTS

- **Document types:**
Labels, Boxes, Package Inserts, Tube Labels
- **Output Formats:** InDesign, PDF
- **Parameters:**
7000 Packaging Materials,
1000 Publication Resources InDesign,
450 Images, 1500 Barcodes, 70 Die Cuts
- **Users:** 25 Users

In addition, SCHEMA ST4 controls the "filling" of the master copies with content and text. Thus errors can be avoided and manual text entry omitted. The interface between SCHEMA ST4 and Adobe InDesign® was implemented in cooperation with the media specialist and SCHEMA partner Wachter GmbH.

In SCHEMA ST4, metadata defining the point in the template the text or image should appear is stored along with the information about the medicinal product. In addition, a Task Viewlet provides the media designer with relevant information for the creation of the packaging.

With SCHEMA ST4, all tasks involved in creating packaging are represented in one system, optimally supporting Weleda in complying with quality requirements and legal guidelines for pharmaceutical drug safety. "With SCHEMA ST4 we were able to efficiently implement our goal of consolidating and restructuring the workflows for creating pharmaceutical product information. In particular system-based release processes ensure a high degree of process safety," Anja Walliser summarizes. "We are already thinking about using SCHEMA ST4 for the creation of packaging and product information for our natural and organic cosmetic products. And our colleagues from Switzerland have also shown interest in the system."



SCHEMA – Complex Documents Made Easy.

SCHEMA GmbH was founded in 1995 in Nürnberg and today has around 100 employees.

SCHEMA ST4 is an XML-based editing and content management system, offering extensive features for all aspects of the creation, management, translation, quality management, publication and distribution of product information of any kind. SCHEMA ST4's scalability makes it suitable for small editing teams as well as for company-wide solutions for information logistics. SCHEMA ST4 can be used as a standard product or a customer-specific solution. With the SCHEMA Content Delivery Server, information can be distributed intelligently to all common platforms, independently of SCHEMA ST4.

Our products and solutions are successfully deployed across various branches of industry to simplify 'complex documents,' including technical documentation, software documentation and help systems, catalogs, labeling for pharmaceutical companies, training material, solutions for specialized publishers, contract and bid management. SCHEMA ST4 is based on Microsoft .NET technology with Windows and web clients, and can easily be integrated and deployed into modern IT landscapes, as it supports the entire bandwidth of documentation standards (XML, XSL:FO, DITA, etc.). SCHEMA ST4 offers a broad line-up of interfaces (XML editors, MS Office, Adobe CS & FrameMaker, SAP, etc.). SCHEMA is proud to be part of an active network of renowned partners, as this enables SCHEMA to offer specialized solutions for its customers as well.

Among the many customers already using solutions based on SCHEMA ST4 are: ABB, Agilent, Avaloq, Bosch, Boehringer Ingelheim, Bundesanzeiger, Carl Zeiss, Daimler, Deutsche Bundesbank, General Electric, Hewlett Packard, Lindauer DORNIER, MAN, Miele, Reifenhäuser, Roche Diagnostics, Schaeffler Gruppe, Siemens, Österreichische Bundesbahnen, Philips, STOLL, T-Systems, Voith and Wolffkran, and many more.

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