



excipient weighing in tablet production

SECURE DATA FLOW IN THE PRODUCTION OF PHARMACEUTICALS

CIDEON Conversion Engine and Output Management at Corden Pharma

In order to be compliant with the strict standards in the pharmaceutical industry, the contract manufacturer Corden Pharma implemented a company-wide document management based on SAP DMS. CIDEON Software was responsible for the complex tasks of conversion, collaborative process and output.

When a customer picks up tablets for high blood pressure at the pharmacy, the tablets have already been on the move for a while: the active ingredients are produced in hermetically sealed facilities, purified and ground to powder. The ingredients are weighed according to a recipe and production regulations, mixed with others and pressed into a form.

Finally the tablets or capsules are packaged initially in blisters, tubes or glass bottles. The majority of finished tablets come in push-through pill packs or blister packs, so that the patient can remove one at a time. Together with the insert they are packaged in folded boxes and finally make their way after final approval via the pharmaceutical

wholesaler to the pharmacy. Between receiving and distribution there are about 20 separate steps, which depending on complexity, can take up to several weeks.

All production steps are monitored and documented continuously by quality control. A batch number is stamped or imprinted on every folding box and blister pack. This ID number is carried through the entire process including the logistic chain and enables the seamless tracking of a medication, as required by the strict regulations of domestic and international controlling authorities.

The Beginnings

Corden Pharma solved this business critical task with a well-thought out document management in SAP and the CIDEON solutions Conversion Engine and Output Management. At the Plankstadt location near Heidelberg there are about 20,000 active documents with up to 100 pages each in the system, of those many must be revised regularly.

Approximately 120 employees have user rights to author documents, 30 have approval rights and another 40 employees have read-only access. They come from all departments in the company: from receiving to the lab, quality control, production, packaging, warehouse and shipping.

In industry jargon one speaks of GMP relevant documents, which require the highest security standards. GMP stands for Good Manufacturing Practices and refers to documents, that originate from the production and trade of medical products for humans and animals which are produced in the EU.



The production facilities in Plankstadt near Heidelberg are an important location for Corden Pharma. Photo: Corden Pharma

The solution at Corden Pharma converts up to 300 updated GMP relevant documents and performs 160 print jobs and more on a daily basis. “We are very happy with the system”, said Dr. Georg Schwarz, project manager at Corden Pharma GmbH. It wasn’t necessarily our expectation considering the circumstances: Selection and implementation of the new system including the migration of 30,000 documents had to be completed within seven months. “It took several weeks to validate the migrated data”, according to the system administrator.

Motivation for a new System

The ICIG group took over the location, which led to the replacement of existing information technology. “After only eight months – driven by the separation from the existing system – our old document management system was history”, recalled the project manager. “This task is essential for our survival. Therefore a new solution was needed urgently.”

SAP DMS was selected, because Corden Pharma uses the ERP System as a strategic platform. All that was needed was to add to the document management components and to migrate the legacy data, which was undertaken by the company’s own SAP specialists with the support of an external consulting firm.



*In the hermetically sealed Containment-Facility high-potency substances are processed up to a TLV of 0,001mg/m³ into tablet form.
Photo: Corden Pharma*

The CIDEON Conversion Engine which was installed, optimizes document flow, in that it allows for the seamless identification of documents throughout the entire lifecycle. The users can apply qualified electronic signatures and use the various tools to add comments and highlights to a PDF. Examples are the digital stamp or watermark, which ensure the exact identification and document status. Investments in additional Adobe licenses are no longer necessary, as CIDEON uses its own PDF Suite.

Output Management

CIDEON’s customized Output Management automated the output and distribution of all sorts of documents. At Corden Pharma these documents are specifications, forms or operating instructions, known as Standard Operating Procedures (SOP) in the pharmaceutical industry. The company must update many of these documents periodically. Every year there are 2,500 new versions, which the authors process in Microsoft Word and after approval distribute as a PDF to the appropriate colleagues. “Our Output Management ensures that colleagues always have the correct version”, said Dr. Georg Schwarz.

“Here not one step can be completed without documentation”, explained the project manager. As an example he mentioned a form used for the production department, a so-called manufacturing guideline, which is also used for the production of the aforementioned high blood pressure medication. There the manufacturing operator enters, for example, what amount of a particular ingredient he added, and signs off with his initials. The form then makes its way to the employee in the next step.



Overview of the packaging area at Corden Pharma at the Plankstadt location near Heidelberg. Photo: Corden Pharma

Flexible Modular Assembly System

What Dr. Georg Schwarz likes about CIDEON's Output Management is particularly the ease of use and the flexibility. So now there are only eight different print layouts, whereas previously there were over 65 variations. "We can combine single elements in a modular assembly system and use the combinations again in other places", explained the system administrator. The elements used range from the header with a digital stamp for the scope to the listing of approvers including the date.

Furthermore all setting copies are applied from the inventory 1:1, so that format adjustments are no longer necessary, such as changing the page margins. "It may appear at first glance that this is not a big deal. When you have to go through tens of thousands of documents, it adds up", emphasized the project manager.

Special requirements for the print management are illustrated by the batch documentation. Basically it is a question of the batch number, which Corden Pharma prints on Blisters and folding boxes. The number acts as a reference, so that in if necessary a medication can be easily tracked. The manufacturer must store the appropriate documentation for 30 years. "It is the most important document in our business", stated the system administrator. In order to automate this task to the greatest possible extent, CIDEON integrated its Output Management also in the specific production control and planning at Corden Pharma. This makes it possible, for example, for a medication's batch documentation to be generated directly from the production order. This has the significant advantage, that the batch number functions as a link between the production process and the imprinted end product. By means of the batch the documentation happens seamlessly in the SAP ERP System.

Practical Experience

The solution has been in place now at the Plankstadt location since October 2008. Dr. Georg Schwarz clarified the solutions performance with a practical example: When an inspector from the licensing authorities asks to see a particular document during a routine audit, it must be available within 15 minutes. The special requirement is to find and print the desired PDF, from a collection of 20,000 active and 10,000 archived documents.

“We have had a very good experience with CIDEON”, summed up the project manager. And when they needed assistance, the software producer supported them via the Hotline or with remote access: “I have seldom seen a Helpdesk that was so competent or that has responded so quickly.”

Corden Pharma GmbH

The company operates as a legally independent company within the Corden Group and has belonged to the International Chemical Investors Group since 2008. ICIG is a private investment group and has acquired more than 15 independent mid-sized Chemical and Pharmaceutical companies.

Corden Pharma looks back on a 25 years of successful history in the areas of ingredient purification, production and packaging of solid and liquid medicinal products on behalf of various suppliers. Additionally the company is active in the production and distribution of clinical investigational new drugs and supplies customers worldwide in more than 30 countries.

The production of tablets takes place in the so called Containment-Facility, which processes high-potency substances in a sealed system up to a TLV of 0,001mg/m³. The facility is therefore well-suited for the production of hormones and hormone blockers.

Due to the positive response usage of the system has expanded: In December 2009 the starting shot for the second Corden Group location in Caponago, Italy was fired. The project was completed within 2.5 months and approximately 12,000 legacy documents were migrated.

Corinna Scholz



The contract manufacturer has the most modern facilities for tablet production at their disposal. A machine for the production of hard gelatin-capsules is pictured here. Photo: Corden Pharma

At a Glance



Company:	Corden Pharma GmbH, Germany and Italy
Challenge:	Generation of a document management with the highest possible security standards
Solution:	SAP DMS and CIDEON Conversion Engine and Output Management
Advantage:	Automated output and distribution of documents, convenient processing in PDF format including electronic signature and stamp, little customization effort for migrated documents
CIDEON Deliverables:	Implementation, Customization, Enhancement, Training



Lab technician at Corden Pharma in front of a facility for high performance liquid chromatography, with which one can measure the purity of active ingredients. Photo: Corden Pharma