



Fermentation Plant Designed in CADISON®

TOOL FOR FAST TRACK

Whoever is responsible for plant documentation, can easily have grey hair unless he uses an object-oriented engineering tool that simplifies the task assigned to him.

In the pharmaceutical and biotechnological industries, the regulatory requirements for plant documents are particularly high. The time and personnel efforts required for creating these documents are equally intensive. In order to minimize the project duration and effectively adapt to project modifications, Pharmatec (a Bosch Packaging Technology Company) uses the engineering tool CADISON® not only for design and engineering but also for creating the qualification and plant documentation as per their customer standards.

Integrated Design and Engineering

Earlier, the Pharmatec engineers worked with the AutoCAD as a CAD platform for plant design and independently created the plant documentation with MS-Office. Since the projects were highly complex and the requirements of customers or authorities were stringent, in 2007 the company started looking for the most efficient engineering tool to meet their needs. The multi-disciplinary approach of CADISON® along with its object-oriented database convinced the engineers to go with CADISON®. As it is possible to integrate all design phases through the object-oriented data models for the different application areas, it saves time and costs. Information can be obtained from the acquisition stage itself and is available for further project phases to all project team members. Thus, whether the engineering data for the project is generated first or graphical data, it is irrelevant.

Each change is automatically shown in all desired views and updated within the project; a redundant and thus costly data management process is completely omitted.

Since 2008, CADISON® is the essential engineering tool within Pharmatec. Dr. Tommy Kern is the coordinator today for working with this engineering tool in Pharmatec, in addition to his daily work in handling

projects for process and bio-systems. His goal primarily is to standardize and harmonize designs using CADISON®. Soon, Pharmatec had the standard templates available for designing frequently re-used systems, which made the design and engineering process faster and brought the quality of design to a higher level. "We have implemented many such standards in CADISON® that increased the productivity as well as the quality of our project work. Our engineers are working virtually in the project to take into account the pipe classes and suppliers preferred by our customers" says Dr. Kern.

For this, at first it was necessary to adapt the standards (i.e. the object models provided in the software) to the requirements of Pharmatec. This customization began with the support from the software consultants of ITandFactory, today it is mainly undertaken by Pharmatec on their own. Torsten Große, Head of Design, is convinced that a huge potential lies in the use of standards. "An engineer familiar with CADISON® can execute his projects in a much faster and reliable way by using the defined templates."

Internal Revision Management is Certainly Beneficial

In a company-wide project within Bosch Packaging, the standardization of customer documentation as per new corporate design was achieved within the pharmaceutical product

range. Originally, the customer documents were created from different data sources that lead to inconsistent header and metadata, discrepancies in layout and formatting between the documents. The aim of the project was that all documents come from the same source. The data and also the templates should be centrally maintained in a database and finally, multiple languages should be implemented (at least German and English is mandatory).

This project is made for CADISON® : The customer documentations were added step-by-step as report templates to the CADISON® database. After a year (as of spring 2014), already more than 70 customer documents were converted, resulting in a significant improvement in quality. Additionally, the preparation of the reports are now much faster as the customer document structure is fully mapped in the CADISON® report selection list. The data is centrally stored in the CADISON® project and acquired via report generator. "The documents are completely formatted for the direct transmission to the customer, reviewing is not required" explained Dr. Kern.

The use of internal revision management proved to be very advantageous. Many documents remain in CADISON® during the project period and can be revised using CADISON® revision management and logic analyzer feature. Revision date and all revision remarks are stored in CADISON®.

Torsten Große expressed that the decision for CADISON® was correct: "Since we started working with this tool, the

expenses for documentation (for e.g. in the technical department) has significantly gone down, because we could access a consistent database."

During project management, Pharmatec works with full-time project managers, who are trained in Robert Bosch and qualified as per PMI (Project Management Institute) and ISPE Project Management systems engineering. The project is executed with optimum (risk-based) target achievement and is documented consistently, such that the traceability is ensured.

Integration Simplifies Fast-Track-Projects

More and more customers are using fast-track-projects in the pharmaceutical and biopharmaceutical industries, where a tight schedule must be adhered to with pressing deadlines. In order to meet complex requirements in less time and without errors, one needs a reliable database and an integrated data system. Thus, CADISON® is the platform for creating and managing documents (concept creation, development, design, procurement, assembly, start-up documentation, qualification, validation documentation and transmission of documents to the customers) which entirely enables all aspects of project management with higher quality. Even after delivery, the documentation is required for maintenance service and expansions and needs to be maintained. Thus, it remains up-to-date over the entire life cycle. The designer saves resources, time, cost and improves the quality.

Software with Additional Value

REPORTING IS A CHILD'S PLAY

That's why CADISON® is suitable for the technical documentation in pharmaceutical plants. All positioned valves and equipment are automatically provided with unique codes (DIN, KKS, etc). Their numbering system can be easily adjusted as per company specific requirements. The texts are aligned as per standards and are managed in their own designation layers. The valves inserted in pipelines take the corresponding specification parameter of the pipeline. Free designations can be additionally created at any time, wherein all properties of the object are executed as fully associative texts. The designation masks are available for simple bill of material or complex designations. They are directly connected with the object and are immediately/dynamically updated with changes.

The reporting of CADISON® is powerful : All data created with the P&ID-Designer or Project-Engineer can

be displayed by the integrated report generator in different forms and formats. For instance, this could be a valve list or a prepayment in order to be able to calculate the necessary numerical data. All reports can be revised and have release mechanism. They are directly saved within the project. All documents can be automatically provided as PDF.

An important advantage for Pharmatec : The designer can store the documents in the databank as standards and in the structure exactly in the form as the customer wants them. "In this way, our engineers work with precision", said Dr. Tommy Kern. CADISON® is particularly efficient in tracking documents, even in case of revisions, which is vitally important in the pharmaceutical industry: "Our customers demand complete traceability of revision work."