

DAIICHI SANKYO EUROPE GmbH, Munich, Germany

## Validated and Highly Available: SAP Hosting for the Pharmaceuticals Industry

»An important basis for our international growth strategy is an efficient IT system. With itelligence as our new hosting partner, we are strengthening this basis further. What particularly impressed us was the high level of quality that itelligence has now achieved in fully validated SAP system operation in the pharmaceuticals environment.«

Waldemar A. Sabais, DAIICHI SANKYO EUROPE GmbH

**itelligence**

Validated SAP system operation in a pharmaceutical environment

## Not only medicines are measured by their effectiveness, IT systems are too!

A clear course has been set at pharmaceuticals company DAIICHI SANKYO: Further global growth – that is the primary objective for the future. The company ultimately plans to develop into a “global pharmaceuticals innovator”. In particular, at its European sites the DAIICHI SANKYO EUROPE GmbH subsidiary plans to drive forward the group’s businesses with innovative products – by providing for stronger structures and expanding in-house development activities.



### **DAIICHI SANKYO EUROPE GmbH**

Researching and marketing innovative medicines to provide for a healthier future. That is the primary objective of global pharmaceuticals company DAIICHI SANKYO, headquartered in Tokyo. The company also ranks among the best represented Japanese pharmaceuticals producers in Europe. The European headquarters in Munich operates successful branches in eleven European countries.

DAIICHI SANKYO EUROPE maintains its own production facilities in Pfaffenhofen (Germany) and in Altkirch (France). The research activities focus on the areas of heart/circulation, hematology, diabetes, anti-infectives and cancer. Based on this research, DAIICHI SANKYO intends to develop medicines that are considered best in their class or establish a new agent class. In Europe alone, around 1,800 employees, of whom 1,050 work as pharmaceuticals representatives, participate in the company’s success. They generate local net sales of EUR 501 million in 2007.

An essential requirement for this is the use of an integrated IT system that supports all the processes that arise. However, as IT systems and their operation are quality-relevant components of the manufacturing process for pharmaceutical products, European and US supervisory authorities require that the systems employed are validated accordingly. Therefore, even processes in the data centers must comply with the stringent statutory requirements of the US pharmaceutical regulatory agency, the Food and Drug Administration (FDA). These requirements played a very decisive role in the selection of a suitable hosting partner.

itelligence thoroughly impressed the decision-makers at DAIICHI SANKYO EUROPE, as the full-service-provider in the SAP environment is not only able to design the entire architecture of a validated SAP system environment in line with the strict ‘Good Manufacturing Practice’ (GMP) guidelines, but also to score on the SAP Global Partner Hosting front: Before the go-live, the data center in Bautzen, together with its tools, server components and IT processes, underwent the demanding GMP audit. All outsourcing and hosting processes were subjected to close scrutiny during the audit. The result: itelligence meets all the criteria for validated data center operation.

### **Optimized Processes for the Pharmaceuticals Group**

So the joint project could now get underway – the itelligence team conceived the future system landscape together with the project team at DAIICHI SANKYO EUROPE GmbH. The landscape largely consists of the ECC 6.0 release of the SAP ERP system based on the SAP NetWeaver system architecture, which, with the aid of the SAP Manufacturing Execution System (MES), is connected to the manufacturing and production process via standardized interfaces. An SAP BI system is also in operation and further interfaces with subsystems



for the areas of production and shipping as well as for the subsidiaries' logistics operations were implemented.

All the DAIICHI SANKYO EUROPE systems are subject to the strict requirements of the pharmaceuticals industry, which are managed and monitored at itelligence via SAP Solution Manager – a centralized solution for incident, problem and change management based on the requirements of ISO 20000 – while in operation.

During the course of the project, the systems and tools employed by itelligence were continuously examined in line with what is known as the V-Model to determine whether they also met these requirements. This model, which is well known in the context of IT projects in the pharmaceuticals industry, defines a process-oriented, structured and goal-oriented approach to the project. Based on the guidelines, the system is developed step by step and continually examined for possible risks. And these measures continue even after the solution has gone live; all the



Daiichi-Sankyo  
Global Pharma Innovator

**Name:**  
DAIICHI SANKYO  
EUROPE GmbH

**Industry:**  
Pharmaceuticals industry

**Products:**  
Medicines

**Employees**  
1,800 employees, of whom  
1,050 are pharmaceuticals  
representatives; 370 SAP  
users

**Sales:**  
EUR 501 million in 2007

**Headquarters:**  
Munich (European HQ)  
Tokyo (corporate HQ)

**Branches:**  
In 11 European countries

processes are optimized further in line with the V-Model and with the aid of the SAP Solution Manager, which is validated as well.

### Outsourcing Guarantees High Availability of all Systems

And so itelligence now operates a three-level, highly available ERP and BI system landscape for DAIICHI SANKYO EUROPE GmbH at its in-house data center in Bautzen. The landscape takes into account all the statutory regulations and industry standards in accordance with Annex 11 of the EU GMP Guide, 21 CFR Part 11, the "Good Automated Manufacturing Practice" Guide (GAMP) and the GAMP Good Practise Guide "IT-Infrastructure Control & Compliance".

All the measures are also closely geared to the GAMP industry standard, in particular, GAMP 4.

And the 370 users can also count on itelligence at any time when it comes to reliability: The employed systems have a high level of availability at 99.5%. This is also ensured by the shadow database of the live SAP ERP system, among other things. And should a failure still occur despite all these measures, itelligence guarantees that the maximum downtime will not exceed two hours at any one time.

So DAIICHI SANKYO EUROPE has achieved a great deal with itelligence – and is reaping the benefits of the validated SAP system operation!

### Facts & Figures

**Solution:** System structure of a validated SAP system environment

**Project duration:** 9 months

**Applications:** Operated from the data center: SAP ERP 6.0, BI 7.0, SAP Solution Manager, SAP HCM planned for the end of 2008

**High availability scenarios:**  
Shadow database for the live SAP ERP system

#### The advantages:

- SAP system structure in line with the GMP guidelines
- Validated SAP system operation in the pharmaceuticals environment
- High availability through outsourcing of 99.5%
- Maximum downtime of 2 hours at any one time

