Reference Project

Bayer HealthCare

Bayer AG is a global research-based and growth-oriented enterprise with core competencies in the fields of health care, nutrition and high-tech materials. Bayer HealthCare, a subsidiary of Bayer AG, is one of the world's leading innovative companies in the health care and medical products industry.

The company combines the activities of the Animal Health, Consumer Care, Diabetes Care and Pharmaceuticals divisions. The company's pharmaceuticals business operates under the name Bayer Schering Pharma AG.

Bayer HealthCare's aim is to discover, develop, manufacture and market products that will improve human and animal health worldwide.

www.bayerhealthcare.com

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Uncompromising Quality

CAPA and Workflow Management in the Heavily Regulated Pharmaceutical Industry

As a globally operating pharmaceutical group, Bayer HealthCare is expected to structure their production processes in a way to ensure compliance with cGMP (current Good Manufacturing Practice) regulations. The highly regulated pharmaceutical industry depends on the compliance with the regulations set forth by the US Food and Drug Administration (FDA) and other national regulatory agencies. A very important part of the cGMP concept are the Corrective and Preventive Actions (CAPA), which Bayer HealthCare manages with the help of an IT system from Werum.

CAPA describes the approach to take actions to effectively tackle deviations and errors in the manufacturing process as well as quality deficiencies later on in the life cycle of products. For this purpose, deficiencies are systematically identified, analyzed, consistently removed and archived. This aims at increasing the quality effectively and in a sustained manner so that the occurrence of deviations is largely prevented in future. The FDA conceived CAPA in the framework of their Quality Systems Inspection Technique (QSIT) and established this regulatory instrument at first in the medical devices industry. When it turned out that CAPA had evidently contributed to lower the error rate significantly, the FDA extended the concept to the pharmaceutical industry.

Development History

In the past, several of Bayer HealthCare's sites relied on self-built proprietary CAPA systems. After an in-depth analysis, the company decided that the establishment of a central solution on an ERP level did not appear very promising. However, the request for a uniform, paperless, user-friendly and flexible solution became more and more pressing and finally resulted in the Company looking for a new CAPA system. In a first step it was intended to harmonize the deviation management in seven production facilities at the German Wuppertal-Elberfeld (active ingredient production) and Leverkusen (solids production) sites.

After careful evaluation of the offers Bayer HealthCare decided on Werum's solution and thus chose a provider who – even though the product development was at that time still in the initial phase – was convincing by its pharmaceutical expertise and business experience with Bayer.

„Werum was awarded the contract not only because of its competitive price-to-performance ratio but also because they offered a solution that would meet our very demanding criteria and guaranteed reliable and lasting support", said Michael Meske, Project Manager at Bayer HealthCare.

Michael Meske

Another decisive factor was the long-standing and successful relationship between Bayer HealthCare and the Lüneburg-based German software house, which had established an atmosphere of confidence and mutual trust. Already since the early 1990's Bayer HealthCare uses various modules of Werum's Manufacturing Execution System (MES) PAS-X.

Customer-driven Product Development

In parallel to the development of the PAS-CAPA product, Werum executed the DEV@COM (Deviation and Complaint) project for Bayer HealthCare. Bayer Technology Services, the central service provider of the Bayer Group responsible for planning, executing, controlling and optimizing production facilities and also Werum's MES implementation partner, was right from the start involved in the project. Together, both companies designed and implemented DEV@COM based on the project specifications defined by Bayer HealthCare. The result is a cGMP-compliant application with the following features:

- Paperless deviation management, complaint management and corrective and preventive actions in one central application
- Rights and role parameterization with clear separation between different user groups
- Browser-based dialogs
- Production facilities are each a logical unit (client) with their own access and master data management
- Manual data supply
- Electronic data acquisition in production facilities with just one MES
- Reporting and evaluation functions – both pre-defined and user definable – to create reports (such as with Crystal Reports)
- Mapping of workflows according to FDA 21 CFR Part 11 – such as Audit Trail or ERES (Electronic Records Electronic Signatures)

Design and Implementation Concept

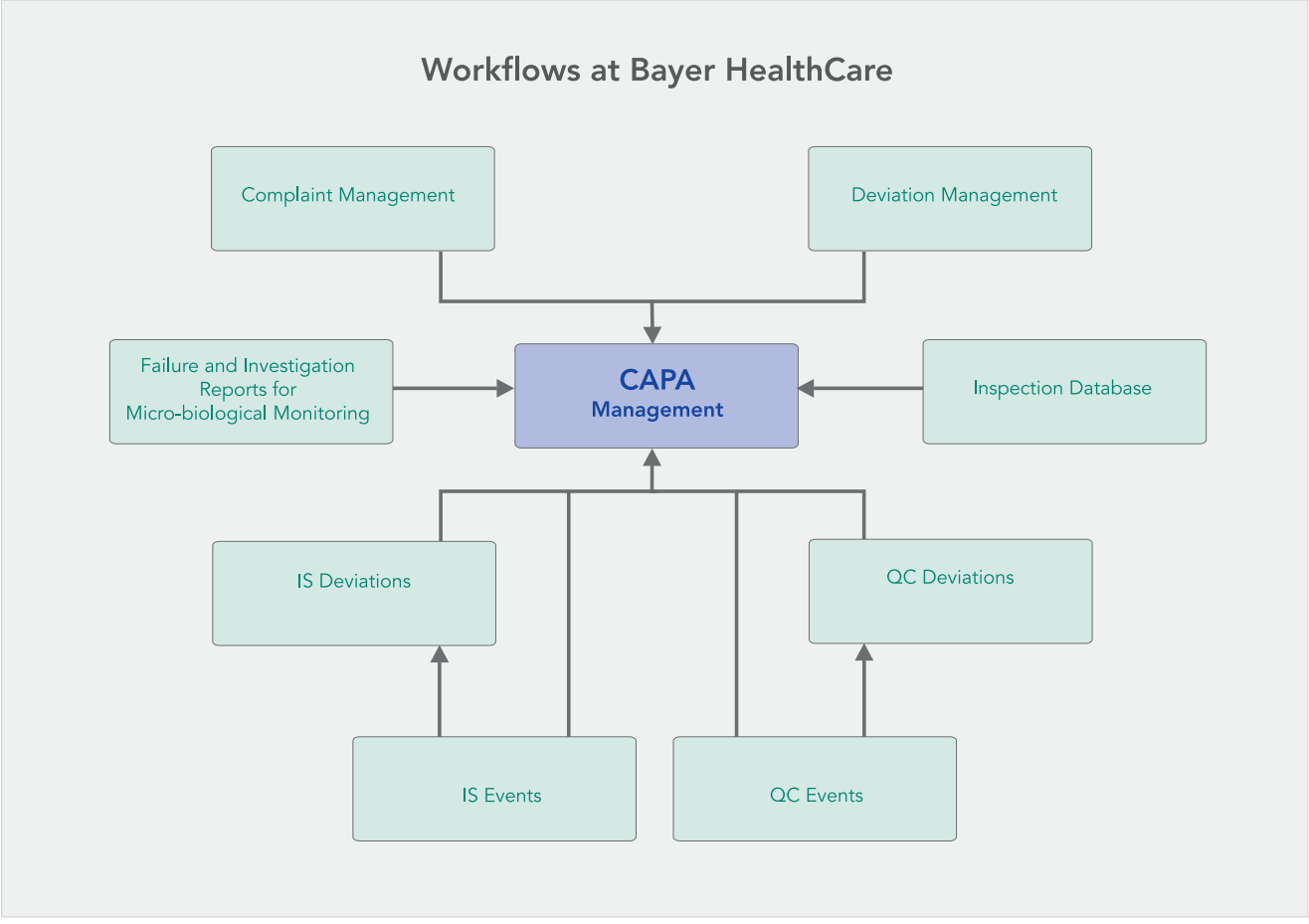
DEV@COM builds upon the Java EE-based component framework JCoffee® (Java Component Framework for Enterprise Environments.) JCoffee® is a development from Werum and closes the gap between individual service-oriented application software and the very powerful, but rather complex base technology: Java EE (Java Enterprise Edition.)

JCoffee® provides DEV@COM with central basic functions, such as user, rights and master data management, as well as audit trails and electronic signatures.

Workflows

The integrated PAS-CAPA workflow engine is one of the core components of DEV@COM. It can be used to map different business processes (workflows.)

A number of processes for the form-based editing, tracking and evaluation of transactions can be defined and configured with the help of this workflow engine. During these activities the user is guided by the system and supported with information, planning, reminder, and escalation functions.



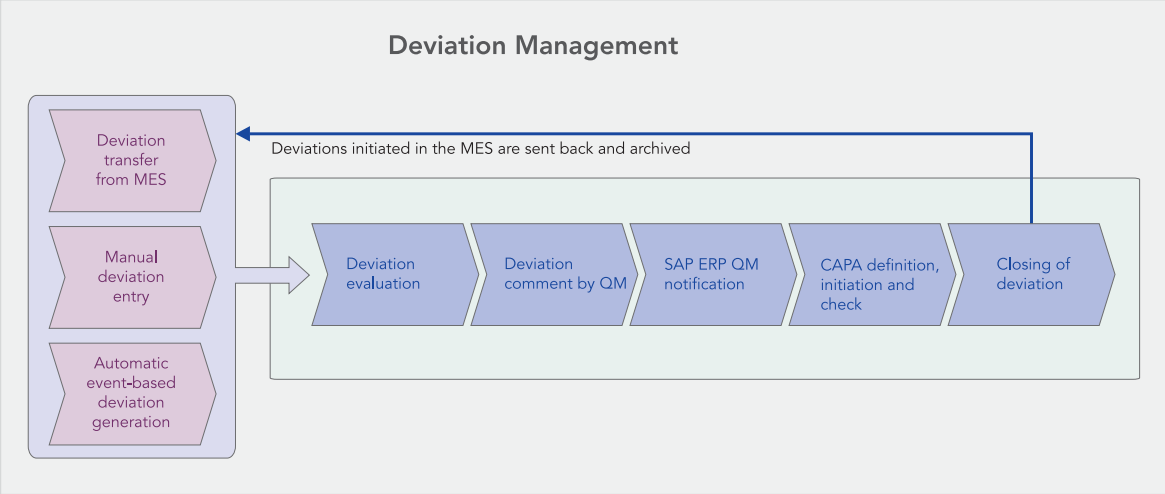
Building upon the workflow engine, three central workflows were initially established in the first project stage:

Deviation Management is used down on the shop floor. With the help of web-based forms the user can record and identify deviations. In subsequent steps, the user can, for example, evaluate these deviations, make them known to others, start investigations, or initiate corrective actions.

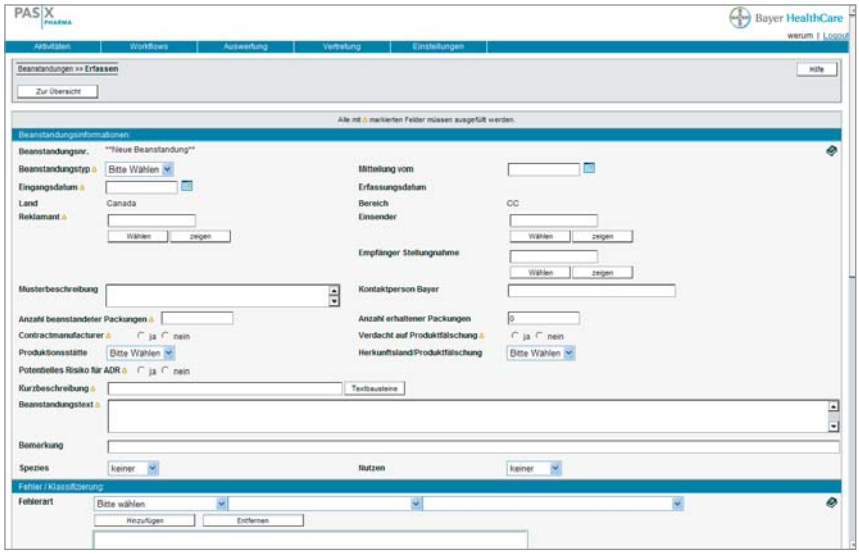
Complaint Management deals with already manufactured products about which a dealer or end consumer has filed a complaint. The user is provided with similar functionality as in the deviation management application. But in addition it is also possible to generate automatic response mails to respond to complaints.

Measures Management enables the gapless execution, monitoring and documentation of measures resulting from the occurrence of deviations or complaints.

In the subsequent time period DEV@COM proved very successful in practical use. Bayer HealthCare identified high potential for other fields of applications and commissioned Werum to further expand and advance DEV@COM in a consistent manner. This has, so far, lead to the integration of six additional workflows:



IS (Information System) Events is concerned with malfunctions in the IT environment. If, for example, a server fails, this may not only have an impact on the quality of the product, but at the same time also cause an incident on the shop floor. For this reason, in the pharmaceutical industry similar strict regulations as those applicable to production processes also apply to information systems.



DEV@COM Screenshot

IS Deviations is put into effect when an incident in the IS Events workflow becomes so serious that it has to be classified as a deviation.

Failure and Investigation Reports for Microbiological Monitoring tracks conspicuous characteristics in the micro-biological environment. This involves, among others, all hygienic issues as well as auxiliary materials necessary for pharmaceutical production, such as demineralized water. During this monitoring, limit values may be exceeded. These limit violations are either Alert or Action Level exceedances and have to be tracked accordingly.

QC (Quality Control) Events centers the focus on the quality control process. All inconsistencies and deficiencies relating to quality control are identified in this workflow. Examples would be the storage of residue samples at wrong temperatures or the failure of measuring devices such as a chromatograph.

QC (Quality Control) Deviations takes effect in much the same way as the IS Deviations workflow, i.e. when a malfunction in the QC Events workflow results in exceeding a critical limit and thus becomes a deviation.

Inspection Database does also support quality control and archives audit data in a GMP-compliant manner. This data may result in observations that in turn may lead to appropriate measures.

System Environment

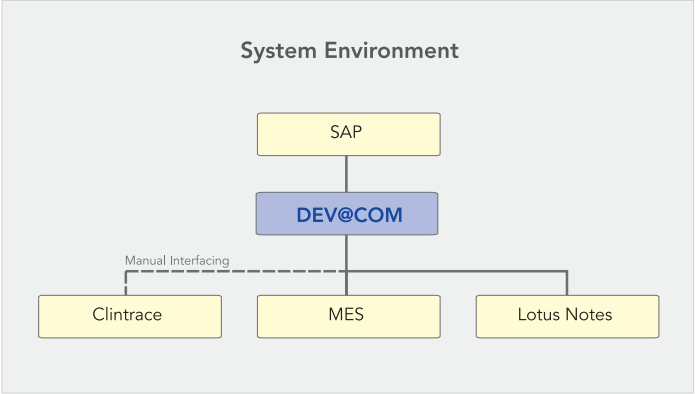
A crucial factor for Werum was the integration of DEV@COM into the existing system environment at Bayer HealthCare. In this respect it has shown to be an advantage that PAS-X has already been used for several years at the Wuppertal-Elberfeld and Leverkusen sites. This made it possible, for example, that deviation data can be transferred online from the MES to DEV@COM, where it is then processed. An equally essential characteristic is the direct linkage with the ERP system. Via an interface, approval and use decisions, master data and material product data from SAP are transferred to subordinate hierarchy levels.

In addition, Werum also integrated Bayer HealthCare's email system Lotus Notes as well as several shop-floor level applications, such as Clintrace, into DEV@COM.

High Acceptance Among All People Involved

DEV@COM has found high acceptance across all users. This is also confirmed by the fact that new workflows are continually added, which are often suggested and inspired by individuals from within the organization. „We believe that also in future there will be good potential to expand DEV@COM to new areas within the company", said Michael Meske to underline the success of the system. The controlling authorities do also respond favorably and positively to DEV@COM.

Bayer HealthCare employs several DEV@COM modules on a worldwide basis. After the acquisition of Schering AG in 2006 Bayer HealthCare rolls out DEV@COM also in the newly formed Bayer Schering Pharma division. DEV@COM offers all traditional advantages of a central IT system. The processes are harmonized and can be carried out in a more transparent way. This ensures that Bayer HealthCare can continue to comply with ever increasing GMP requirements. The system controls the user through an electronic deadline management feature and alerts him or her whenever the expected processing time is exceeded, so that processing is consequently much faster. This, in turn, lowers the error rate.



Interfacing between DEV@COM and BHC System Environment

Features of DEV@COM / PAS-CAPA

Full compliance with GMP and FDA 21 CFR Part 11
Paperless, flexible and user-friendly solution
Library of preconfigured business processes (workflows)
Extendable with new business processes
Easy integration into the existing system environment
Harmonized business processes across multiple sites

Benefits in terms of business process execution

User guidance during process execution
Time/deadline tracking and monitoring
Easily interpretable and understandable processing status
Shorter response times
Reduced processing times
Lowering of the error rate

Workflow Management with PAS-CAPA

In the course of the successful DEV@COM project Werum brought the PAS-CAPA product to the market. PAS-CAPA is a universally usable web-based software tool for workflow management in pharmaceutical operating environments where the focus is primarily on „CAPA-Management." It can be employed as a PAS-X module or as an independent solution - optionally provided with an interface for connecting to an alternative MES system. With PAS-CAPA, Werum offers an extendable out-of-the-box solution with a continuously growing number of pre-configured workflows.

Close Partnership between Bayer HealthCare and Werum

Since 2007 Werum has a frame agreement for providing MES systems to Bayer HealthCare. The fruitful and successful relationship of the two companies dates back to the early 1990's. Bayer used Werum's Manufacturing Execution System PAS-X for the production of Aspirin at the then newly constructed Bitterfeld site in the East of Germany. Later the system was also deployed at the German sites in Wuppertal-Elberfeld, Leverkusen and Weimar.

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Werum Software & Systems

Werum Software & Systems is one of the worldwide leading suppliers of Manufacturing Execution Systems (MES) for the pharmaceutical and biopharmaceutical industry. Thirteen of the world's top 20 pharmaceutical companies and leading biotech companies use Werum's standard product suite PAS-X to run their manufacturing business.

Werum's solutions and services range from software consulting, creation of functional specifications, and software development to turn-key delivery of integrated and validated Manufacturing Execution Systems. A global partner network ensures reliable local support services all over the world.

With U.S. headquarters in Parsippany, New Jersey, world headquarters in Lueneburg (North Germany), regional offices in South West and West Germany, the IT company currently employs more than 300 highly qualified experts.

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