

BSP

BSP Solutions GmbH

Smart Places

For the chemical and
pharmaceutical industries



Carry out your daily
GxP-relevant tasks and processes
easily, efficiently and effectively
in SAP® – paperless, of course.

SAP® can do more.

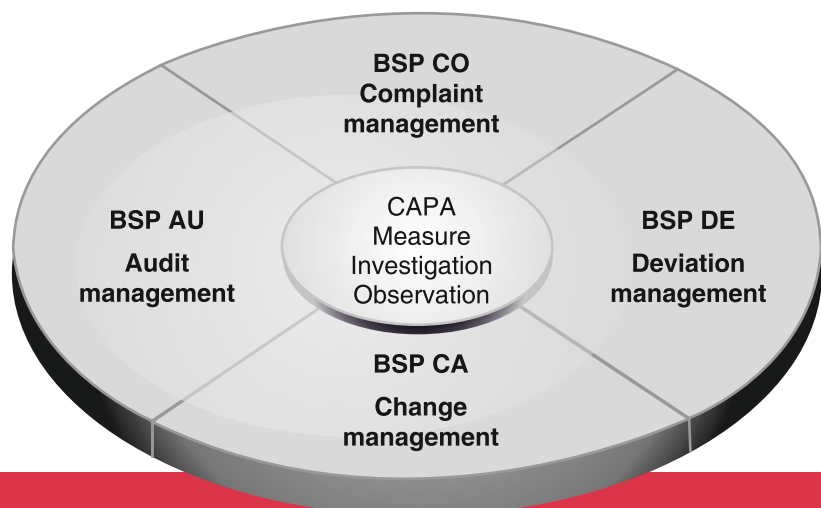
GxP-Processes

Paperless in SAP®
Easy, fast and reliable

Your daily routine could soon look like this

- You work more efficiently and have less work – despite increasing requirements
- You can reliably observe specifications, guidelines and agreements
- Documents are created quickly and distributed to the right recipients
- Approvals and signatures are issued more quickly
- You have quick access to the desired documents during audits and inspections
- You have an integrated compliance and risk strategy at your disposal
- Your data are made available in SAP® automatically and can be used comprehensively
- Process participants receive direct access to working documents via system notification
- All documents such as reports, statements and approvals are presented together in a clear, uniform file structure
- Seamless integration into an existing SAP® landscape enables a comprehensive quality management process representation

With Smart Places you work easily, efficiently and effectively.



Smart Places

Reliable good quality
for all requirements

BSP Smart Places electronically control quality assurance processes such as deviations, complaints and the involved measures and changes in SAP®. Thus, for example, an integration with the SAP® logistics application ensures that no open deviations exist for a batch release. Smart Places consist of several modules that cover all GxP tasks and processes.

BSP AU - Audit management for the carrying out of internal and external audits. BSP AU assists you with inspection processes such as the observance of licensing agreements in the context of clinical studies. Complete SAP® integration makes possible the integration and thus the supplementation of the SAP® Audit Management already included with SAP® Standard. Deviations occurring during an audit can be directly created in BSP DE by the interaction of the Smart Places modules.

BSP CA - Change management controls and documents changes. The current status of the documentation is immediately available in the system without gaps. Thanks to the complete integration, you have access to deviations that occur during the change or have caused the change. In the event of official audits, you have all of the data necessary for the implementation of official requirements at your disposal.

BSP CO - Complaint management enables the secure and efficient handling of customer complaints. Deviations or changes are created directly from the complaints and are linked to these. This makes it possible for you to react quickly to complaints and satisfy the requirements of product safety guidelines. Thanks to complete SAP® integration, SAP® master data such as business partner and product data are available in BSP CO.

BSP DE - Deviation management for the representation of the entire deviation process. Unplanned and planned deviations are controlled by the system without gaps. The electronic representation of inspections and measures, such as a CAPA (corrective action/preventive action), improves compliance with internal and official deadlines. Changes arising from a deviation can be created directly. You can retrace the resulting activities at all times.

Safe. Efficient.

With BSP Smart Places
based on SAP® Technology

With Smart Places for GxP processes, the user works entirely in SAP®. He can jump from the Smart Places module to other SAP® transactions at any time and branch off into GxP modules. Access is controlled through authorisations. Activities are protocolled in their entirety.

Documents such as e-mails, MS Office documents, scanned documents and others can be directly filed in the process file. Created documents such as reports are automatically placed in the file. Deadline monitoring takes place supported by the system with automatic resubmissions. Processes such as authorisations or releases are directly initiated from the GxP application. Workflows and evaluations round off the package.

Convincing Advantages

Quick access to information

- Central filing of GxP-relevant documents for access independent of location and time
- Viewing of GxP processes directly from SAP® applications

Up-to-date and transparent

- Information is always current
- Transparency of content and compliance with deadlines

Reliability

- Observance of compliance guidelines
- Access rights

Automated processes

- Resubmissions, reminders
- File and document circulations for approvals and releases
- Electronic signatures
- Start and checking of GxP-relevant processes from the application (e.g. signature, approval, 4-eyes principle)

IT strategy

- Usage of the SAP® platform in a validated environment
- Seamless integration into SAP® applications



BSP Solutions GmbH
Antonstraße 2
D 72488 Sigmaringen

Phone +49 7571 645808-0
Fax +49 7571 645808-80

info@bsp-solutions.com
www.bsp-solutions.com