



## SAP Validation and GMP Compliance Services

GenBioCa has a validation solution for the life sciences industries. If you are newly implementing or planning an upgrade to SAP S/4HANA, whether on-premise, cloud or hybrid,

### The GenBioCa Advantage

Validation service is based on GenBioCa's extensive industry knowledge and expertise accumulated from years of experience with pharmaceutical, medical device and biotechnology companies. GenBioCa's SAP compliance service allows you to meet your obligations to both domestic and international authorities (e.g. BfArM, FDA, HPRA, MHRA, and TGA) in a timely and cost effective manner.

### Compliance Offering

As an alternative to manual, labour-intensive validation efforts, GenBioCa's validation service incorporates industry compliance best practices to include:

- Business Requirements model
- Validation Plan template
- Traceability Matrix
- Installation Qualification test scripts
- Operation Qualification test scripts
- Performance Qualification template
- Validation Summary Report template
- Full Maintenance Program

### Full Maintenance Program

Product Support is a maintenance program that assures validation documentation integrity for GenBioCa enterprise software compliance packages and deliverables. Updated documentation is provided in conjunction with regulatory compliance expertise that ensures an ongoing compliant environment. Collectively, our validation services, maintenance program and industry professionals combine to form a comprehensive SAP compliance solution.

### SAP S/4HANA Business Suite Compliance

SAP Business Suite 4 SAP HANA is an ERP solution that has been developed to take advantage of SAP's in-memory computing platform, SAP HANA. S/4HANA is the enterprise choice of leading companies in the pharmaceutical, medical device and biotechnology industries. Complex landscapes require expansive capabilities, and S/4HANA delivers a powerful solution with industry specific functionality to the Life Sciences, whether on-premise, cloud (public/private) or hybrid. SAP S/4HANA On-Premise is a deployment scenario where a company has its own server, database, applications and data centre.

Consequently, a company is responsible for maintenance when SAP releases any upgrades that need to be implemented and tested. On-premise is ideal for companies who need a high degree of flexibility when customizing their system and have the dedicated IT staff to support large-scale maintenance. SAP S/4HANA Cloud is fully managed option in which SAP handles the maintenance of the hardware, software and databases. The SAP S/4HANA Cloud provides an agile option for companies that are



rapidly growing and need a flexible platform. Hybrid options are also available that include operating S/4HANA in an Infrastructure-as-a Service mode.

### **Validating Your SAP S/4HANA ERP Solution**

Whether on-premise or in the cloud, software in the Life Sciences must be validated to meet the requirements of regulatory agencies. SAP S/4HANA complies with data privacy acts and industry-specific data protection legislation. Their compliant virus scan interface is dedicated to increase the security of your system. GenBioCa has the global regulatory expertise to deliver high-quality consulting services to Life Sciences companies.

Demonstrate to the FDA and other international agencies that your SAP software is compliant with our validation services, whether as an on-premise ERP or in the cloud.

### **The GenBioCa Assurance**

This SAP validation service assures you the maximum investment protection in your investment by providing the following primary benefits:

**Shorter Timeframes:** Our time-tested, field proven pre-packaged validation product certifies compliance in an optimally expedient and secure manner. This means you are able to accelerate the time-to-value of your commercial business software investment.

**Regulatory Agency Approval:** Properly validated solutions are more likely to avoid regulatory scrutiny in the form of citations and audits. These time consuming and disruptive events can pose a real business risk as it relates to Agency approval of new product introductions and brand acceptance in the marketplace.

Whether you are installing SAP for the first time, converting from a legacy system or applying a patch/upgrade, GenBioCa's expertise in validation services will help you manage your business risk quickly and reliably.