

## ERP Validation in Life Sciences

***With more than 10 years experience implementing and validating ERP systems, Business & Decision are the leading choice for risk-based and cost effective ERP Validation***

### ERP Systems and Life Sciences

In all sectors within Life Sciences Enterprise Resource Planning (ERP) systems continue to deliver great benefit in terms of business process improvements and their accuracy, reliability and repeatability. ERP systems also have a widespread impact upon a number of regulated business processes and are the subject of increasing scrutiny by various international regulatory agencies.

It is important that organizations owning ERP systems or considering acquiring new ERP systems ensure that these applications are implemented, maintained and supported in compliance with regulatory expectations.

### Validating an ERP System is Different

Using traditional methods to validate an ERP system can slow down the implementation and increase costs. The validation approach for an ERP system must recognize the unique life cycle approach used for such systems. These life cycles vary between ERP applications and between system integrators and are very different from the regulated company's standard validation life cycle.

The successful and cost effective validation of an ERP system requires an approach which recognizes the specific implementation model, the complexity of the project and the specific verification activities that are required to implement an ERP system in a manner that complies with regulatory expectations.



It is also important that the roles of the software vendor, the system integrator and the end user organization are fully integrated. Failure to align activities and responsibilities can increase costs and can compromise the validated state of the system.

Cost effective validation also requires a risk-based approach to validation which recognizes that there is a great deal of variation in risk for the various transactions within what is usually a very complex application.

### Business & Decision – the Experts

Business & Decision's in depth knowledge of computer systems validation, industry regulations, regulatory significant business processes and ERP technologies is unrivalled.

With more than ten years experience implementing and validating ERP systems Business & Decision have helped leading ERP vendors to develop their applications and validation tools. This includes systems from leading vendors including:

- Oracle E-Business Suite, JD Edwards, PeopleSoft and Siebel,
- SAP (all product lines),
- Microsoft Dynamics Business Solutions,
- Other legacy applications such as Infor (Baan, BPCS), Ross (RenCS) etc.

## Business & Decision's ERP Validation Services

Depending upon the requirements of each individual client, Business & Decision offers a number of ERP validation services. These are all based upon GAMP® 5 Key Concepts, which Business & Decision helped to define.

**Prospective Validation** – Often leading on from Business & Decision's package and vendor selection services, prospective validation allows Business & Decision to work with clients and their vendors to define the most cost effective way of successfully validating their ERP system.

This includes defining the implementation life cycle using the best of the software vendor, system integrator and end user's standard life cycles. Appropriate risk-based verification activities will be defined with the entire process being described in appropriate validation plans and reports.

Depending upon the agreed project roles and responsibilities, Business & Decision will then provide resources to guide the validation process and to undertake verification and validation activities agreed with the end user.

A final key activity is the development of IS processes that will continue to ensure that the system can be maintained in a validated state once the system has reached 'go live'.

**Compliance Assessments** – Many end users will not have completed a thorough review of their ERP system since initial 'go live'. In many cases, ERP systems may have become non-compliant through on-going changes in use or because of a failure to define or follow appropriate maintenance and support processes.

Business & Decision will consider all aspects of compliance, including compliance of supported business processes against

appropriate regulations, compliance of the supporting IT infrastructure and maintenance of the validated state through the use of appropriate processes.

**Retrospective Validation** – Where ERP systems may have become non-compliant or undergone a change in use, Business & Decision assists clients to regain (or achieve) a documented state of validation. Again using a cost effective risk-based approach, Business & Decision will consider existing statistical or empirical evidence as the starting point and provide a clear rationale for the approach being taken.

**Maintaining the Validated State** – Once a state of control has been established by prospective or retrospective validation, Business & Decision then provides on-going support to maintain client's ERP systems in a validated state.

Whether by providing on-going oversight for everyday maintenance or support activities, conducting periodic reviews or supporting revalidation exercises upon change of use, Business & Decision provides the continuity of support needed to ensure that client's ERP systems continue to meet regulatory expectations and are always able to support regulatory inspections.

These services have been delivered to some of the largest international life sciences companies in the world as well as to small, specialist companies implementing their first ERP systems.

With specialist ERP implementation and validation teams across the globe, Business & Decision are able to support clients on local or global ERP projects, where our combination of specialist skills, local teams and global reach makes Business & Decision an unrivalled choice in the validation of ERP systems.