

Retrospective Validation / Revalidation of ERP Systems

Business & Decision are the leading choice for risk-based and cost effective retrospective validation or revalidation of ERP systems.

The Need for Retrospective Validation or Revalidation

While regulatory guidance suggests that there should no longer be a requirement for retrospective validation (i.e. because all applicable ERP systems should have been prospectively validated at the time of implementation) there are justifiable reasons why ERP systems may need to be retrospectively validated or revalidated.

Reasons include:

- Introduction of new products bringing an organization within the scope of Good Manufacturing Practice (e.g. a fine chemicals manufacturer starting to manufacture Active Pharmaceutical Ingredients or a components manufacturer progressing to manufacture complete, licensed medical devices),
- The functional scope of an ERP system is extended (e.g. from Financials and HR, to now include manufacturing and quality),
- Organizational changes that mean a non-validated ERP system will now be used by a regulated Division or Business Unit (e.g. through reorganization or acquisition),
- An organization starts to sell products to new markets where computer system validation is a regulatory requirement.¹

Whatever the underlying reason, there are often good reasons for retrospectively validating or revalidating an existing ERP system.

¹ Note that prospective validation is now a requirement in most countries under WHO GMP regulations.

Retrospective Validation vs. Revalidation

Retrospective validation is required where an existing ERP system has not previously been validated. This is usually the case in the examples described above, where there is a change in use of the system, but it may also be applicable in circumstances where the ERP should have been validated, but was not validated at the time of implementation.

Revalidation infers that the system was originally validated. While minor changes in use can usually be handled under change control, in some circumstances it may be more useful to completely revalidate the system.

This is most appropriate in cases where:

- There is a technical upgrade taking place (e.g. SAP R/3 4.x to SAP ECC 6.x, Oracle E-Business Suite 11i to R12.x Microsoft Dynamics AX 3.0 to 4.x),
- There are significant changes in business process and applicable ERP functionality, also often associated with an upgrade.

In some cases, especially those where the original implementation may have been many years ago, it is usual for the retrospective validation or revalidation to address significant changes in the organizations business model as well as changes in the technical platforms.



Business & Decision's Services

As acknowledged experts in the field of ERP validation, Business & Decision provides a range of services to support the retrospective validation or revalidation of ERP systems.

These services may be combined with upgrade projects implemented by our own specialist ERP teams or may be provided as stand-alone services, working directly with the Regulated Company and/or a third party system integrator.

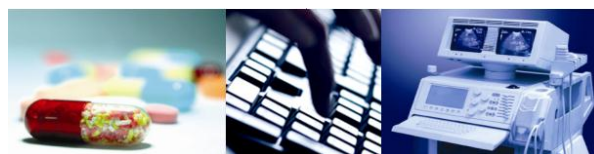
Regardless of whether the project is a retrospective validation or a revalidation, Business & Decision's expert consultants ensure that the following objectives are achieved:

- Validation planning documents provide an appropriate regulatory rationale for the approach taken, thereby demonstrably bringing the ERP system into a defined and documented state of control, regardless of the previous state of the system.
- Risk-based validation principles are leveraged to ensure that the validation activities are conducted as efficiently and cost effectively as possible.
- The validated state of the system can be cost effectively maintained throughout the remaining operational life of the system.

Key Principles

In order to achieve these stated objectives, our consultants leverage defined key principles, including:

- Identification of current and future state business process and user requirements, including identification of applicable GMP, and GDP regulations (predicate rules),
- Detailed functional risk assessment, based upon the client specific processes and products. This is used to appropriately



scale validation and verification activities such as design review and testing. Where possible, existing system documentation (i.e. service desk records, problem and incident management records etc.) will be used to provide empirical evidence supporting the risk assessment.

- Identification of existing vendor and project documentation which can be referenced (and, where necessary, brought under control) to support the validation.
- Identification of existing plans, reports, processes and procedures that can be used (and, where necessary, formalized) to support the validation.

Current State Assessment

Such projects begin with an assessment of the current system, in order to determine the best approach to be taken and also identify any constraints (e.g. where a legacy ERP system will be unable to support Electronic Record, Electronic Signature regulations).

Even where systems are being significantly upgraded or replaced, it is possible to leverage original documentation to support the validation (e.g. original requirements, business process flows etc).

Where there is appropriately documented experience of the operation of an existing system it is also possible to demonstrate low risk likelihood and high risk detectability and use this to justify a reduction in the scope and rigor of verification activities when compared to a completely new implementation.

Depending on the project objectives, this cost effective approach has helped Business & Decision's clients to successfully extend the life of legacy ERP systems or to significantly reduce the cost of revalidating upgrades.