

# ERP/BUSINESS SYSTEMS VALIDATION

**ERP and Business Systems are vital components to running and growing a successful business. Risk and reliance on key IT systems has increased as IT systems have been elevated to a position of business enabler; delivering critical business information at a key stroke to decision makers.**

The majority of ERP and Business Systems being implemented today include many elements of GxP criticality and as such are being exposed to increasingly intensive regulatory (FDA, MHRA) scrutiny with resultant regulatory exposure and significant business risk and impact.

By understanding our client's business and the inherent compliance risks, we lead, support and tailor our services to deliver a high integrity, scalable and pragmatic lifecycle validation solutions.

Our support of your project can be adapted to your needs and resource gaps within your project. Clarity can provide a fully staffed project team from:

- Project Management,
- Strategic Principal Consulting,
- Validation Consultants,
- Testing Resources
- Independent in-project Auditors

All of which will be designed to provide you with confidence of compliance and operation on day 1. Our programme involves the effective management and focus of four business critical issues, these are:

## **Business Focus**

The objective of business focus is to ensure project deliverables are combined into an integrated business validation and compliance process. The key drivers for this are minimisation of business interruption and compliance to external business audit requirements, both GxP and SOX.

## **Project Management Focus**

Project management focus aims to manage project risk and ensure the project delivers on time, in full and in line within a planned budget. The integration of project practices with other partners is a key part of our process to ensure the whole project team is performing at the highest level.

## **Operational Landscape Focus**

Operational landscape focus ensures that all associated business processes are adequately fulfilled within the SAP modules and where appropriate regulatory compliance ensured.

- Finance
- Sales Distribution
- Materials Management
- Quality Management
- Controlling
- Production Planning
- Warehouse Management
- Human Resource

**clarity**

compliance solutions

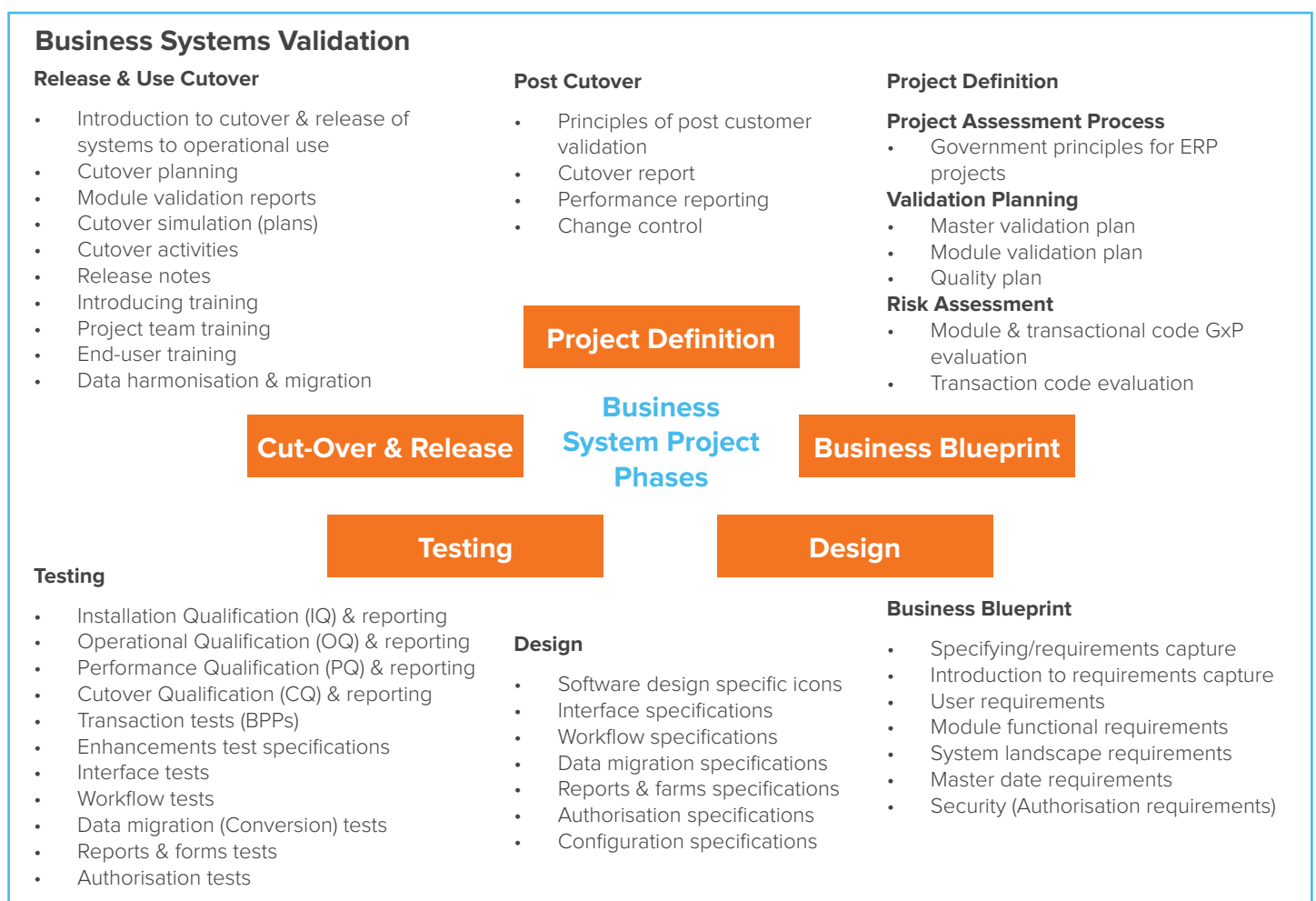
## Technical and Regulatory Focus

Technical and regulatory focus seeks to develop a controlled development of an ERP/Business System design. The system must be reliable and fit for purpose in line with the project objectives and regulatory requirements. Key drivers are management of project deliverables to technical standards, achieving and maintaining the GxP licence to operate, and financial regulatory compliance (Sarbanes Oxley).

Our practices follow a structured method to achieving technical and regulatory assurance, improving the reliability and availability of business critical systems. Regulatory compliance protects your corporate image, shareholder value and your manufacturing license.

Our programme consists of a set of techniques used to manage an ERP/Business System project. The aim is to drive out action plans to ensure seamless integration of new technology, operating practices and procedures into the organisation.

Our consultants are experienced in applying standard ERP implementation methodologies and can dovetail into your project team, to lead, drive or deliver the component parts of a successful ERP/ Business Systems implementation.



Our risk based approach to criticality assessments and associated validation strategy ensures a cost effective approach to ERP/Business system compliance. We focus effort and resources on critical areas resulting to reduce validation costs for the project.

With an integrated approach to organisational change, project management and validation Clarity Compliance Solutions can deliver the greatest business benefit in terms of business operation, project outcome and audit exposure.