

# Business Process Management

***With twenty years experience in the Life Sciences industry, Business & Decision's process knowledge and regulatory background helps clients to achieve sustainable business process excellence.***

Life Sciences companies face the challenge of not only ensuring that their business processes are improved through initial reengineering, but that such processes are optimized on an on-going basis and continue to meet important regulatory expectations.

## Business Process Excellence

Many Life Sciences companies embark upon business process re-engineering or process improvement projects without fully understanding the delicate balance that needs to be achieved between streamlining a process to make it more efficient and ensuring that the process continues to comply with regulatory requirements.

To achieve best-in-class performance it is also necessary to sustain improvements through the ongoing business process management of lean, flexible and adaptive business processes.

With twenty years experience in the Life Sciences industry Business & Decision combines industry specific knowledge with best practices from other industries

Business & Decision fully understands not only the current interpretation of GxP regulations, but also brings knowledge of other regulations such as financials, health and safety etc



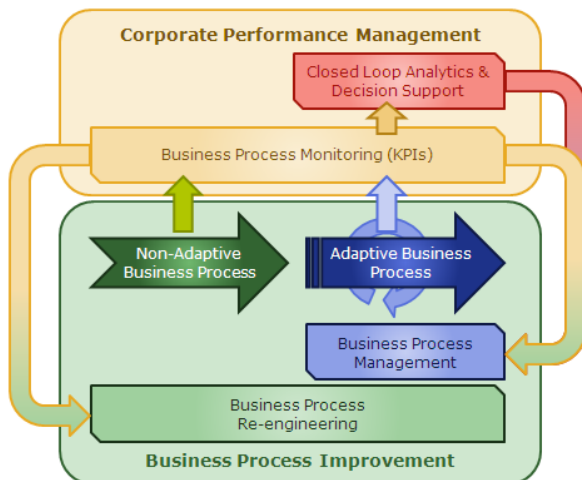
## Process Breadth

Business & Decision's experience of the Life Sciences industry covers all sectors including pharmaceutical, biomedical, medical devices and biotechnology.

As an international consulting organization Business & Decision has experts in all areas of business including:

- Discovery, research and development,
- Pre-clinical and clinical trials,
- Scale up,
- Manufacturing and operations,
- Sales and marketing,
- Supply chain and distribution,
- Customer relationship management,
- Field service,
- Regulatory affairs,
- Financials, budgeting and planning.

Business & Decision also leverage modern tools to design and implement cross functional business processes to bridge the gap between traditional business silos.



**Business & Decision's Business Process Management Model, incorporating Adaptive Business Processes, KPIs and closed loop analytical decision support**

## Consulting Approach

Business & Decision's approach to business process excellence consists of three stages

Throughout the process, consultants work with client's business process owners, subject matter experts and regulatory groups to assure that business processes are not only re-engineered and compliant, but represent best-in-class operations when measured against industry benchmarks and are sustainable in the long term.

**Business Process Definition** – Business Process Management starts with the definition of the 'to-be' business process. In all cases, Business & Decision's experienced consultants draw on industry best practice to benchmark client's existing processes against best-in-class organizations, define Key Performance Indicators to support on-going process optimization and assure sustainable process improvements.

Consultants also work with the client to not only identify industry specific best-in-class processes, but to challenge assumptions by reviewing models from other industries e.g. why does a pharmaceutical secondary manufacturing and packaging line have only a 35% utilization where an equivalent process in a best-in-class consumer packaged goods manufacturer has an up-time of 95%?

**Regulatory Compliance Mapping** – In many cases, differences between industries are attributed to regulatory constraints. While many of these constraints are real, in some cases they are a result of applying out-of-date regulatory interpretation to new technologies or processes.

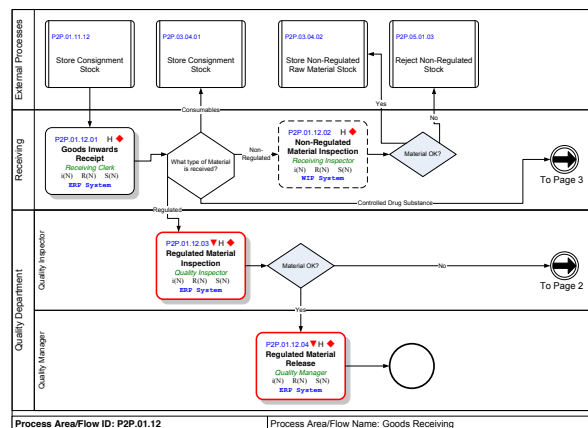
Working with the client's regulatory experts, Business & Decision uses the knowledge of our regulatory compliance consultants to ensure that regulations are consistently interpreted and that business processes include only those additional steps that are required by an up-to-date interpretation of Life Sciences regulations. This helps to achieve the correct balance between a



business process that is efficient and compliant

This approach is extended for those business processes which cross multiple regulatory boundaries e.g. where the purchasing and receipt of a chemical raw material has financial controls, GMP requirements and health and safety implications.

As a result of these stages, a set of business process flows will be produced based upon Business & Decision's unique business process mapping approach, using simple tools which clients use to maintain their business process definitions.



Based upon an extended version of the Business Process Markup Notation (BPMN) standard, Business & Decision have extended the approach to develop a hierarchical process model which is specifically designed for use in Life Sciences and includes regulatory critical information.

**Business Process Management** – Using Business & Decision's unique Business Process Management model, clients are then able to manage their adaptive business processes on an on-going basis, to ensure that their business remains sustainably efficient, compliant and competitive.

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