



# Microsoft Dynamics AX 2009 ERP Solutions for Life Sciences

## SOLUTION OVERVIEW

Based on 20 years experience in the Life Sciences industry and fifteen years experience in delivering validated ERP solutions, Business & Decision provides a range of scalable Microsoft Dynamics AX solutions for the Life Sciences industry.

- Medical Devices
- Pharmaceuticals
- Biotechnologies

Standard solutions are leveraged to accelerate the delivery of sector specific solutions.

## THE VALUE OF THE STACK!

By choosing Microsoft as your ERP platform you gain the added advantage of the integrated MS stack of products. From OS to Desktop to Enterprises Apps (ERP, CRM, BI, etc)

## SERVICES OFFERED

- Enterprise Resource Planning
- Business Intelligence
- FDA Compliant and secure Hosting (SaaS)
- Data Integration



As a Gold Certified Microsoft Partner, we design and implement business transforming solutions that focus on Life Sciences compliance requirements



and that amplify ROI by building on Microsoft's People Ready vision for Dynamics AX 2009.

ask for *people\_ready* ERP solutions

## EXTENSIBLE SOLUTIONS

Due to the specific nature of the drug profiles and device classes being manufactured, and the manufacturing and distribution techniques employed, every Life Sciences organization has its own interpretation of current Good Manufacturing Practice (cGMP) which can vary greatly from situation to situation. This is not a size specific issue and in many cases even smaller Life Sciences organizations will manufacture a combination of pharmaceuticals and devices, and may operate across a number of sites and in a number of regions, or will have specific regulatory requirements that must be fulfilled. All these factors drive the need for uniform but adaptable processes.

Business & Decision supplies solutions designed to meet the specific needs of Life Sciences clients. These solutions leverage the core Microsoft Dynamics AX solution (with its familiar look and feel) and the Business & Decision project accelerators to reduce project timescales and costs, while providing a solution that is specific to both the regulatory requirements and business needs of the individual organization.

Our approach ensures the right balance between accelerated delivery, cost effectiveness, and the need to meet specific regulatory requirements in a compliant and validated solution.

Microsoft Dynamics AX 2009 offers unrivalled benefits in the Life Sciences industry including:

- Integrated financials and process/discrete manufacturing, compliant with US and EU Good Manufacturing Practices (GMP),
- Full quality support, integrated throughout procurement, manufacturing and distribution processes and supporting quality specific functions such as CAPA,
- Standard solutions to support any combination of discrete, process and lean manufacturing environments
- The ability to configure technically compliant Electronic Records and Electronic Signatures, including as part of configurable workflow,
- Built in Business Intelligence based on a range of standard BI reports and dashboards, supporting better decision making, GxP decision support,
- Built-in integration with other Microsoft products including Exchange/Outlook E-mail and calendars, SharePoint document management and collaborative working,
- The ability to integrate customer facing processes such as sales force automation, service management and complaints management through CRM functionality.

## STANDARD SOLUTIONS

The standard solution offered by Business & Decision includes the following software extensions and services:

- Microsoft Dynamics AX 2009
- Business & Decision standard best-practice business processes,
- Configuration of best-in-class business processes to meet sector and regulatory specific requirements,
- Full documentation in accordance with regulatory / validation requirements (e.g. Quality Plan, User Requirements / Functional Specifications, Test Plans and Test Cases etc),
- Document templates for client use (e.g. Validation Plan and Report, User Acceptance Test Plan etc).
- Compliance Center storage of documents
- Device Manufacturing Record (DMR)
- Engineering Control Management
- Device History Record (DHR)
- Approved Manufacturer List (AML)
- Device Identification
- Business Intelligence & Statistics

# Solution Details

## Core Business Process Flows

- Customer Invoice to Receipt,
- Order to Shipment,
- Purchase requisition to Receipt,
- Plan to schedule
- Additional flows are tailored to needs

## Sector Specific Functionality

- Pharmaceuticals and/or Biotechnology;
  - API and contract manufacturing,
  - Secondary manufacture and packaging.
- Medical Devices;
  - Class I, II and III device manufacturers,
  - Low volume capital equipment,
  - High volume diagnostics and devices.
- Other Life Sciences sectors;
  - Biologics and biomedical; Good Tissue Practice; Veterinary and animal health.

## Regulatory Compliance and Validation

Accelerated solutions from Business & Decision provide full support for regulatory compliance and validation.

- Compliant Business Processes:
  - Business Process Flows specifically based upon GMP and GDP regulatory (predicate rule) requirements,
  - Ability to support multi-national regulatory requirements, for US FDA, EU and other international regulatory requirements.
- Technically Compliant Electronic Records and Signatures:
  - Leverages fully configurable electronic/digital signatures and audit trails,
  - Technically complies with US FDA 21CFR Part 11 and PIC/S PI 011 guidance,
  - Configurable ERES support available across all transactions.
- Integrated Validation:
  - Solution includes full set of risk-based validation accelerators, templates and documentation,
  - Leverages GAMP® 5 Key Concepts for efficient and cost effective validation,
  - Built upon more than fifteen years of ERP validation expertise.

## Manufacturing Solutions

Core solutions utilize the flexibility inherent within the Microsoft Dynamics AX product to support a variety of:

- Manufacturing modes;
  - Process manufacturing,
  - Discrete manufacturing,
  - Flow manufacturing,
  - Mixed-Mode (process/discrete/flow) - single or multiple site,
  - Lean manufacturing.
- Business models;
  - In-house manufacturing.
  - Outsourced (contract or toll) manufacturing.
- Appropriate quality and GMP / GDP requirements including:
  - ISO 9000,
  - 21CFR Part 820 / ISO 14971,
  - 21CFR Part 810

## Accelerated Implementation

All Business & Decision implementations employ:

- A fully defined Microsoft Sure Step based project lifecycle (Business & Decision "V-Step", incorporating Validation),
  - Full alignment with regulatory requirements for project governance and computer system validation,
  - Designed to support any scope extensions needed to support the specific product and market needs of individual Life Sciences clients
- Leverages the latest GAMP® Guide and GAMP® good practice guides.

Additionally, for organizations wishing to focus on core business activities and outsource the hosting and management of their ERP system, Business & Decision provide a complete and compliant service.



**Business & Decision**

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