itelligence NTT DATA Business Solutions

it.lifescience for pharmaceuticals – Our Expertise for the Pharma Industry

Optimizing Process Outcomes to Meet Global Compliance Requirements

itelligence helps companies meet unique pharmaceutical industry needs using higher quality information – throughout the entire value chain – based on all relevant compliance requirements.

The Right Formula for Pharmaceutical Challenges

Remove Process Gaps to Increase Your Business Efficacy

Meeting Challenging Requirements

Pharmaceutical companies worldwide are confronted with many different enterprise-wide challenges, including coordinating product development, production, formula management, storage and logistics, while also complying with legal requirements (e.g., FDA and GxP). Increasing competition is also forcing companies to reduce inventory management costs and optimize through-put time.

Companies also face particularly tough production requirements. Different aspects, such as whether solid or liquid products are manufactured, must be accounted for in the system. This also includes filling different container sizes or producing different types of blister and packaging units. Additional challenges including validating software and processes according to GMP requirements (GAMP 5), demonstrating transparent audit trail management, effectively integrating scales, creating process instruction sheets and ensuring active ingredient and yield management.

Achieving High Levels of Quality with Reduced Effort

Our experience spans large-scale pharmaceutical production through to specialist medical technology facilities. We offer unrivalled knowledge of pharmaceutical industry regulations, processes and best practices, and we work with our customers to tailor solutions that improve the management and traceability of product development and production processes.

Our comprehensive approach combines security with enhanced functionality for R&D, distribution, materials management, storage, logistics, production and quality management.

We know the pharmaceuticals industry is all about compliance, and we can help you fully comply with every regulation in cost-effective ways. Our strengths include extensive knowledge of compliance requirements, including REACh, FDA, GMP, and validated project methodologies.

100%
compliance with regulatory requirements

We Provide Everything You Need for Business Success

itelligence will support you with an integrated business solution that provides key industry and advanced technology capabilities, including:

Compliance

- Comply with all regulatory requirements, i.e. FDA, GxP, REACh, etc.
- CAPA (corrective and preventive action) process with efficacy test for actions taken
- Project methodology and tools for compliant ERP implementation

Research & Development

- Formula management for product development and production
- Product development process including sample management, controlling and project management

Production

- Simple and efficient sales and production planning responding effectively to changing demands
- Optimized production management with PI sheets
- Continuous batch management (batch report)

Quality Management

- Integrated quality management with extensive LIMS functionality
- Automatic printing of delivery certificates
- External and internal claim management
- Stability studies
- Batch management

Supply Chain Management

- Inventory management and scheduling at the packaging level
- Labeling including pharmacodes
- Real-time operation insights

80+
industry processes

Flexibility to Meet Customer Specifications

Implementing customer specifications require flexible processes for production and formula management. We do this by distinguishing between different groups of materials (carriers and active ingredients) that must comply with different requirements during production processes.

Complete Formula Management

Formula management brings together all information relevant to the formula, including quality and specification information, production components and complete documentation. Furthermore, a comprehensive permissions model protects formulas and can be modified to meet company specifications.

> Compliance and validation are the key functions for a successful ERP implementation.

Validated Project Methodology

In addition to the FDA and GxP requirements, our project method ensures compliance with validation requirements. We also provide implementation methods based on GAMP 5, including numerous document templates. All additional project steps and documents, such as specifications and test documents, are controlled and managed based on a Business Process Master List and risk analysis of industry processes. PI sheets and quality inspections are digitally signed and documented within a system audit trail.

Ready to Support Your Business and SAP Investment Globally

When you expand internationally, SAP solutions grow with you. To grow intelligently and profitably, pharmaceuticals companies need integrated business management solutions that provide the flexibility for future growth. Whether your future IT landscape will be on-premise, cloud, or a combination of both, itelligence has the global expertise and choice of services and deployment options – including hosting and application management services.

With more than 25 years of experience working with pharmaceuticals companies, we enable real-time, data-driven insights for higher customer value, empowering you to turn opportunities into real business.

Learn more about our pharmaceuticals industry expertise at

www.itelligencegroup.com