

Pharmaceutical Industry Solutions “At-a-Glance”

Pharmaceuticals



- *Clinical Trial Support to complement in-house strengths, stretch budgets, and accelerate schedules*
- *Submissions Support Services to help ensure fast regulatory compliance*
- *Global Project/Program Management professionals to manage change on a global basis*
- *Manufacturing Operations Support to improve processes and standard operating procedures*

Services and Solutions

Fujitsu Consulting provides innovative services and solutions to global pharmaceutical organizations in the areas of:

- **Clinical Trial Support** – these services include a “One Stop Shop” solution for global pharmaceutical companies which often do not have the resources to invest in establishing these capabilities within their own firms:
 - Electronic Data Capture Total Support Services
 - Clinical Trial Management Support (Outsourcing)
 - Clinical Trial Data Management and Data Security
 - Clinical Trial Business Process Reengineering (BPR), which incorporates our
 - Envisioning framework to enable clients to tap the power of their innovative capabilities and focus on the most critical processes
- **Submissions Support Services** – these services address the critically important need for global pharmaceutical companies to ensure regulatory compliance in the area of submissions and associated data management:
 - Documentum/CoreDossier Systems Architecture, Development and Support
 - Standard Operating Procedure (SOP) Development
 - Global Electronic Submissions BPR
 - Common Technical Document (CTD) and e-CTD Architecture, Design and Implementation
- **Global Project/Program Management** – providing organizations with the ability to architect and implement the organizational capacity to manage change on a global basis
 - Manufacturing Operations Support:
 - Packaging and Labeling BPR
 - SOP Development

Success Stories

Clinical and Regulatory Document Management System

Fujitsu Consulting designed and delivered, over a five month period, a turnkey clinical and regulatory document management system for a major Japanese pharmaceutical company. The system contains a document collection component exceeding 25GB. Regulatory documents include INDs, NDAs, and annual reports. The system also manages clinical trial related documents such as protocols, data resolution forms and adverse event reports.

Packaging Process (Pharmaceutical Company)

In order to create a unified and optimized process for the creation, routing and control of Packaging Specifications and Bill of Materials documents, a Global2000 Packaging Services engaged Fujitsu Consulting to conduct a business process redesign of their existing business processes. This redesign project examined the packaging processes for four different business areas: New Technology and Package Testing, Package Design and Development Animal Health Products, Package Design and Development Consumer Healthcare Products, and Package Design and Development Pharmaceutical Products.

Solutions that Meet the Needs of the 21st Century Pharmaceutical Industry

The pharmaceutical industry is in the business of discovering, manufacturing, and distributing new drug compounds, therapies, and devices to improve the health and well being of people and animals. These knowledge-intensive processes create new knowledge and information that, when analyzed, stored, shared, and used appropriately, are the foundation for creating even more products and the cornerstone of sustainable competitive advantage. Competitive advantage, however, no longer depends on the technologies used for drug discovery, such as chromatographs or gene libraries. Any company with enough capital and the right training can deploy these technologies. We call this “dematerialization”. The threat of dematerialization is serious when we pause to consider that the average cost of developing a new drug is approximately \$800 million with an average time of development somewhere between 10–12 years!

To meet this and other threats, pharmaceutical companies have embarked on aggressive initiatives to globalize their R&D, clinical trial, and manufacturing facilities as well as accelerating mergers and the formation of alliances for collaborative research, co-development and co-marketing of pharmaceuticals. Globalization also requires pharmaceutical organizations to be compliant with the complex and stringent information requirements of all regulatory agencies that govern the development, manufacture and distribution of pharmaceutical products such as the FDA (United States), EMEA (European Union) and MHW (Japan). Global regulatory compliance demands that pharmaceutical companies collect, store, manage, and publish vast amounts of information to one or more of these government agencies (e.g., new drug submissions) but retain consistency and accuracy of the underlying records and information that support regulatory filings.

Why Choose Fujitsu Consulting

Fujitsu Consulting enables pharmaceutical companies to attain sustainable competitive advantage in meeting their requirements to:

- Continuously innovate new pharmaceutical products
- Substantially enhance R&D and clinical trial productivity
- Manage projects and leverage assets on a global basis, and
- Maintain a cost-effective compliance posture with respect to all relevant regulatory agencies.

Fujitsu Consulting works with you to develop sustainable competitive advantage in the pharmaceutical industry. We do this via a unique set of techniques, tools, and methodologies that enable pharmaceutical companies to envision a future state focused on the absolutely critical processes, organization, technology, and architectures—all driving competitive differentiation and success in the marketplace.

Experience the Fujitsu Consulting Difference

As the management- and technology-consulting arm of the US\$45-billion Fujitsu group, Fujitsu Consulting integrates the core expertise of Fujitsu companies and its partners to deliver complete solutions to businesses and government in the areas of Information Management, Legacy Modernization and Managed Services. The scope of these offerings extends from strategic management consulting to the tiniest detail of infrastructure operations. Through its industry-recognized strategic methodology, MacroScope®, Fujitsu Consulting assists clients in incorporating more value into their investments and driving their leadership in the marketplace.

We work with you to create solutions and produce results that drive your business.

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