

CASE STUDY

Catalyst

SAP Success Stories in Life Sciences



Infosys[®]

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Transformation Projects

Infosys' SAP transformational solutions are designed to help clients attain operational efficiencies and derive competitive advantage.

They help customers plan, implement and roll out SAP applications that:

- Integrate smoothly with business processes
- Improve visibility across the supply chain
- Make business outcomes more predictable

We collaborate with clients to ensure best-in-class implementations, equipping them to achieve business goals and maximize return on Investment (roi) from sap.

Global Pharmaceutical Major Streamlines Operations with Re-engineered, Leaner Supply Chain

The Client

One of the world's top five innovation-driven, integrated, bio-pharmaceutical companies.

The Challenge

To implement a new supply chain model in line with changing business requirements, so as to:

- streamline the supply chain by eliminating multiple stages
- reduce inventory by providing products directly to pharmacies
- reduce dependency on levels in the existing supply chain

The Solution

An end-to-end solution based on the Infosys Package Implementation Methodology that leverages our Global Delivery Model, while addressing concerns of multiple stakeholders (including

financial institutions and selling agents) and minimizing the disruptive impact of business process change.

Solution Highlights

- Co-ownership of implementation based on a fixed price contract
- Program optimization, achieved by reusing assets like existing components, reports, programs, tests and documents
- A To-Be model (based on the existing European template) for seamless implementation, that standardizes processes with minimum customization to meet localization requirements
- Integration of three complex systems, including a credit and quota management system used by agents
- Deployment of a unique Integration Testing Strategy to reduce the testing

phase timelines

- Testing of the solution under more than 450 test conditions in a bi-lingual, multi-stakeholder environment

The Results

- A business transformed, thanks to a re-engineered supply chain model.
- Support of a complete IT solution for the new supply chain model
- Saving of 10 weeks in testing phase timelines, leading to prompt implementation within contractual and legal timelines
- Continuity of business notwithstanding the concurrent implementation of a high impact business process change
- Annual savings of approximately US \$8 million, due to a leaner supply chain, better inventory management, and lower overhead costs



Pharmaceutical Major Gains Competitive advantage through Operational excellence

The Client

The eye care division of a global pharmaceutical company with a revenue exceeding us \$2 billion per annum.

The Challenge

To eliminate operational constraints arising from multiple, disparate systems, harmonizing multiple business processes on a single saP instance.

The Solution

A 3-phase (sales, distribution, manufacturing value chain) saP 4.7 implementation and support program, covering 8 countries and multiple business processes including Order-to-Cash (OtC), Finance-to-Manage (FtM), Procure-to-Pay (PtP), and Plan-to-Produce (PLtP). Operated in a hub-and-spoke model, it had a central team based in america controlling the program, and traveling to the countries involved to implement specific phases.

Solution Highlights

- The program, started with another global systems Integrator, was running 16 months behind schedule and 40% over budget at the time Infosys entered the engagement, taking on program management, integration management, functional and technical consulting for the rest of the program life cycle
- Infosys re-scoped the program, recreating the business case, establishing a formal program organization and defining roles and responsibilities at the individual level to define governance mechanisms
- To accelerate deployment across geographies, Infosys developed a common template, and harmonized business processes across the region while accommodating country-specific requirements
- This program was executed in a phased manner adopting specific change management and stakeholder

management tactics for each country

The Results

A setup that could function as the global entity it was, now that it had a data model that facilitated analysis and enabled an integrated view of business processes across the enterprise.

- Implementation of the program with very lean local teams
- Reduction in order creation cycle time by almost 40%
- Reduction in the cost of back office financial processes, like invoice creation and payment cycle, by over 35%
- significant reduction in spend on back office financial process management
- Reduction in account receivable days outstanding and days of inventory on hand



Healthcare Conglomerate Integrates acquired Company's accounting systems into its Financial ecosystem using saP New General Ledger

The Client

The us-based vaccines and diagnostics division of a global healthcare conglomerate manufacturing innovative pharmaceuticals, generics, vaccines and consumer health products.

The Challenge

To align the accounting standards and processes of the division – a recent acquisition and formerly an independent organization – with those of the parent company:

- So as to ensure financial integration of the organizations with common standards of process standardization and financial reporting
- In the face of diverse systems, complex processes, multiple third party interfaces and stringent schedules

The Solution

End-to-end re-implementation services - including program management, functional and technical consultancy – to:

- Deliver one of the first new gl implementations on the sap platform

- Revamp existing applications with enhanced functionalities from sap fico

Solution Highlights

- A customized approach based on infosys' package implementation methodology,
- global delivery model, and the 'v model' recommended by good automated manufacturing practices (gamp) for validation
- Adoption of sap tools, such as strategic landscape optimization (slo) and migration cockpit, to minimize the impact on business, processes and people
- Leveraging of tools such as livelink (for change management) and aquas (for testing) during project execution, to avoid the development of customized tools
- Devising of to-be business processes in line with the group's core standards, after identifying gaps in accounting setups, nomenclatures and reporting processes
- Function-wise staggered approach to

go-live, minimizing resources required, system down time and risks to business continuity

- Use of the infosys global delivery model to minimize implementation costs
- Management of user expectations – including those of the senior management team – through effective communication by the infosys organization change management team

The Results

streamlined global reporting powered by standardized accounting processes that facilitate real-time financial reporting.

- Reduction in project timeline by three months, thanks to use of livelink and aquas
- Simplified local reporting with a parallel ledger in new gl
- Reduction in implementation costs by us \$100,000 due to utilization of tools and reusable assets



Pharmaceutical Major Harmonizes and Integrates Financial Processes by Rolling Out saP solution in the Greek and turkish Markets

The Client

Pharmaceutical Major Harmonizes and Integrates Financial Processes by Rolling Out saP solution in the Greek and turkish Markets

The Challenge

To roll-out the european template on sap to the highly complex greek and turkish markets, with minimal deviations, as a pre-cursor to transitioning them to the shared service center (ssc) for transaction processing.

The Solution

An end-to-end, minimally-disruptive, process transformation exercise involving country-specific complexities, complex integrations with hardware (like printers, digital signature devices and bar code printers), and a non-unicode-compliant output management system.

Solution Highlights

- A customized approach based on infosys' package implementation methodology,
- Identification of suitable hand-off

points between the client's local teams in greece and turkey and the ssc team

- Supplementary installations on both sap ecc 6.0 And bi systems, in both greek and turkish markets
- Implementation of add-on module for the greek market, which included components like analytical ledger and warehouse book
- Development of 2d bar coding prototype for turkey using sap ecc 6.0
- Automation of post-dated-cheque processing based on the files provided by banks
- Development of bespoke functionality for weighted average due date
- Customization of optical character recognition systems to deal with greek and turkish characters
- Optimization of stock control by implementing standard system-based inventory management (sim)

The Results

On time and under budget delivery of the entire program, powered by template expertise, the Infosys Global delivery

Model, and knowledge of validation processes.

- Re-engineering of complex finance and accounting local country processes for alignment with the european common processes
- Creation of a standardized sap platform, scalable for all future business expansions
- Minimal disruption between work being outsourced and work being retained
- Inclusion of the two markets – greek and turkish - into standardized application maintenance framework for sap support
- Provision of local reporting as required
- Creation of solutions like 2d bar coding with sap ecc 6.0, Which can be extended to other countries
- Reduction in head count as envisaged in the business case, by consolidating financial transaction processing with the global shared service for both the markets, leading to savings of us \$2-2.5 Million per annum



Global Pharmaceutical Major Harmonizes Core Processes and Modernizes Legacy system by Replacing it with Regional saP Platform

The Client

One of the world's top five innovation-driven, integrated, bio-pharmaceutical companies.

The Challenge

To modernize the legacy platform that the Swedish business was using for corporate planning, marketing, research and development, and operations, so as to:

- Standardize, simplify and improve processes
- Improve the quality and availability of data while retaining control
- Reduce the cost of system maintenance and upgrades
- Optimize the process management and integrate the back-end process execution with the global shared service

The Solution

Migration of the financial processes and data of the Swedish business, from its legacy applications to the company's European template, on a common saP eCC 6.0 and saP BI 7.0 system. The project included the following:

- A scoping study to assess the feasibility of the change

- Contributing inputs to create a business case for change
- Conducting multiple workshops for the Swedish business to highlight the benefits of saP as a financial landscape and secure stakeholder buy-in for to-be processes
- Prototyping of processes and solutions
- Implementation in a short timeframe
- Validation as per client requirements

Solution Highlights

- Development of 120 custom objects in saP, with a majority of them interfacing with satellite applications
- Mapping of 300+ business object reports to saP BI 7.0 Along with complex financial modules like COPA, FI special ledger
- Seamless integration of more than 80 interfaces (both inbound and outbound) with saP, with complex error handling
- Design of interfaces and changes to 25+ satellite applications
- Implementation of additional components, such as CATS, project systems and investment management, facilitating the re-structuring of

business processes

- Completion of the development phase in 3 months with a peak team size of 112 consultants across geographies

The Results

Replacement of an expensive legacy system with a single instance saP solution that combines financial, operations, research and development, corporate planning and marketing processes with minimal impact on business performance.

- Standardization of processes between the Swedish and British businesses, facilitating the outsourcing of financial transaction processing
- Rationalization of reporting (300+ Business Objects reports were replaced by just 14 BI reports) and attendant savings in application maintenance
- Reduction of support cost by 8-12% compared to legacy system, by consolidating business processes
- Reduction in transaction processing costs, due to headcount reduction brought about by automation of business processes



Pharmaceutical Major Gains Competitive advantage through Operational excellence

The Client

One of the top ten pharmaceutical companies with portfolio of products for major disease areas including cancer, cardiovascular, etc.

The Challenge

Regional set of processes and tools resulting in operational overheads and process inefficiencies

The Solution

A poc (proof of concept) based approach addressing the client's current environment challenges while ensuring zero impact on business continuity. Poc was build using infosys pre-configured solution in solution manager especially addressing the life sciences industry needs.

Solution Highlights

solution Manager 7.1 capabilities used as a transformation tool for Organization Change Management (OCM) to harmonize across geographies and processes such as -

- Solution implementation and template management
- Solution documentation
- Test management
- Change control management
- It service management
- Technical operations
- Business process operations
- Maintenance management
- Upgrade management
- Custom code management
- Reporting

The Results

- Replaced the years old legacy document management system which was not integrated with the change management tool thereby causing high lead time for the tickets
- Single source of truth for the entire process repository thereby improving the knowledge management across the team and also increasing the process efficiency of the it team



Biopharmaceutical Major Replaces Legacy Laboratory Information Management systems (LIMs) with saP Quality Management (QM) Module

The Client

A leading american multinational biopharmaceutical company.

The Challenge

- Replace the existing LIMs system at all manufacturing and testing sites by plugging in the saP QM module into the existing saP landscae.
- Integration of Qa (Quality assurance) and QC (Quality Control) processes into other critical manufacturing and clinical trial processes
- Harmonize the existing Qa /QC business processes across the client's business locations.

The Solution

- A customized approach based on infosys package implementation methodology
- To-be business processes devised in line with client's standards after identifying gaps in qa/qc setups
- Detailed sample management process addressing the white spaces in sap and meeting customer requirements
- Inspection of lot management for raw material, finished goods, in process, enviornmnetal monitoring and stability

samples

- Managing qm master datas such as inspection plan, sampling procedure, inspection characteristics, etc
- Infosys state-of-the-art solution for environmental monitoring and gowning operations adrrssing white spaces in sap standard qm functionalities
- Solution for quality certificates including creation of a 'certificate of analysis' to document the test results based on the certificate profile assigned to the material

Solution Highlights

solution Manager 7.1 capabilities used as a transformation tool for Organization Change Management (OCM) to harmonize across geographies and processes such as

- Solution implementation and template management
- Solution documentation
- Test management
- Change control management
- It service management
- Technical operations
- Business process operations
- Maintenance management

- Upgrade management
- Custom code management
- Reporting

The Results

- Erp realignment – defined the approach of btia for all sites in order to identify the impacted processes
- System build prototype – configured sandbox and maintenance of configuration logs for future reference
- Infosys pre-configured solution covered 85% - 90% of standard out-of-the-box solution matching client's needs and is used as an accelerator to help reduce project timelines
- Identified the most important sources of business value in client's qa/qc processes and assessed capabilities from sap ecc package to be implemented for realizing value
- Infosys provided global template build and rollout program plan and approach for sap based qa/qc solution implementation



Global Pharmaceutical Major drives Operational excellence through saP solution Manager Implementation

The Client

One of the world's leading multinational pharmaceutical company specializing in the consumer health care, generic drugs, eye-care products.

The Challenge

- Paper based approvals requiring physical signature.
- each local division had their own documents and synchronizing updates was a huge challenge.
- synchronizing document updates from each local division to ensure single source of truth across division
- Identifying differences between global template and local requirements in roll-outs and synchronize the differences to ensure global templates are updated with local requirements
- Centrally manage global change management process
- Integrate change management with other controls such as document management systems (dMs)

The Solution

An industrialized solution leveraging standard solution manager functionalities and customization to meet specific needs of the client to ensure the implemented solution is compliant with 21cfr part11.

Solution Highlights

- Building the digital signature functionality thereby reducing paper work
- Creating a unique document identifier in solution manager. This single document is updated for all the core processes, reducing synchronizing challenges
- Creating a template project to act as 'the master' for content changes across cross-divisional, divisional and local processes data
- Implementing the scoping and de-scoping functionality to synchronize the template with the implementation projects
- Handling all cross division changes as

change request management (charm) supported division based requirements

- Charm integrated to document management system (dms) thus providing strict control over system changes

The Results

- All documents managed in the solution manager
- unique documents can now be created in the solution manager for core business processes and synchronization
- ability to synchronize template projects, implementation projects and help run implementation and support modes simultaneously using solution manager
- controlled global change management process as per compliance using charm
- charm controlled document updates resulting into proper audit trails and governance





Upgrade Projects

Infosys' saP upgrade services teams have delivered more than 30 saP upgrade projects - on time and within budget - over the last two years. Of these, 10 have been in a validated environment in the Life sciences industry. Our customized

auto-upgrade toolset and upgrade methodology makes upgrade projects more cost-competitive and predictable by:

- automatically executing development of changes for the targeted version
- reducing the effort for development

- and testing by 40%
- increasing predictability of the upgrade program by 95%, thanks to accurate upgrade assessment

Healthcare distribution Company upgrades eRP Platform with 23tB database

The Client

A fortune 20 corporation specializing in the distribution of healthcare systems and services, medical supplies, pharmaceutical products and health information technology solutions.

The Challenge

To upgrade the existing sap ecc 5.0 Installation to sap ecc 6.0, Including enhancement package 3, with no interruption to business. To simultaneously implement the latest tools and services, like sap mobile defense and security (mds), so that future applications can handle new business needs.

The Solution

An end-to-end sap upgrade implementation that involved program management, organizational change management, and conversion of a huge database to unicode.

Solution Highlights

- Multiple-option approach – mds v/s non-mds, combined upgrade and unicode conversion (cuuc) v/s twin

- upgrade and unicode conversion (tuuc) - to enhance predictability and reduce the risk of failure in an extremely complex sap landscape
- Well-defined test strategy for end-to-end testing of functional processes and security design
- Use of global delivery model to ensure a risk-free, on-schedule and cost-effective upgrade
- Use of proprietary tools for project and program management to ensure prompt analysis and rapid decision-making at critical testing and cut-over points
- Upgradation of plug-ins and service packs for integrated enterprise systems such as business intelligence (bi), supply chain management (scm) and customer relationship management (crm)
- Integration of a web application security (was)-based internet transaction server solution with the travel and expense module
- Well-defined cut-over strategies to handle the challenges posed by

multiple projects with several complex, custom objects

- Detailed communication plan for assisting impacted user communities to cope with change

The Results

smooth execution of one of the most complex upgrade projects Infosys and saP have ever handled together. Business continued uninterrupted, thanks to our minimizing the downtime of business-critical applications inherent in all saP upgrades.

- Conversion of the 23tb database to unicode was deemed by sap to be the first global instance of its kind
- Simplification of the interfaces of more than 130 legacy systems enhanced its efficiency considerably
- Enhancement of application availability to 100%, with resolution of long-pending issues
- Establishment of a platform for next-generation sap initiatives



British Pharmaceutical Company Gears up for Next-Generation Business Processes

The Client

One of the world's top five innovation-driven, integrated, bio-pharmaceutical companies.

The Challenge

To improve operational efficiencies and establish a framework that could incorporate new business functionalities such as governance, risk and compliance (grc), supplier relationship management (srm) and composite applications that support operations across all 27 countries in europe. Also, to upgrade sap r/3 4.6 To sap ecc6.0 And sap bw 3.5 To sap bi 7.0, And execute unicode conversion.

The Solution

An end-to-end sap upgrade with multiple document multiple code page (mdmp) in 23 languages. The engagement covered program management, integration management, technical and functional consulting, unicode conversion, basis landscape management, testing, and cut-over execution.

Solution Highlights

- Combined upgrade and unicode conversion (cuuc) approach to manage the project
- Detailed cut-over planning and custom object migration for each interfacing system
- Extensive validation and documentation of business- critical interfaces and processes to comply with regulations such as sarbanes-oxley act (sox) and good manufacturing practices (gmp)
- Adjustment of more than 700,000 words with unassigned languages in the unicode conversion exercise
- Extensive testing in the development and pre-production phases, including a 2-month user acceptance testing (uat) phase
- Smooth change management facilitated by a quarterly newsletter that communicated progress of the project across 27 markets

The Results

A smooth upgrade to sap ecc6.0 And sap bi 7.0, To support next-generation business processes in 27 countries.

- Uninterrupted business continuity during the upgrade - 150 third party interfaces continued to function uninterrupted, as did local customizations of the system
- Validation of 320+ activities, with 100% adherence to schedule
- Replacement of the standalone internet transaction server (its) with an integrated its
- Compliance with unicode, enabling the system to handle the european languages and logins, leading to resolution of multi-language vocabulary issues and reduction in development cost
- Elimination of errors in all the functional processes, including gxp relevant functions
- Saving of 20% on license costs, and elimination of the risk of running out of product support enable usage of ecc functionalities like new general ledger



Pharma Major Revamps It Landscape with Holistic saP upgrade approach

The Client

A leading pharmaceutical company specializing in drug development and healthcare products.

The Challenge

To implement a sap upgrade program, for seven instances of sap r/3, across 30 countries with minimal disruption to business, so that the organization can benefit from new-generation enterprise applications such as composite applications, supplier relationship management (srm) and governance, risk and compliance (grc).

The Solution

A tool-based automated upgrade solution for end-to-end upgrade of sap r/3 systems and several satellite applications interfaced with sap.

Solution Highlights

- Adoption of a upgrade and unicode conversion (tuuc) approach after executing scenario-based planning for tuuc and cuuc (combined upgrade and unicode conversion)

- Creation of microsoft sharepoint-based templates to enhance the efficiency of processes introduced for collaborative activities such as code fixing and testing
- Adoption of an innovative approach to testing based on test case screening, formal screening and formal testing
- Just 20% project execution effort expended in technical remediation due to extensive automation; 55% allocated to functional testing
- Deployment of upgrade coaches to resolve issues quickly and suggest tips for automation and new functionalities
- Effective program management execution by infosys ensured smooth communication and conflict resolution in seven inter-dependent upgrades
- Efficient governance of the core template architecture
- Deployment of benchmark models and tools such as microsoft sharepoint and hp quality center for regular processes
- Optimization of cost and coverage with the right mix of offshore, core and regional teams
- Use of the managed services model for shared support
- Enhancement of the value derived from the upgraded system, through use of add-ons such as
- Enterprise portal, master data management (mdm), solution manager and redwood
- Reduction in the number of legacy systems
- Minimization of the cost of remediation through use of automation and diversion of the saved development effort to thorough testing of gxp relevant business functions

The Results

- Savings of about 50% in development effort, thanks to use of the infosys auto upgrade tool that automatically replaces obsolete syntax
- Minimization of the need for user training due to extensive screening of scenarios guided by subject matter experts





Support Projects

Infosys' SAP Support Services ensures it's "business as usual" for customers, by providing end-to-end application support and maintenance services. We offer clients an innovative commercial model, including outcome-based pricing, that maximizes returns. Our approach to engagements focuses

on continuously simplifying business processes and improving service levels. We are able to commit to reduction of incidents through effective problem management. Our proven transition methodologies and robust knowledge retention practices help reduce the risk of knowledge attrition.

We provide committed cost savings on Information Technology Operations (ITO) as we operate with risk and gain sharing mechanisms. We have consistently delivered tangible business benefits in terms of increased flexibility, scalability, and application availability, while reducing the Total Cost of Ownership (TCO).

Global Pharmaceutical Leader Achieves Operational Excellence

The Client

A global leader in drug development and consumer healthcare products, having revenues of more than US \$30 billion per annum.

The Challenge

To optimize the costs and enhance the operational efficiency of the SAP support setup by creating and implementing an appropriate outsourcing model.

To ensure that this attempt, the second, was successful, unlike a prior offshoring pilot project undertaken with a consulting major.

The Solution

A transformation initiative that delivered substantial benefits for the company:

- By moving it to an outcome-based managed services model
- Through process improvements, automation, business process simplification, and application rationalization

Solution Highlights

- Creation of a roadmap that split the project into 3 phases: Prove, Trust, Transform, each with specific goals

- 100% adherence to Service Level Agreements (SLAs) during the Prove phase, to win over end users and secure their buy-in for the engagement
- Resolution of incidents and suggesting and implementing improvements to applications and service delivery process during the Trust phase
- Large, cross-divisional, global upgrade implementations and transformational initiatives that focused on delivering business value and cost benefits during the Transform phase
- Introduction of a structured governance model to translate the company's financial and operational goals into engagement goals
- Creation of a dedicated offshore Compliance Center of Excellence (CoE), the first of its kind in the pharmaceutical industry where regulatory compliance is a business critical function but cost of compliance is very high
- Redefinition of incident management processes as a part of service improvement plans
- Use of the Infosys Global Delivery Model to reduce support costs

The Results

Step-by-step execution of the roadmap over a three-year engagement period, resulting in shorter cycle time of processes and lower compliance costs.

- Streamlining of multiple processes, including configuration change management, incident management, change management, testing and deployment
- Monthly savings of 25% on SAP support cost
- Development of tools to automate and standardize processes, increase the accuracy of shared data and save manual effort
- Reduction in throughput time of incident management cycle by 43%
- Increase in customer satisfaction from 0.7/1.0 to 0.85/1.0, as per the End User Satisfaction Survey conducted by the customer
- Establishment of a strong partnership that has seen Infosys participate in the client's IT leadership forums as a trusted advisor



Pharmaceutical Company Turns Business Around with Strategic ERP Partnership

The Client

One of the world's top five innovation-driven, integrated, bio-pharmaceutical companies.

The Challenge

To take on:

- The support of a complex sap landscape, with disparate applications across geographies
- Development of new dimensional products so that the company could focus on its core business

The Solution

A 100% managed services outsourcing model with Infosys owning incident management, problem management, change management, configuration management and compliance management.

Solution Highlights

- Implementation of Information Technology Infrastructure Library (ITIL)-based support processes and best practices to help the client achieve their process standardization objectives
- Integration of support for seven diverse applications, including SAP's new dimension products such as Supplier Network Collaboration (SNC) and Application Planning & Optimization (APO), with multiple business processes spanning multiple divisions, vendors and time zones

- 19x5 support across Helpdesk, SAP Security, Business Analysis, Application Link Enabling (ALE), Electronic Data Interchange (EDI), Workflow Application, and Business Information Warehouse (BW) Monitoring
- Support - including enhancements, production support and release upgrades - for all SAP R/3 modules such as MM, SD, PP PI, PM, EHS and FICO
- Contractual commitment of six service improvements every quarter for business and technical processes
- Creation of reusable documents and solution components to optimize timeframes and effort for development of enhancements
- Use of the Infosys Global Delivery Model (GDM) to reduce the cost of application support by moving 75% of the effort offshore
- Implementation of a systematic organization change management process to enable end users to operate under a managed services model
- Devised Service Introduction (SI) model to ensure smooth introduction of new applications into the Application Maintenance Support model

The Results

A strategic partnership that went beyond Service Level Agreements (SLAs) to enterprise-wide value addition and value creation in a span of 4 years. Based on a non-linear incident-based model, it

provided maximum flexibility in pricing structure, shifted ownership of the outcome to Infosys and converted capital expenditure into operating expenditure for the customer. The financial model also bound Infosys for service credits and penalties for non-adherence to the SLAs.

- Simplification of the complexity of SAP instances by elimination of 10% of interfaces
- Integration of application support and compliance support
- Greater predictability of support outcomes and reduction in the cost of SAP support through incident-based pricing model
- Improved SLAs due to extended service window available as a result of implementing the Infosys GDM
- Flexible staffing model with quick ramp-up and ramp-down
- Improved system performance due to fine-tuning of technical processes
- 100% application availability through the entire financial year
- Reduction in the cost of compliance and throughput time for incident management and change management
- Reduction in the Total Cost of Ownership (TCO) of supporting applications by headcount reduction, standardization of global processes and integrated validation process, leading to savings of US \$1.1 million





Compliance Management

In today's competitive environment, all pharmaceutical organizations need to address regulatory imperatives while reducing the cost of compliance. Infosys' Compliance Management Center of Excellence helps pharmaceutical

companies achieve these twin objectives by automating the validation process. Our in-depth knowledge of GxP, 21 CFR Part 11, and Corrective and Preventive Action (CAPA) processes, combined with our extensive experience in System

Development Life Cycle (SDLC) helps companies move validation and reporting offshore, thus reducing the cost of compliance by as much as 40%.

Global Pharmaceutical Major Implements Offshoring Model for Regulatory Compliance

The Client

The over-the-counter, vaccine, diagnostics, and eye care divisions of a leading pharmaceutical company.

The Challenge

To reduce the cost of Good X Practice (GxP) and Sarbanes-Oxley (SOX) compliance by re-engineering computer validation processes.

The Solution

To outsource regulatory compliance activities in an offshore model.

Solution Highlights

- Creation of a roadmap that split the project into 3 phases: Prove, Trust,

Transform, each with specific goals

- Optimization of system lifecycle and validation methodologies
- Execution of a zero defect process
- Validation and compliance training programs for client teams

The Results

A trend-setting engagement that covered support for Quality Management, validation protocol and reporting, high-level risk assessment, functional risk assessment, and project document management. Review and approval process administration of project deliverables resulted in:

- Streamlining of multiple processes,

including configuration change management, incident management, change management, testing and deployment

- Reduction in cost of compliance by 40%
- Accelerated execution of validation activities by 35%
- Efficient testing and implementation of GxP and SOX compliance, complete test coverage and establishment of mandatory core test setup
- Improved data integrity
- Improved traceability of documents
- Reduced risk due to faster ramp-up and consistent quality of compliance

For more information, contact askus@infosys.com



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