Pharmaceutical, Biotechnology, and Healthcare Industry

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GP™

Leading the World to Better Performance

TRAINING

ENGINEERING

TECHNICAL SERVICES

CONSULTING

PERFORMANCE IMPROVEMENT · PERFORMANCE IMPROVEMENT · PERFORMANCE IMPROVEMENT · PERFORMANCE IMPROVEMENT · PERFORMANCE IMPROVEMENT · PERFORMANCE IMPROVEMENT ·
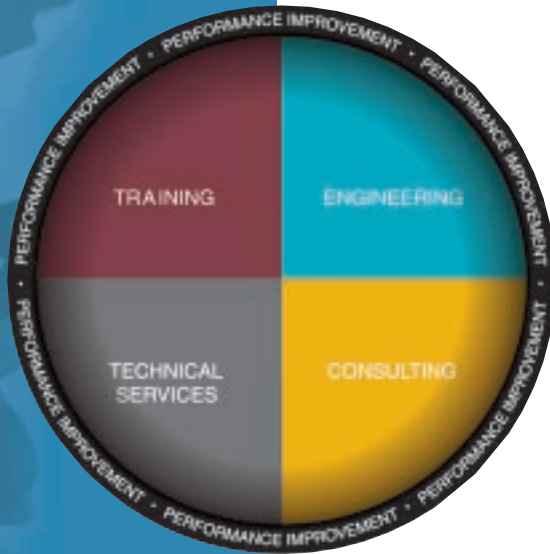
GP is a world leader in performance improvement

services and products, integrating people,

processes, and technology.

GP provides training, engineering, technical

services, and consulting to large multinational

companies, utilities, and governmental customers.

Founded:	1966
NYSE Symbol:	GPX
Annual Sales:	In Excess of $200 Million
Number of Employees :	Over 1,500 Professionals Worldwide
World Headquarters:	Columbia, MD, USA
Global Office and Training Centers:	48 Locations
Global Locations:	United States United Kingdom Mexico Malaysia Canada Brazil

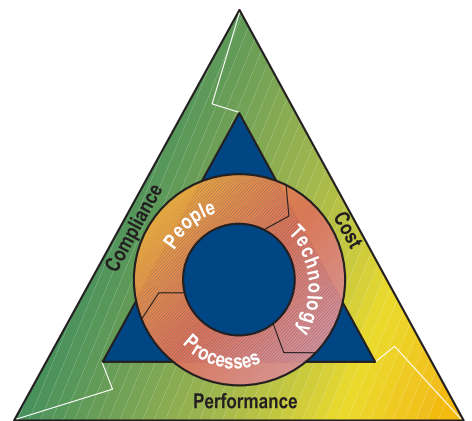# Pharmaceutical, Biotechnology, and Healthcare Industry

Employing more than 1,500 professionals worldwide, GP is one of the world's largest companies specializing in enterprise-wide performance improvement. We provide these services to clients in more than 60 countries and have developed a worldwide network of over 48 offices positioned to serve our clients effectively.

GP is one of the largest global companies providing enterprise-wide performance improvement services. GP has provided services in more than sixty countries and is well positioned to serve customers through offices in North America, Latin America, Asia, and Europe. We have more than thirty-five years of experience in providing a wide variety of products and services to optimize workforce performance, including technical and professional training; information, technology, and learning management; engineering and facilities support; and consulting services.

We excel at integrating these services and optimizing each customer's business performance enterprise-wide. We are proud of our ability to provide our customers with high-impact, sustained bottom-line improvements by integrating and optimizing the performance of the entire organization. GP offers a complete improvement package, addressing information and technology management, the workforce, as well as changes to facilities and processes. Our total quality management culture ensures that we offer world-class products and services.

GP believes that successful companies are characterized by an unrelenting focus on effectively linking their people, processes, and technology–three interrelated elements that directly impact the achievement of an organization's performance, cost management, and compliance objectives. GP's services are focused on integrating these three elements to provide the right solution to optimize your business results.

We develop and implement advanced technology and information management solutions and state-of-the-art training, engineering, consulting and technical services. We believe that our commitment to partnering with our customers, coupled with our values and quality approach, will facilitate building long-term professional relationships based on trust and customer satisfaction. GP is creating solutions for the wide-ranging challenges our customers face today–and anticipating those they'll face tomorrow.

By objectively analyzing production and business processes, GP can determine whether opportunities for performance improvement reside in people, processes, technology, or a combination of all three. We then recommend integrated, enterprise-wide solutions on how to best achieve a sustainable and measurable improvement on performance, cost, and compliance.
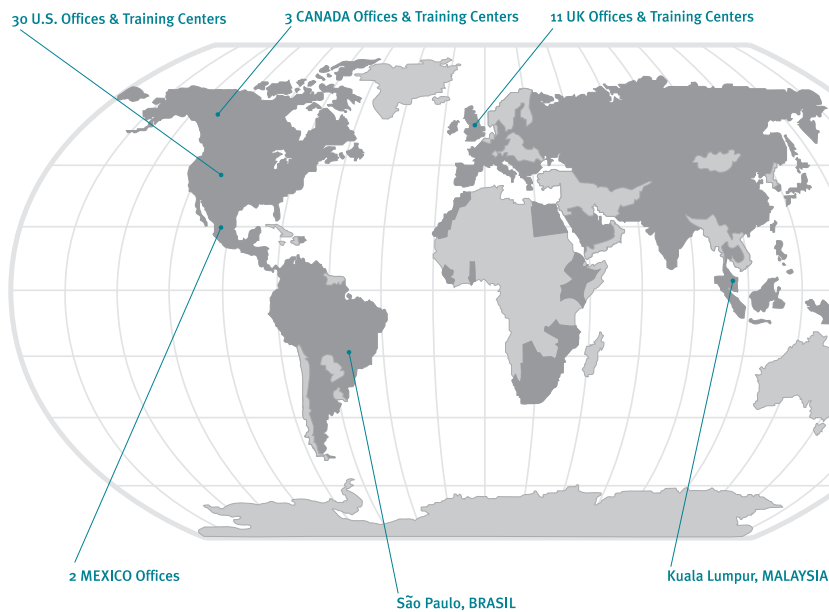
People - GP is well known for enhancing the performance and productivity of its customers' human resources. Our people help customers analyze, design, develop, implement, and evaluate effective training programs for all levels of employees.

Processes - GP has developed specialized and innovative techniques for the evaluation and improvement of its customers' business processes and procedures. Our people help customers benchmark critical processes and reengineer those in need of improvement.

Technology - GP has developed significant expertise in the integration of technology with our many products and services. Our people provide customers with high-technology solutions that successfully meet their needs.

Office & Training Center Locations

30 U.S. Offices & Training Centers

3 CANADA Offices & Training Centers

11 UK Offices & Training Centers

2 MEXICO Offices

São Paulo, BRASIL

Kuala Lumpur, MALAYSIA

Services Overview

GP categorizes its services by the type of support that customers require. The major classifications of support include the following:

Information, Technology, and Learning Management Services
- Information Technology and e-Business Consulting
- e-Learning Technology-Based Training
- Business Applications Training and Consulting
- Learning Resource Management (LRM) (Training Outsourcing)

Learning Architecture and Implementation Services
- Training Program Analysis, Design, Development, Implementation, and Evaluation

Manufacturing and Process Solutions Services
- Technical Training and Documentation Services
- OEM Support Services

Compliance, Safety, and Quality Management Services
- Process Safety Management (PSM) and Risk Management Services
- Environmental Services
- cGMP Validation Services
- Training and Documentation Development

Engineering and Facilities Services
- Engineering and Design (EE, ME, AE, etc.)
- Environmental Engineering

Plant Launch/Line Launch Services
- Planning
- Design
- Construction and Installation
- Commission and Startup
- Operation and Maintenance

Operational Excellence — Lean Enterprise, Six Sigma, Maintenance and Reliability — Consulting and Training Services
- Opportunity Definition
- Leadership and Priority Setting
- Change Infrastructure
- Methodologies for Excellence
- Organizational Change and Performance Improvement

Personnel

GP's greatest asset is its employees. Our staff consists of professionals with degrees/advanced degrees in all engineering disciplines, organizational development, information and technology management, and instructional systems design (ISD). Our employees maintain memberships and participate in technical societies, including the International Society of Pharmaceutical Engineers, The Parenteral Drug Association. The American Society for Training and Development, the American Institute of Chemical Engineering, and The American Society of Mechanical Engineers.

The diversity of our talented personnel is depicted in the following chart. GP takes great pride in our ability to provide the highest quality information and technology management, engineering, organizational development, as well as training services to our customers. GP employs over 1,500 experienced professionals in 48 offices worldwide, including:

- Instructional Systems Designers
- Training Specialists
- Operations and Maintenance Specialists
- Information Technology Consultants
- Web and Database Programmers
- Systems Administrators
- Project Management Specialists
- Organizational Development Professionals
- Occupational Assessment Specialists
- Maintenance and Reliability Specialists
- Engineers and Scientists
- Environmental Specialists
- Technical Specialists
- Logistics Specialists
- Multimedia Specialists
- Computer-Aided Design Specialists
- Graphic Designers
- Simulation Specialists
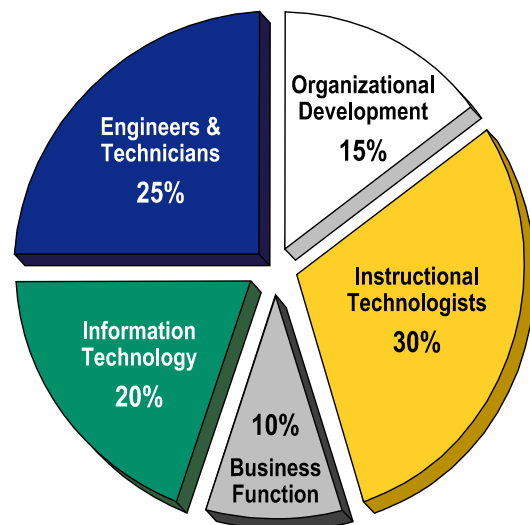
GP is well recognized as a provider of performance improvement solutions in the pharmaceutical and healthcare industry. As the industry has shifted to a global operating environment, GP has continued to expand to meet customers' needs. With key offices in the United States, the United Kingdom, Mexico, Brazil, Canada, and Malaysia, GP is able to provide a full range of services throughout the world.

Partnership Philosophy

GP's client base is diverse, providing services to more than one-third of the Fortune 500 companies. Our success is based on a commitment to develop long-term, mutually beneficial working partnerships with our customers. This commitment, coupled with GP's diverse experience, provides the opportunity to incorporate best practices from each industry into our services and to provide effective and flexible solutions to meet customers' needs, regardless of their industry and size.

Our professional staff works with you to gain a complete understanding of your organization's culture, environment, business drivers, values, and goals. This understanding is an essential ingredient in the success of each partnership. We believe that mutual success is achieved by:

- Having strong senior-level support from both organizations for project success
- Keeping constant communications
- Building trust through performance and flexibility
- Providing dedicated project resources
- Understanding the customer's workflow, processes, available technology, and business plan
- Using our combined experience and global resources
- Establishing clear performance criteria
- Building a long-term relationship
- Providing quality services
- Being flexible

The Pharmaceutical, Biotechnology, and Healthcare Industry and GP— Facing New Challenges Together

In the past few years, the pharmaceutical, biotechnology, and healthcare industries have undergone significant changes. Mergers, global competition, and the rapid pace of technology advancement and biotechnological discoveries have changed the business landscape forever. The demand for high quality products and health services has never been greater. The pressure to rapidly develop and manufacture affordable, accessible pharmaceuticals places stress on every part of the industry. All of these factors can occur in an environment where errors can be enormously expensive. The challenges are immense.

Pressure is on to reduce drug prices, and to bring more advanced products to market in less time. Simultaneously, the costs of regulatory compliance, increased emphasis on formal assessments of the cost and clinical effectiveness of new medicines (Health Technology Assessments), and aggressive R&D programs continue to rise. Every arm of the organization must cut unnecessary costs and achieve maximum efficiency.

Over the last decade, a revolution has occurred in the use of electronic technologies, such as the submission and review of regulatory documentation for pharmaceuticals and protection/ privacy of data for health services. Successful companies must be able to integrate information technology and information management with every aspect of the business, including: research, quality assurance, regulatory compliance, engineering and facilities, business practices, manufacturing, operations, and records management. Legacy systems including past databases, spreadsheets, and data systems must be kept current and available to researchers, manufacturers, and regulators while ensuring data integrity. Gaps within the IT structure lead to inefficiencies in every aspect of the enterprise, driving up costs.

To be competitive, today's pharmaceutical, biotechnology, and healthcare organizations must be simultaneously proficient in the management and performance of people, processes, technology, quality, compliance, and cost performance. GP specializes in the improvement of overall customer performance through the maximization of the relationships among these critical elements, within a framework emphasizing regulatory compliance, worker health and safety, and environmental protection. Based upon your business needs, we accomplish this by providing integrated, enterprise-wide solutions on how to best achieve sustainable and measurable improvement.

Our staff includes experts from an exceptionally broad range of technical areas. We have the flexibility to provide unified, comprehensive solutions to the most complex issues. From e-Business and IT solutions to project management, process improvement, training, safety and regulatory compliance, to engineering and facilities services, GP can help.

Information, Technology, and Learning Management Services

Information Technology and e-Business Consulting

- Web/Database Design, Development, and Maintenance
  - Systems Analysis
  - Policies and Procedures
  - Software Documentation
  - Software Testing
  - Data Migration
  - Custom Applications
  - Custom Reporting
  - Data/Knowledge Management
  - Electronic Performance Support Systems (EPSS)
- Application and Technical Problem Resolution
  - Custom Application Help Desk and Technical Support
  - Desk Side Support
  - Custom Application Training
- Network/Systems Support and Data Center Operations
  - Systems/Network Planning, Integration, and Maintenance
  - Systems Monitoring
  - Intranet/Internet/Extranet
  - Digital/Internet Security and Privacy Compliance
  - 24 x 7 Operations
  - Microsoft Solutions Partner™
- Logistics Support
  - Asset Management
  - Technical Writing
  - Amenities and 'Hoteling' Services
  - Event Planning, Coordination, and Implementation
  - Compliance
  - Training
  - Data Center Facilities Support
- Project Management/Administration

Information, Technology, and
Learning Management Services

Learning Architecture and
Implementation Services

Manufacturing and Process
Solutions Services

Compliance, Safety, and Quality
Management Services

Engineering and Facilities Services

Plant Launch/Line Launch Services

Operational Excellence — Lean
Enterprise, Six Sigma, Maintenance
and Reliability — Consulting and
Training Services

e-Learning Technology-Based Training

- Vision and Planning Assessment (Infrastructure / Culture)
- Web-Based Training (WBT)/Computer-Based Training (CBT) Design, Development, and Repurposing
- Learning Management System (LMS) Selection, Integration, Implementation, and Customization
- Content Selection, Development, Aggregation, and Distribution (Make/Buy Decisions)
- Site Hosting and Maintenance Services

Learning Resource Management (LRM) (Training Outsourcing)

- Consultation
- Analysis
- Design
- Development
- Administration
- Delivery
- Evaluations

Business Applications Training and Consulting

- Needs Assessment and Strategies
  - Existing Program Audits/Evaluation
  - Training Needs Analysis
  - Job and Task Analysis
  - Curriculum Architecture
  - Media/Mode Evaluation and Strategies
  - Change Readiness Assessments
  - Software Selection
- Program Design, Development, Implementation, and Maintenance
- Delivery Methodologies
  - Structured On-the-Job Training (OJT)
  - Instructor-Led Training (ILT) – Vendor and Custom
  - Hybrid (ILT plus on-line CBT, Distance Learning, WBT combinations or standalone delivery mechanism)
  - Train-the-Trainer
- Systems/Applications
  - Business Process Review/Reengineering
  - Role Mapping and Definition (Software and Training)
  - Delta/Software Upgrade Training
  - Enterprise Wide Applications, ie., ERP, CRM, SFA, EAM from vendors such as, Oracle, Baan, PeopleSoft, SAP, Seibel, Optima
  - Desktop, e.g., Microsoft and Lotus
  - Home-Grown
- Change Management
  - Training and Consulting
  - Communication Planning and Implementation
- Auxiliary Tools/Services
  - Reference Level Knowledge Support (Fast Tips™ Job Aids)
  - Electronic Performance Support Systems (EPSS)
  - Desktop or Web-Based On-Line Help
  - Ready II Role™ Product Plus
  - Project/Program Management
  - Training Administration
  - National Resource Management
  - Translation Services

Learning Architecture and Implementation Services

Training Program Analysis, Design, Development, Implementation, and Evaluation

- ISD Methodology
- Analysis
  - Needs Assessments
  - Job and Task Analyses
  - Training Population Evaluations
  - Existing Program Audits
  - Skills Gap Assessments
  - Tabletop Analyses
- Design
  - Media/Mode
  - Curriculum Architecture
  - Technology-Based Options
- Development
  - Training Program
  - Training Materials
- Implementation
  - Training Conduct–Technical and Professional
  - Train-the-Trainer Programs
- Evaluation
  - Program
  - Course
  - Performance

Manufacturing and Process Solutions Services

Technical Training and Documentation

- Documentation
  - Operations Production Procedures
  - Operations Manuals
  - Specific Equipment/System Operations Manuals
  - Site-Specific Equipment/System Maintenance Manuals
  - Maintenance Procedures
  - Documentation Revisions
  - Newsletter Production
  - Field Guides
  - Problem Solving/Troubleshooting
  - Emergency Operating Procedures
  - Emergency Planning
- Technical Training Centers
- Training Program/Course Support
  - Development and Conduct
  - Planning and Scheduling
  - Implementation Plans
  - Testing and Evaluations
  - Laboratory Exercises
  - System/Equipment Training Manuals
  - On-Site Instruction (hands-on or classroom)
  - Self-Paced Courses
  - Custom and Off-the-Shelf
- Training Programs
  - Apprentice
  - Structured OJT
  - Pay-for-Skills
  - Certification
- Training Types
  - Operation and Maintenance
  - Electrical, Electronics, and Mechanical
  - Manufacturing and Process Engineering
  - Applied Mechanical/Electrical Engineering
  - Instrumentation and Control
  - Train-the-Trainer
  - Cross-Craft
  - Multi-Craft

OEM Support Services

- Owner Manuals
- Training Manuals
- Parts Manuals
- Operating Procedures
- Maintenance Procedures
- Flowchart Development
- P&IDs/Document Support
- Instructor Support
- Technical Training for Sales Force

Compliance, Safety, and Quality Management Services

Process Safety/Risk Management (PSM/PRM)

- Compliance Assessments and Program Plans
- Mechanical Integrity Program Development and Implementation
- Management of Change Program Development
- Operating and Maintenance Procedures
- Process Safety Information and Documentation
- Training Services

Environmental Services

- Compliance Planning and Management
- ISO 14000 Services
- Radiological Health and Safety Engineering
- Environmental Protection Agency (EPA)
  - Clean Air Act (CAA) Compliance
  - Pollution Prevention
  - Wastewater Discharge
  - Environmental Assessments

Good Manufacturing Practices (cGMP 21 CFR Parts 210 & 211-226) and the ICH Q7A Harmonized Tripartite Guideline Good Manufacturing Practices for Active Pharmaceutical Ingredients

- Equipment/Facility Design, Construction Management, and Commissioning
- Development and Updates to Electronic Maintenance Information Management Systems (e.g., CMMSs and ERPs)
- Programs for Equipment Maintenance and Cleaning
- Operating Procedures for Critical and Noncritical Processes
- Development and Execution of Validation Protocols for Equipment/Systems

Training and Documentation Development

- ISO 14000 (EPA, DOT)
- QS-9000
- ISO 9000-2000
- HAZMAT and HAZWOPER
- OSHA
- Quality Production Procedures
- Quality Tools Training and Application

Engineering and Facilities Services

Engineering and Design (ME, EE, AE, etc.)

- System and Component Design and Analysis
- Specification, Drawings, and Plans
- Fabrication, Construction, and Modification Management
- Startup Operations and Maintenance Support Services
- Engineering Audits and Evaluations
- Field Engineering Process Design and Optimization
- Relief System Analysis
- Process Hazards Analysis

Environmental Engineering

- Planning and Pollution Prevention
- Air and Water Quality
- Natural Resources Planning and Management
- Solid and Hazardous Waste Management
- Industrial Hygiene
- Asbestos/Lead Investigation and Abatement
- Environmental Assessments
- Underground and Above ground Storage Tank (UST/AST) Management
- Remedial Investigation, Feasibility Studies, Design, and Action
- Geographical Information Systems (GIS)

Information, Technology, and
Learning Management Services

Learning Architecture and
Implementation Services

Manufacturing and Process
Solutions Services

Compliance, Safety, and Quality
Management Services

Engineering and Facilities Services

Plant Launch/Line Launch Services

Operational Excellence — Lean
Enterprise, Six Sigma, Maintenance
and Reliability — Consulting and
Training Services

Plant Launch/Line Launch Services

Planning
- People Side of Project Vision
- Change Management
- Quality System

Design
- Equipment Reliability, Availability, and Maintainability
- Quality Assurance System
- Facility Layout for optimum workforce efficiency and lean manufacturability
- Training Needs Analysis

Construction and Installation
- Maintenance Program Design
- Recruiting and Selection Methods
- Training Plans
- Qualification Checklists
- Equipment/System Training Materials
- Procedures and Work Instructions

Commission and Startup
- Maintenance Program Implementation
- Training Program Implementation

Operation and Maintenance
- Cross-Training Implementation
- Continuous Training Program Design
- Apprentice Program Implementation
- Training Function Outsourcing

Operational Excellence – Lean Enterprise, Six Sigma, Maintenance and Reliability – Consulting and Training Services

Opportunity Definition

- Benchmarking
- Assessments
  - Value Stream Analysis
  - Opportunity Assessment
  - Maintenance Assessment
  - Quality Systems Audit
- Change-Readiness Evaluation

Leadership and Priority Setting

- Leadership Development
- Leadership Alignment
- Goal Setting and Deployment
- Change Management

Change Infrastructure

- Improvement Office Setup
- Black Belts, Green Belts, and Rapid Improvement Leaders

Training

- Balanced Scorecard
- Customer Relationship Management Solutions

Methodologies for Excellence

- Lean Enterprise: 5S, Continuous Flow, Setup Reduction, Pull Systems, Supply Chain
- Six Sigma: Measurement Systems Analysis, Root Cause Resolution, Statistical Techniques, FMEA, Control Plans
- Maintenance and Reliability Systems
  - Reliability-Centered Maintenance
  - Planning and Scheduling
  - Computerized Maintenance Management Systems
  - TPM
  - Preventive Maintenance
- Business-Wide Transformation: Organize, Stabilize, Synchronize, Optimize
- Rapid Improvement®
  - Lean Manufacturing
  - Lean Transactional/Service
  - Reliability
  - Autonomous Maintenance
  - Systems Development

Organizational Change and Performance Improvement

- Situational Assessments and Program Architecture
- Team Building/Work Teams
- Change Management Services
- Organizational Design Consulting
- Project Management Training
- HR, Leadership, and Communications Training
- Job Performance Measures
- Pay-for-Skills/Performance Training Support
- Just-in-Time Training Tools Including Visual Procedures and EPSS Systems

This section outlines some of GP's project experience. With our broad experience and knowledge, GP can help you to optimize the performance of your workforce and your organization.

BECKMAN COULTER

e-Learning Technology-Based Training

- Develop one-hour web-based training course on Beckman Coulter Expense Reports

BIOMERIEUX VITEK, INC.

Web/Database Design, Development, and Maintenance

- Provide IT consulting and client server/web development support for a clinical trial management application that integrates automated forms processing and contact management data to quickly develop trial-specific information and reports from a single data repository with FDA 21 CFR Part II compliance
- Develop website for bioMerieux European site access for Trial Trax and Inventory Log
- Develop software validation protocol for Trial Trax Management System

Technical Training and Documentation

- Developed service manuals, operations and maintenance manuals, maintenance and repair manuals, and troubleshooting flowcharts for eleven pieces of automated microbiological testing equipment used by clinical microbiology and industrial control laboratories

BIOPSIS CORPORATION (SUBSIDIARY OF JOHNSON & JOHNSON)

Application and Technical Problem Resolution

- Provide Levels 1 and 2 technical support to Johnson & Johnson and customers for national repository of breast biopsy data
- Monitor server through remote access and periodic site visits
- Maintain hardware and software
- Develop and install fixes and upgrades

Custom Application Training

- Develop and deliver training on the use of the application and repository
- Demonstrate application (Breast Center Manager) and use of the national repository of information during sales presentations of a breast biopsy device

CATALYTHICA PHARMACEUTICALS

Engineering and Design

- Inspect cooling tower basin tank

COLORCON (DIVISION OF BERWIND PHARMACEUTICAL SERVICES, INC.)

Business Applications Training and Consulting

- Provided ISD and Oracle Tutor support for GEMMS and Financial applications training for R&D, inventory, purchasing, customer services, shipping, and formula creation staff
- Conducted process flow conferences to design all procedures and process flows for GEMMS application functions and non-GEMMS processes
- Developed educational overview of all Oracle GEMMS application areas
- Developed tutor navigation documents for GEMMS application functions
- Developed GEMMS General Navigation Desk Manual
- Assimilated Colorcon UK versions of tutor procedure documents to US versions

CONFIDENTIAL GLOBAL PHARMACEUTICAL COMPANY

Operational Excellence

- Provided performance improvement consulting services for new product launch worldwide (client has 45,000 employees in sixty-three countries with different regulatory requirements)
- Maximized the revenue generation cycle of patented pharmaceuticals by increasing the amount of time that the drug was available during the life of the patent
- Reduced variation in the methods used in obtaining regulatory approval in major markets
- Implemented repeatable marketing packages as a standard rollout method; performed many of the activities in parallel rather than the traditional sequential process typically used in the pharmaceutical industry
- Appointed the apparent successor to the leadership of the worldwide marketing organization as the process owner of new product introduction
- Formed an improvement team of the most credible staff from central marketing and the ten top world markets to launch a "test case" drug nearing the end of clinical trials; team efforts included
  - Design of the worldwide process using the corporation's past experiences and best practices, as well as input from physicians and regulatory agents, after benchmarking the new product launch process in three world-leading companies
  - Development of a standard work and methods kit in sixty-three languages for use by each country manager and his/her team
  - Development and deployment of a measurement system related to the successful launch process; each country manager's bonus was tied to these results in his/her country
- Supported this company in redesigning their organization so that the pipeline between compounds on-patent could more easily and quickly move to off-patent and continue generating revenue under a consumer name
- Changed the role of discovery, research, and development across the company so that pharmaceutical and consumer staff could jointly plan and execute strategies across the life of a compound rather than across their functional groups

CONFIDENTIAL MEDICAL INSTITUTIONS

Operational Excellence

- Support the merger of three complex medical systems to provide an integrated cancer treatment program
  - Working with senior management teams to design the new organization
  - Developing transition management roles and structures
  - Planning communication
  - Integrating focused work teams for process streamlining, process standardization, implementation planning, and project execution

    Coaching individual managers on managing change

ELI LILLY AND COMPANY

Business Applications Training and Consulting

- Provided development and implementation services of custom maintenance business practice processes, formal process training, and field coaching support for the implementation of a Global PAM program
- Ensured the program supported the maintenance organization to enhance planning and scheduling of maintenance work performed on plant assets
- Provided direction for configuration and efficient use of MAXIMO as an asset management tool
- Monitored and mentored maintenance managers, maintenance planners, maintenance supervisors, and craft personnel in process application

Technical Training and Documentation

- Provided support to the upgrade of the Greenfield Powerhouse
  - Develop and upgrade boiler operating procedures
  - Develop and upgrade boiler maintenance procedures
  - Implement water validation implementation procedures
- Provided training and coaching support for the pilot rollout of a program designed to improve plant maintenance practices (proactive asset management) at the Clinton, IN, plant
  - Taught maintenance planning concepts and plant-specific maintenance practices
  - Coached operations and maintenance personnel in new practices and use of the plant
  - CMMS, MAXIMO Enterprise, Release 3.0
  - Set up value lists in MAXIMO, identified columns for assignment in MAXIMO data tables, and defined SQL strings for maintenance reports from MAXIMO
  - Presented a Basic Planning Concepts course to new maintenance planners at the Indianapolis, IN, plant
  - Coached new planners in planning and scheduling practices

Compliance, Safety, and Quality Management

- Developed and executed validation protocols for several utility systems throughout the Lilly Corporate Center campus in downtown Indianapolis, IN
  - These protocols covered the installation qualification, operational qualification, and process or product qualification standards established by the Food and Drug Administration's current Good Manufacturing Practices
  - The utilities validated included clean steam, HVAC, oil-free compressed air, nitrogen, water for injection, and water for bulk sterile operations
- Validated two programmable logic controllers (PLCs) controlling the system
- Installed several system upgrades involving Lilly's change control process

ELI LILLY AND COMPANY (CONT'D)

- Installed, tested, and qualified new components in stages, qualifying new components before replacing existing ones, allowing continuous purified water delivery to Lilly's customers, including analytical and research laboratories, animal research laboratories, and one of the manufacturing lines within the Lilly Corporate campus
- Developed and executed installation and operational qualification protocols for three Getinge autoclaves, including two that were relocated within the Lilly Corporate Center and one that was purchased with modifications; provided electronic copies of the qualification protocols to support ongoing efforts
- Developed a preventive maintenance program for Lilly's Analytical Development Group, facilitating compliance with the Good Manufacturing Practices as described in 21 CFR parts 210 and 211, including the following:
  - Interviewed the technicians and equipment owners to identify the equipment that required preventive maintenance
  - Identified the areas responsible for the performance of the maintenance
  - Determined the exact type and frequency of maintenance required
  - Updated equipment records by surveying actual equipment and entering the information in their electronic maintenance information management system
- Developed a preventive maintenance program for Lilly's Plant Engineering and Maintenance Department, facilitating compliance with the Good Manufacturing Practices as described in 21 CFR parts 210 and 211, including the following:
  - Located at the following Lilly facilities: Indianapolis, IN; Clinton, IN; Puerto Rico; and Stroudsburg, France
  - Encompassed the following functional areas: Dry Products; Parental Products; Clinical Trials; Quality Control Laboratories; and Analytical Development Laboratories
  - Established equipment/facility configuration and updated the electronic maintenance information management system
  - Developed preventive maintenance program for the equipment
  - Developed and revised preventive maintenance and operating procedures for the equipment
  - Executed equipment validation protocols for the equipment

GENENTECH

Engineering and Facilities Services

- Baselined seventeen pressure vessels
- Provided vessel program support services such as collecting nameplate data, providing project management, and developing program guidelines
- Provided tank assessment services
- Replaced corroded process tanks in manufacturing area

Technical Training and Documentation

- Developed a site-specific inspection program and training for front-line operators and maintenance personnel
- Delivered training for tank inspectors

GENETIC THERAPY, INC.

Compliance, Safety, and Quality Management/Environmental Engineering

- Perform environmental compliance assessment to determine current and near-term compliance status
- Calculate air emissions for permit exemption and/or permit requirements
- Conduct environmental assessment of operations
- Review air regulations and advise client of compliance requirements

HARTON REGIONAL MEDICAL CENTER

Engineering and Facilities Services

- Performed UST closure and generator belly tank at Manchester and Tullahoma Regional Medical Centers
- Installed belly tank at Manchester and Tullahoma Regional Medical Centers

HERITAGE MANOR

Engineering and Facilities Services

- Remove and install aboveground 280-gallon diesel tank

HOFFMANN LA ROCHE

Technical Training and Documentation

- Designed and developed process descriptions for production and utility systems
- Designed and developed self-study training materials for the PERMAC maintenance and inventory control system

JOHNSON & JOHNSON CORPORATION (CODMAN GROUP)

Database Design, Development, and Maintenance

- Brought existing Surgical Instrument Set application on-line by repairing nonfunctioning applications
- Developed enhancements to Surgical Instrument Set application

Application and Technical Problem Resolution

- Provide Levels 1 and 2 technical support to Johnson & Johnson and customers for two national data repositories: Surgical Instrument Set Data and Hip Replacement Hardware Implant Data
- Monitor server through remote access and periodic site visits
- Maintain hardware and software
- Develop and install fixes and upgrades

JOHNSON & JOHNSON PROFESSIONAL, INC.

Database Design, Development, and Maintenance

- OrthoComplete Program
  - Develop software build requirements
  - Research compatibility and Y2K compliance issues
  - Develop, implement, and analyze Software Problem Reports
  - Develop on-line and hard-copy documentation
  - Develop automated testing, installation, and setup utilities
- PRIZM Plus Program
  - Develop software enhancements, testing, and documentation
  - Research Y2K compliance issues

Application and Technical Problem Resolution

- Provide technical help desk support
- Provide field service installation support

Custom Application Training

- Provide PRISM Plus application training to end users

MEDTRONIC-AVE

Business Applications Training and Consulting

- Provided Jetform training

MERCK AND COMPANY

e-Learning Technology-Based Training

- Developed a CD-based, six-hour, self-paced, multimedia-training course for Merck's remote sales force of 3000, suitable for use on their own laptop computers. The objective was to provide the medical and scientific knowledge needed to effectively promote Merck's new migraine headache medication
  - Included professional audio, high-resolution graphics, 3-D models, and eye-catching animations to engage the learners' attention and keep their interest throughout the training
  - Included tools for topic searches, review, score reporting, progress tracking, and a dictionary where learners could obtain definitions for complex terms and hear them pronounced
  - Provided presentations and interactive exercises about migraine headaches, neurology, migraine pathogenesis, and pharmacology
  - Upon implementation, achieved an average grade of 96% on a separately administered final evaluation exam to measure long-term retention and the ability to transfer the learning to on-the-job performance

Technical Training and Documentation

- Developed a self-study course including OJT for mail table checkers
- Developed and delivered a mechanical inspection course

Compliance, Safety, and Quality Management

- Performed mechanical integrity testing
- Developed monthly equipment walk-down inspection routines as part of a preventive maintenance program

MERCK AND COMPANY (CONT'D)

Maintenance and Reliability

- Gathered equipment and location information to support the launch of a new computerized maintenance management system (CMMS)
- Performed an assessment of the Flint River Plant's equipment and maintenance program to provide cost and technical recommendations in the establishment of a vibration analysis program
- Reviewed preventive maintenance tasks and schedule frequencies as part of a maintenance optimization program
- Provided implementation support during rollout of Merck-MAXIMO to the Flint River plant
- Developed equipment records and preventive maintenance procedures in MAXIMO

MICROSURGICAL TECHNOLOGY

Operational Excellence–Organizational Change and Performance Improvement

- Performed a six– phase, business-wide assessment and performance improvement program using lean manufacturing and Six Sigma to reduce raw material-to-shipment manufacturing time from 32 days to 2 days and enable make-to-order rather than ship-from-stock for a medical device manufacturer. The six phases were as follows:
  - Performing assessment, assessment debrief, leadership education, and leadership alignment
  - Engaging the workforce
  - Leading the transformation
  - Beginning the transformation–order fulfillment
  - Beginning the transformation–product development
  - Maintaining continuous improvement

ORTHO-CLINICAL DIAGNOSTICS

e-Learning Technology-Based Training

- Provided web-based training course on Vitros 250
- Provided ECI prerequisite courses

PARKE-DAVIS

Technical Training and Documentation

- Rewrote a technical manual for the operation of a capper machine in the filling area
- Developed two additional system manuals
- Developed and delivered two training courses: one for a production line operation and one for a bar code reader operation

PFIZER, INC.

Web/Database Design, Development, and Maintenance

- Provide consultative and specialized support, including database development
- Develop new code for implementation of new functionality utilizing skills with Access, ODBC, Oracle, and VBA; design new code to implement upgrades
- Conduct documentation and code reviews
- Review coding standards
- Review procedure development
- Provide client intranet support
  - Develop policies and procedures
  - Develop new content
  - Maintain site
- Update and improve internal legacy databases to allow access to knowledge base information
- Assist in migration of databases to new servers
- Develop methods to protect proprietary information
- Develop Corporate Information Technology Financial Database; provided upgrades, enhancements, and security features
- Develop database documentation including user's guide and administrator's guide
- Provide technical writing and programming services to assist in identifying and capturing support information and organizing material to populate a prototype knowledge base
- Develop knowledge base for help desk analysts

Application and Technical Problem Resolution

- Deliver software technical support for Procurement Management Application
- Support Microsoft- and Pfizer-unique application packages
- Provide Levels 1 and 2 technical problem resolution/help desk support
- Coordinate and provide support for user desktop upgrades
- Provide post-upgrade/installation of Windows 95 desk-side visits to users for problem resolution
- Install, upgrade, and troubleshoot problems on NT and Windows 95 desktops
- Provide one-on-one and group training, including "how-to" and technical desktop support

Network/Systems Support and Data Center Operations

- Operate and manage Computer Data Center
  - Provide 24 x 7 staffing, problem resolution, reporting, etc
  - Monitor critical application and system checkouts, backup execution, data restores, first-level troubleshooting, escalation, and event notification
  - Provide Level 1 help desk support
- Provide hardware and software upgrade installation support for client's digital systems

Business Applications Training and Consulting

- Scheduled new applications training for new systems/applications rollout

PFIZER, INC. (CONT'D)

Year 2000 Compliance, Planning, and Coordination Support

- Assessed software, hardware, and documentation for compliance
- Tested hardware and software to ensure compliance
- Tracked status of testing results
- Contacted critical vendors to ensure vendor business continuity and product compliance, including status tracking of responses, non-responses, milestones reached, etc.
- Identified training requirements
- Promoted and provided Year 2000-related training
- Worked with business units and subject matter experts to determine business needs

Logistics Support

- Provide computer resource procurement support
- Write and track justification for purchases (JFPs)
- Provide workplace solutions amenities services
- Provide technical writing services for brochures
- Provide IT asset management support
  - Receipt inspection of incoming equipment and parts
  - Bar code and enter data for all equipment and parts
  - Provide inventory management
  - Provide inventory distribution
- Provide event planning, coordination, and implementation
- Provide training services
  - Conduct training analysis and needs assessments
  - Develop and deliver targeted training modules in a myriad of media based on needs assessments, such as follows:
    - Corporate Dictionary Services Group
    - Adverse event tracking and reporting
    - POLARIS, an order entry application
    - Update and maintain Pfizer-unique courses
    - Levels 1 and 2 help desk analysts
    - Special projects
    - Developed Y2K informational workshops and seminars for business unit owners

Project Management and Administration

- Provide project management services
  - Computer Data Center
  - Software application review and GAP analysis development
  - Transcribe business processes and needs into software requirements
  - Coordinate and oversee programming activities associated with development and maintenance of Pfizer custom applications
- Provide project administration support
  - Schedule maintenance, financial analysis, and communication
  - Organize documentation, project folders, etc.
  - Coordinate meetings: scheduling, preparing agenda, and recording and publishing meeting minutes
  - Track consistency and compliance

PHARMACIA CORPORATION

Organizational Change and Performance Improvement

- Provide an assessment program for skilled trades pre-employment screening and apprenticeship program feedback to improve the apprenticeship program
  - Develop hands-on exams and tests
  - Identify the necessary equipment for procurement to conduct the tests

PHARMACIA AND UPJOHN

Compliance, Safety, and Quality Management

- Performed extensive design, documentation search, verification, and development activities for process equipment
- Developed a step-by-step guide and flowchart to ensure timely and accurate retrieval of all required equipment documentation
- Developed and assisted in the implementation of a comprehensive Mechanical Integrity (MI) Program and reconstructed design basis documentation for the processes covered by Process Safety Management (PSM), including the following:
  - Institute a trestle piping inspection program covering all trestle piping in the chemical and fermentation operations areas
  - Develop protocols for ultrasonic thickness testing
  - Perform calculations, such as remaining life, next inspection date, and maximum allowable operating pressure, using UltraPipe software
  - Develop a program for ongoing inspections of all trestle piping, facilitating a smooth transition to P&U personnel so they can conduct all ongoing trestle inspection activities.
  - Gather design basis documentation for all pressure vessels, tanks, and rotating equipment to ensure compliance with the mechanical integrity provisions of OSHA's PSM rule; enter information into a database for use in scheduling preventive maintenance and other activities (gathered documentation from the site, the original equipment manufacturers, or the National Board; if not available, GP performed the necessary calculations to determine design pressure and temperature for the vessel and generated the required documentation)
  - Develop a complete maintenance program, conduct workshops for maintenance team members, and supervise the implementation of the program

SHIONOGI QUALICAPS

Compliance, Safety, and Quality Management

- Developed validation master plans and validation protocols to support construction and Food and Drug Administration (FDA) approval of two new capsule manufacturing facilities in Greensboro, NC, and Alcobendas, Spain

SHIONOGI QUALICAPS (CONT'D)

- These protocols covered receipt verification and inspection for all equipment, Installation Qualification (IQ), Operational Qualification (OQ), and Process or Product Qualification (PQ) to standards established by the FDA's current Good Manufacturing Practices (cGMP)
- The systems validated included all the utility systems, laboratory equipment (scales, autoclaves, incubators, environmental chambers, etc.), the capsule-making machines, and the capsule-making machine support equipment

Maintenance and Reliability

- Reviewed and revised existing procedures, including the manufacturing tickets, to incorporate the change to a computer-integrated manufacturing (CIM) environment
- Developed a preventive maintenance program determined by the maintenance needs of the various validation protocols. The equipment to be maintained, the type of preventive maintenance to be performed, and the frequency of the maintenance were determined through a survey and incorporated into the program

Engineering and Facilities Services

- Developed validation protocols for the building utilities such as chill water and HVAC
- Developed protocols for the capsule-making machines and their support systems, and for laboratory equipment such as incubators

SMITHKLINE BEECHAM

Technical Training and Documentation

- Delivered a two-week Instrumentation course

3M PHARMACEUTICALS

Technical Training and Documentation

- Designed and developed operator and technician training, including on-the-job training (OJT) materials and operator certification
- Developed operating procedures and checklists
- Developed new employee orientation training
- Conducted train-the-trainer courses as part of a turnkey operation

VISTAKON

Technical Training and Documentation

- Performed job and task analysis (JTA) for three lines
- Constructed twenty-two hands-on mechanical and electrical testing stations
- Proctored hands-on testing
- Built hands-on assessments

WARNER LAMBERT

Engineering and Facilities Services

- Developed the relief system design basis
- Developed draft specifications for pressure relief devices
- Developed a relief system design for the new tank farm

Clients

ABB
ACCU-SORT
ADVANCED MICRO DEVICES
AK STEEL
ALCOA ALUMINUM
AMD
BP AMOCO
AMP
APPLIED MATERIALS
ARCO
BASF
BAUSCH & LOMB
BECKMAN COULTER
BELL & HOWELL
BETHLEHEM STEEL
BIOMÉRIEUX VITEK, INC.
BIOPSIS CORPORATION, (SUBSIDIARY OF JOHNSON & JOHNSON)
BIRMINGHAM STEEL
BOEING
BOISE CASCADE
BONNEVILLE POWER ADMINISTRATION
BRISTOL-MYERS SQUIBB
BROOKHAVEN NATIONAL LABORATORIES
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HERITAGE MANOR
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HOFFMANN-LAROCHE
HUDSON INTERNATIONAL CONDUCTOR
IBM
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IMMIGRATION AND NATURALIZATION SERVICE (INS)
INLAND CONTAINER
INTERNATIONAL PAPER
ISPAT-INLAND STEEL
JAMES RIVER
JEFFERSON SMURFIT
JOHNS HOPKINS UNIVERSITY/APPLIED PHYSICS LAB (JHU/APL)
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PEPSI-COLA
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PHARMACIA CORPORATION
PHARMACIA & UPJOHN
PHILADELPHIA WATER DEPARTMENT
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PRINTED CIRCUIT CORPORATION (PCC)
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SHIONOGI QUALICAPS
SIEMENS TRAY MANAGEMENT SYSTEM (TMS)
SITA-EQUANDT
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SMITHKLINE BEECHAM
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