

Life Sciences Organizations Speed Discovery, Facilitate Compliance, and Boost Efficiency

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Oracle Products & Services:

Oracle Life Sciences Data Hub
Oracle Healthcare Transaction
Base
Oracle Clinical
Oracle Remote Data Capture
Oracle Adverse Event Reporting
System
Siebel Clinical Trial Management
System
Oracle Process Manufacturing
Oracle Advanced Supply Chain
Planning
Oracle Order Management
Oracle Inventory Management
Oracle Demand Planning
Oracle Virtual Directory
Oracle Access Manager
Siebel Customer Relationship
Management
Agile Product Lifecycle
Management

It is a time of great expectation in the life sciences industry as organizations stand on the cusp of new discoveries that will advance the treatment of serious and chronic disease as well as open new commercial avenues for biotech and pharmaceutical companies. Anticipated progress in the area of personalized medicine—which leverages genetic and genomic information to predict, prevent, and treat disease—is just one example of a frontier that holds tremendous potential.

At the same time, however, pharmaceutical and medical device manufacturers as well as biotechnology companies face unprecedented operational challenges. Cost pressures are increasingly acute across the enterprise as the investment needed to bring a major drug to market closes in on US\$1 billion dollars and many pharmaceutical manufacturers see a dwindling pipeline of traditional drugs, as well as greater competition from generics. The medical device industry is experiencing similar cost and time-to-market pressures.

As important, life sciences organizations across the spectrum face escalating challenges around the complexity and costs associated with an ever-expanding set of regulatory requirements both in the United States and around the globe.

The industry understands that information—and the ability to harness and analyze it—is fundamental to seizing the potential of new treatment frontiers while navigating challenging economic and compliance realities. Many are turning to Oracle and its infrastructure software and extensive suite of integrated applications for clinical research and development, manufacturing, supply chain management, and customer relationship management (CRM) to help them thrive as they extend the boundaries of medical care.

Oracle solutions support life sciences organizations in identifying the most promising compounds and medical devices in the pipeline, keeping clinical trials on track, quickly aggregating clinical and operational data for analysis and reporting, managing

Key Benefits:

- Enhance operational efficiencies and outcomes in clinical trial management
- Increase efficiency and quality of clinical data with electronic data capture
- Streamline analysis, reporting, and submission with integration of all clinical and non-clinical data
- Reduce risk via process validation and compliance
- Improve product quality with applications that automate compliance requirements
- Implement lean manufacturing initiatives with flexible and agile manufacturing applications
- Automate and streamline compliance requirements with rules-based and 21 CFR Part 11-compliant applications
- Increase marketing and sales effectiveness
- Improve customer segmentation and targeting with integrated analytics
- Deliver more effective and personalized interactions with closed-loop marketing
- Provide a 360-degree view of the customer and optimize interactions at every touch point

production to ensure optimal quality and efficiency, facilitating compliance, and targeting the right customers with product messages that build brand loyalty.

A recent study by independent IT consulting firm Mainstay Partners quantifies the benefits that Oracle delivers to the industry. Companies in the life sciences industry running Oracle applications have returns on capital that are four times higher and are three times more profitable than peer organizations not running Oracle.

Improving Research and Development Efficiency

In the high stakes arena of drug, biologic, and medical device discovery and development, every second counts as organizations seek to accelerate time to market to help patients in need, as well as optimize patent utilization. For a blockbuster drug, delays in reaching the market results in millions in lost revenue that cannot be recovered due to patent-protection limitations.

As development costs continue to escalate, selecting the right candidate compounds for testing and screening in early-stage research is critical. Also vital is the ability to quickly identify non-performing candidates. Since the vast majority of candidates—95%¹ in the pharmaceutical industry—will not become usable products, the faster they can be removed from the pipeline, the sooner an organization can redirect time, talent, and lab/design resources to more promising endeavors.

Oracle's infrastructure software, including Oracle Life Sciences Data Hub, Oracle Fusion Middleware, and Oracle Healthcare Transaction Base, enables organizations to achieve dramatic improvements in research and development (R&D) productivity with solutions that help to aggregate clinical and non-clinical data for more effective analysis and discovery, and later for expedited reporting and submission.

Dana-Farber Cancer Institute, one of the leading cancer research and care centers in the United States, is using Oracle Healthcare Transaction Base and Oracle Fusion Middleware components as the foundation for its new translational research infrastructure. The new infrastructure is designed to maximize the value of clinical and research data, and help improve disease understanding and patient care.

¹ "Pfizer: Making it 'Leaner, Meaner, More Efficient,'" *BusinessWeek*, February 27, 2009

“Oracle Healthcare Transaction Base enabled us to securely integrate our clinical, sample, and genomic data—helping us to maximize the use of this information in our quest to develop a better understanding of and treatments for serious diseases.”

John Quackenbush,
Ph.D.
Professor of Biostatistics
and Computational
Biology
Dana-Farber Cancer
Institute

“Oracle Healthcare Transaction Base enabled us to securely integrate our clinical, sample, and genomic data—helping us to maximize the use of this information in our quest to develop a better understanding of and treatments for serious diseases,” said John Quackenbush, Ph.D., Professor of Biostatistics and Computational Biology, Dana-Farber Cancer Institute.

Dana-Farber, through its research, collects large amounts of patient and clinical data, as well as thousands of biological samples. It also relies on outside data sources to advance its research and understanding of complex diseases. To design new studies and address complex questions, Dana-Farber researchers need to aggregate clinical, sample, and genomic data from within and beyond the organization’s collections.

Like many life sciences organizations, it lacked a single, integrated data infrastructure that enables aggregation and provides a comprehensive view. Using Oracle Healthcare Transaction Base, Dana-Farber created an integrated data repository that enables researchers to access clinical and sample data using a single platform and seamlessly connect it with experimental data.

The new data infrastructure helps researchers investigate clinical data more thoroughly, make complex queries and more complete data analysis, and improve experiment design. It also enables more rapid queries, providing researchers with answers in minutes to queries that previously required days to process.

Enhancing Clinical Trial Efficiency

Clinical trials—which average US\$124 million per drug candidate after accounting for drug failure² rates and whose costs are rising faster than pre-clinical research and development activities—are another prime target when life sciences organizations look for ways to improve operational efficiency and accelerate time to market. Safety, however, can never be compromised. So, along with greater efficiency, life sciences organizations seek means to help them quickly spot any adverse events related to a drug or medical device.

With Oracle’s integrated suite of clinical applications, which includes Oracle Clinical, Oracle Remote Data Capture, Oracle Adverse Event Reporting System, and Oracle Thesaurus

² Di Masi, J.A., Hansen, R.W., Grabowski, H.G. “The Price of Innovation: New Estimates of Drug Development Costs,” *Journal of Health Economics*, 2003.

Management, along with Oracle's Siebel Clinical Trial Management System, life sciences organizations are achieving new operational efficiencies in clinical trial development. As important, they are increasing the efficiency and quality of clinical data; streamlining analysis, reporting, and submission with integration of clinical and non-clinical data; and gaining new levels of clinical trial decision-support with clinical analytics.

Electronic data capture (EDC) systems are a growing focus in the life sciences industry as they prove their potential to improve data quality, accelerate data collection, and reduce costs. Studies show that organizations have been able to reduce case report form (CRF) cycle times from 45 days to nine days with EDC.³ By reducing the time spent rectifying transcription errors and inaccurate data values, trial sponsors can focus on more important tasks—including regulatory compliance and source document verification. Further, the near real-time analysis of results that EDC enables helps to improve decision making in terms of expanding or discontinuing a study.

LEO Pharma A/S, a pharmaceutical company specializing in treatments for dermatological and vascular-related conditions, is realizing the power of Oracle Clinical applications, including Oracle Remote Data Capture, to help improve clinical trial site productivity and accelerate drug approval submissions to regulatory agencies.

LEO Pharma designs and manages its clinical trials using Oracle Clinical, an application the company installed in 2002. The move helped increase productivity and data quality, executives said, but the company still faced delays getting data into the system in the first place—in large part because LEO Pharma used paper case report forms (CRFs) to record data at each trial site.

To minimize such delays, the company moved to Oracle's site-based EDC system—Oracle Remote Data Capture. Instead of paper forms, researchers enter clinical data directly into a Web-based application located on a PC at the investigation site, often on the same day the patient is examined. The remote application integrates with the backend Oracle Clinical application, eliminating the need to ship paper forms and load data into the system later.

³ Brian Chadwick, "To e or Not to e," *Pharmaceutical Visions*, Spring 1999.

With Oracle Remote Data Capture, LEO Pharma can now reduce processing time from the patient's final visit to database lock—the point at which the study can be closed and unblinded—to just one-to-two weeks, down from the six-to-12 weeks it usually takes with paper systems.

Beyond closing trials faster, companies like LEO Pharma find that EDC systems improve the integrity of the data collected. Oracle Remote Data Capture comes with multiple quality checks that flag discrepancies and help researchers and data managers understand the reasons for follow-up changes. Cleaner datasets lead to fewer development and regulatory bottlenecks because pharmaceutical companies spend less time reworking the data—or repeating parts of the trial.

LEO Pharma also takes advantage of automated trial randomization capabilities to securely and rapidly randomize participant treatments. It then leverages Oracle's automated unblinding capability at the conclusion of a trial, eliminating a previously labor-intensive process.

Ensuring Manufacturing Efficiency and Product Quality

Life sciences organizations, particularly pharmaceutical manufacturers, are looking to increase the efficiency of their operational and manufacturing processes—optimizing resources, improving efficiency and quality, reducing waste, and gaining greater control over inventory. In this climate, manufacturers are looking to lean manufacturing and Six Sigma principles—among others—to help them boost operational efficiency and improve quality, while facilitating compliance.

Lean Manufacturing focuses on eliminating manufacturing waste, with the objective of making manufacturers more responsive to customer demand and market changes. Six Sigma is a business process methodology that focuses on minimizing variation—in product and process—to reduce product defects.

IT factors heavily in the transition to a Lean Six Sigma enterprise and the subsequent journey of continuous improvement. Because of the complexity of the pharmaceutical manufacturing environment, organizations require flexible and interoperable IT systems that provide information, not just data, across the enterprise. In a Lean Six Sigma environment, information flows must complement and keep pace with physical flows to deliver the information needed. Just as important is the ability to mine

data and interpret it efficiently, quickly, and seamlessly. Having the right data readily available when it is needed also makes it easier to respond to inquiries from regulatory agencies, such as the U.S. Food and Drug Administration (FDA).

Oracle's integrated enterprise applications for supply chain, manufacturing, and inventory along with analytics and business intelligence capabilities support the introduction of Lean Six Sigma manufacturing initiatives designed to improve efficiency and quality with end-to-end visibility and real-time information.

Polpharma, one of Poland's top manufacturers of generic drugs and a leading supplier of pharmaceutical chemicals and services, is realizing the benefits of an integrated Oracle application infrastructure as it improves product quality, reduces inventory, and boosts manufacturing efficiency.

Polpharma was privatized in 2000—a move that opened up opportunities for growth and investment in new markets across Europe and North America. To compete in these markets and ensure compliance, Polpharma invested in a large-scale enterprise resource planning (ERP) and supply chain solution based on Oracle E-Business Suite applications. Mainstay Partners assessed the costs and benefits of Polpharma's investment, and found that it should realize approximately US\$6.3 million in total (gross) benefits from its Oracle solution through 2010, and achieve a 23% net return on investment.

By introducing standard, transparent business processes, Polpharma established tighter control over its supply chain operations—achieving substantial performance and labor productivity gains in purchasing and inventory management as the automated system cut down on manual administration.

Other efficiencies come from the system's ability to create optimal order sizes based on current inventory levels, order forecasts, and material requirements. In the past, the company calculated orders manually using less reliable data.

Following the implementation of Oracle manufacturing and production planning systems, Polpharma has seen a 5% increase in production capacity at the company's 25,000 square-meters

manufacturing facility in Starogard Gdanski. The system's advanced production-scheduling module has been key to the improvement, helping managers optimize material and labor inputs and schedule production runs more efficiently.

While in the past it took days or even weeks to compile production-planning data, managers now receive daily reports detailing equipment and labor utilization rates, and related performance metrics. Rapidly generated production reports enable managers to pinpoint factors that affect yields and take corrective actions after each run to minimize waste and optimize output.

Using the Oracle system, Polpharma can also precisely control the mix of raw material inputs. Consequently, the company's output forecasts are more consistently on target.

In addition, production efficiency—measured as the variance of materials used compared to a pre-Oracle baseline—improved by 7% since the Oracle implementation, reflecting a decrease in the average amount of raw materials consumed per unit output.

By taking advantage of the system's sophisticated planning and scheduling capabilities, Polpharma can quickly shift production runs from one manufacturing line to another, in effect increasing the capacity of its Starogard Gdanski facility.

In addition, more sophisticated bills of material (BOMs) allow the company to create multiple BOMs for the same product, so it can switch ingredient lists depending on what is in stock. The enhancement has helped Polpharma cut materials waste by about 1%, resulting in estimated savings of US\$125,000 per year, according to Mainstay.

Other BOM-related improvements, such as better tracking of dates of receipt and use, drove engineering efficiencies that resulted in production time savings of approximately 15%. Better resource management and quality control has translated into faster production cycles overall, managers reported, reducing time to market by about half.

Polpharma's inventory management module gave the company more control over its stocks of pharmaceuticals and fine chemicals. Managers said the system's planning tools and modules will enable Polpharma to stock an optimal mix of

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Alastair Clewlow
Former Head of Clinical
Data and Document
Management
LEO Pharma A/S

products and reduce inventory levels overall. The system’s unified data model was key to the improvement, managers said, ensuring a consistent view of inventory levels.

Ensuring Effective Compliance

Life sciences organizations face compliance challenges at nearly every corner of their operations—from clinical trials through final delivery of their products. In the clinical trial phase, organizations must validate data using precise criteria, report potential adverse events rapidly, as well as prepare and complete extensive reports and submissions that comply with the requirements of the FDA as well as other international regulatory agencies.

Oracle’s suite of integrated clinical applications supports compliance by helping organizations to accelerate data validation as well as reporting and submission processes.

LEO Pharma is leveraging the power of Oracle Clinical applications to ensure submission compliance. To speed regulatory review, the FDA encourages companies to submit new drug applications (NDAs) electronically. Among other requirements, e-submissions must include portable document format (PDF) versions of case report forms that are extensively cross-referenced, hyperlinked, and bookmarked.

Oracle Remote Data Capture facilitates the FDA e-submission process by enabling LEO Pharma to generate, in one step, a single PDF combining all CRFs for a patient. Each change made to the document is backed by electronic signatures that comply with the FDA’s 21 Code of Federal Regulations (CFR) Part 11 Guidance. The consolidated document, known as a patient data report, along with an audit trail and discrepancy information, comprise a significant portion of the overall submission.

The PDF tool helps the company avoid hundreds of hours of document preparation that would be required to convert paper forms into an FDA-approved electronic document.

“With Oracle Remote Data Capture, you can generate a bookmarked and hyperlinked PDF in one step. So it’s a dramatic difference in time and money when it comes to submitting the data,” said Alastair Clewlow, former head of Clinical Data and Document Management, LEO Pharma A/S.

Privacy, Please

Life sciences organizations are responsible for protecting the privacy and security of patient data. Non compliance can lead to significant financial as well as reputational risk. At the same time, life sciences organizations are finding that collaboration—within different parts of the organization, as well as with partners—is more important than ever.

The industry faces a unique set of challenges when it comes to balancing the need to share information and extend collaboration against requirements to protect sensitive patient and business data. Oracle Identity Management applications are helping life sciences organizations balance these priorities with capabilities that enable them to securely manage the end-to-end lifecycle of user identities across all enterprise resources both within and beyond the firewall.

Pfizer Inc., a global leader in the pharmaceutical industry, is taking aim at this challenge through a comprehensive, yet flexible identity management strategy designed to enable efficient authorized access to information while helping to facilitate compliance with requirements imposed by Sarbanes-Oxley, 21 CFR Part 11, and the Health Insurance Portability and Accountability Act (HIPAA).

The company's strategy is to treat authentication as an infrastructure service, so that each application can require the proper form of authentication from users. This structure is important because the company's pharmaceutical research and development efforts around discovering and marketing new drugs entail both applications that are low sensitivity, with a low risk of information disclosure and loss of data integrity, and high sensitivity, with high requirements for absolute data integrity and for ensuring that data not be disclosed to those who should not have access. The company started its identity management initiative by leveraging two Oracle products—Oracle Access Manager and Oracle Virtual Directory—to build a unified and centralized portal for more efficient internal and external access.

With its Oracle Identity Management solution, Pfizer greatly reduced its risk of exposing intellectual property and privacy-related data. Operating in the strictly regulated pharmaceutical industry, Pfizer must adhere to multiple regulatory requirements that relate to protecting the personal information of clinical trial participants as well as validating its clinical trial practices. To

ensure the highest levels of security, Oracle provided Pfizer the ability to require two-factor authentication for access to particularly sensitive data.

“Oracle Access Manager allowed us to build the capability into our infrastructure once, and make it available to any application that chooses to use it,” said William Barnes, director, Identity Services, Pfizer Worldwide Technology.

Ensuring Compliance in the Manufacturing Cycle

Compliance is also an integral part of the manufacturing process in the life sciences industry. The FDA, for example, mandates that medical device companies must have separate processes in place to ensure compliance—from corrective and preventive action systems to control systems for product design, materials, records and documentation, to production facilities and equipment. Meeting these rigorous compliance and quality requirements can impact time to market, costs, competitiveness, revenue, and profitability.

Pharmaceutical manufacturers face similar challenges, including the need to track the origin and validate the content of raw materials as well as document and validate manufacturing processes. California’s ePedigree initiative will soon add a new layer of compliance complexity by requiring manufacturers to track their products from manufacture to the pharmacy.

Oracle applications for supply chain, procurement, manufacturing, quality, and distribution as well as business intelligence and infrastructure software, enable life sciences organizations to reduce risk via process validation as well as automate and streamline compliance requirements with rules-based and 21 CFR Part 11-compliant applications.

Stryker Endoscopy—which manufactures equipment that is utilized in minimally invasive surgery—is aware of how complex FDA compliance mandates can be.

“We selected Agile Product Lifecycle Management because it was important for us to be on the latest technology platform for our compliance documentation and reporting.”

Glenn Boehnlein
Vice President and Chief
Financial Officer
Stryker Endoscopy

Stryker Endoscopy is implementing Oracle’s Agile product lifecycle management (PLM) applications to help the company address its compliance mandates. Agile PLM applications provide one central solution for aggregating, analyzing, and acting on product quality issues, from customer complaints to manufacturing deviations to adverse-event information or supplier corrective actions.

“We selected Agile Product Lifecycle Management because it was important for us to be on the latest technology platform for our compliance documentation and reporting,” said Glenn Boehnlein, vice president and chief financial officer of Stryker Endoscopy. “Agile will allow us to be under one system. It will also allow a common format across all divisions at Stryker Endoscopy, which will be useful for us in terms of making sure that we have consistency in our compliance efforts.”

In addition, Agile PLM applications provide the infrastructure to meet the requirements outlined by the FDA’s quality system regulations, and provide a platform for full compliance with 21 CFR Part 11.

Enabling Customer Centricity

In the global pharmaceutical industry, manufacturers face new sales and marketing hurdles as the time that physicians can spend with drug representatives continues to shrink. At the same time, products and company’s sales and marketing organizations are more complex.

Oracle’s sales and marketing applications, including Siebel Pharma Sales, enable life sciences organizations to increase marketing and sales effectiveness; enhance customer segmentation and targeting with integrated analytics; deliver more effective and personalized interactions with closed-loop marketing; provide a 360-degree view of the customer; and optimize interactions at every touch point.

To continue to compete successfully in a changing landscape, Boehringer Ingelheim Pharma GmbH & Co. KG, one of the world’s 20 largest pharmaceutical companies, rededicated itself to creating a more customer-centric business that delivers the best possible service to its customers—doctors and patients. An important part of this strategy was optimizing its sales representatives’ physician visits by equipping them with the most

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Wolfgang Schaupp
Head of System
Management,
Marketing and Sales
Boehringer Ingelheim
German

up-to-date information on the provider. The company also committed to developing and rolling out standardized sales and marketing processes.

Boehringer Ingelheim, like many pharmaceutical organizations, found that it did not have a comprehensive view of all outreach its representatives were conducting. Short visits with doctors often require follow up as well as careful documentation. The company found this process was not transparent, and representatives generally acted on their own instead of as a team. If, for example, a doctor was a specialist in more than one area, the company might have sent more than one representative to the office, each one covering different drugs. This led to confusion, duplicate efforts, and inefficiencies.

Boehringer Ingelheim selected Oracle’s Siebel applications to manage its sales force. With Siebel applications, Boehringer Ingelheim has improved the efficiency of its sales force.

Boehringer Ingelheim uses Siebel CRM applications to track each interaction with a physician, ensuring a consolidated, consistent customer experience. The Oracle applications also help the company better target drug information to the appropriate physicians and specialists. To date, Boehringer Ingelheim has rolled out the solution in 40 countries.

“We market to doctors working in various different specialties depending on what drug we are marketing,” said Wolfgang Schaupp, head of System Management, Marketing, and Sales, Boehringer Ingelheim Germany. “Using Oracle’s Siebel CRM applications, our sales force teams are better able to organize and, perhaps most importantly, work together as a large team with our customer support organizations.”

Why Oracle?

As life sciences organizations confront today’s difficult business challenges, many are turning to Oracle and experiencing the real-world benefits of Oracle’s technology and applications for life sciences. With Oracle solutions, life sciences organizations are advancing their efforts to improve research and development efficiency, enhance product quality and manufacturing efficiency, streamline compliance, and increase the effectiveness of sales and marketing initiatives.