

# Oracle Accelerate Solutions for Life Sciences: Biotech & Pharmaceutical

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# Oracle Accelerate Solutions for Life Sciences: Biotech and Pharmaceutical

## ORACLE APPLICATIONS FOR SMALL AND MEDIUM BUSINESS

**"As an experienced user of Oracle Advanced Supply Chain Planning, we're excited about Oracle's integrated offering of a truly best in class manufacturing planning, scheduling and execution solution, to drive our company to an even higher level of performance that will benefit our customers in terms of on-time delivery."**

—Peter Billiaert,  
Vice President, Business Process  
Improvement, TEVA Pharmaceutical  
Industries Ltd.

**"We remain convinced that Oracle Remote Data Capture is an effective tool to improve the quality and efficiency of our clinical data and is here to stay."**

—Stéphane Collet,  
Head of Data Management and Clinical Trial  
Support, Boehringer Ingelheim

## EXECUTIVE OVERVIEW

Biotech and Pharmaceutical companies face constant competitive pressures to bring new drugs to market faster than be able to manufacture and sell them more efficiently – even as they contend with unique ever-increasing regulatory compliance burdens.

As commercially available enterprise software vendors have increased their Life Sciences vertical footprint, biotech and pharmaceutical companies have increasingly embraced industry-specific solutions to improve clinical trial efficiency, manufacturing quality and compliance, and the effectiveness of their launch and sales process.

Small biotech and pharmaceutical companies face the same issues as their larger counterparts, and in addition also face some very specific concerns of their own. Because one size does not fit all, smaller biotech and pharmaceutical companies have special concerns about ease of use, affordability and speed of deployment. These concerns have slowed the adoption of these IT solutions by small biotech and pharmaceutical companies, despite the demonstrated benefits.

Oracle offers a new class of Life Sciences solutions that now brings these industry-specific capabilities within reach of small biotech and pharmaceutical companies. This paper discusses the primary benefits of Oracle's Life Sciences solution and how it addresses the key challenges of biotech and pharmaceutical companies with an affordable and scaleable solution designed and built for small biotech and pharmaceutical companies.

## AN INDUSTRY OVERVIEW

Innovation, Product Quality & Safety, Compliance Pressures, Customer Centricity, - these leading business trends are driving industry players to focus on efficiencies and visibility to information across all processes in order to make right decisions at the right time.

To take timely and well informed decisions executives need to get answers to questions like:

- "How can I streamline my clinical data and trial management processes to improve quality and quantity of drug pipeline and shorten time to

market?”

- “How can my organization meet the increasing regulatory compliance demands and improve product quality?”
- “How can I increase the efficiency of my sales and marketing organizations to provide greater value to our customers and maximize revenue growth?”

Small and medium sized companies compete with and face similar issues to those of large enterprises. In addition they need to figure out how to continue to be nimble and differentiate themselves, often through their service and delivery capabilities. For small and medium businesses (SMBs) in the biotech and pharmaceutical segment, the main challenges are around product innovation and successfully bringing products to market faster than their competitors while meet addressing all regulatory requirements. Many smaller biotech companies focus solely on research while outsourcing the development (clinical trials) process to contract research organizations (CROs), and manufacturing operations to contract manufacturing organizations (CMOs). They may also choose to partner with large pharmaceutical companies to commercialize and sell their products in the market. However, it is every biotech company’s desire, large, medium and small, to successfully launch a product or two to market quickly, thus generating substantial revenues that drive additional innovation and research and ultimately broaden their product pipelines.

Small and medium biotech and pharmaceutical companies also face additional challenges of having silos of information systems, thus limiting their overall ability to address their daily business challenges. To successfully compete, these firms need to implement business applications that enhance their ability to:

- *Improve Operational Efficiencies and Outcomes in Clinical Trial Management* – Modern life science companies manage dozens or hundreds of simultaneous trials, often across the globe. And every day of every trial brings mounting costs. That’s why Oracle is the trusted market leader in clinical data and trial management systems. With the only combined clinical data management and electronic data capture, Oracle Clinical improves both efficiency of data collection and data accuracy. Oracle’s Clinical Data Integration brings together both clinical and non-clinical data to streamline analysis reporting and submission. Integrated Complaint and Adverse Event capabilities provide the industry’s only direct integration of adverse events reporting to the clinical data management system. This creates a unique single source of truth for both adverse event submission and reporting. Look to Oracle to help manage large numbers of trials, high volumes of data, and stringent reporting requirements worldwide.

“Oracle has been quietly expanding its Enterprise Resource Planning (ERP) products for Small and Midsize Businesses (SMBs). It has added vertical industry tools to E-Business Suite Special Edition, but it has also welcomed the old J.D. Edwards reseller channel and expanded the available market in which it is allowed to sell the World and EnterpriseOne product lines.”

—AMR Research,  
May 2005

- *Reduce Risk via Process Validation & Compliance* - Even if a product is successfully introduced to the market and promises profitability, there are always other risks. Risks often result from the inability to view data globally and nonintegrated processes, which can lead to the failure to comply with regulations. From planning and procurement through manufacturing, Oracle applications are uniquely built to help minimize risks, ensure compliance, and avoid costly recalls. Oracle is the only company that provides “out-of-the-box” high risk GxP business events that provide rapid process validation and 21 CFR Part 11 and GMP embedded compliant applications. It includes pre-built tools that enable comprehensive and inherent electronic signatures and automate regulatory record keeping. Oracle’s flexible and agile manufacturing applications enable companies to implement lean manufacturing initiatives which can further increase efficiencies and lower costs. A leader in Master Data Management, Oracle ensures product quality by allowing all processes to be monitored from a single integrated data repository. .
- *Increase Marketing, Sales & Service Effectiveness* – The evolution of customer entities, sales channel saturation, proliferation of newer channels and media, and the increase in regulations covering sales and marketing expenditures pose tremendous challenges in the industry. Oracle has the largest sales user community in the world with proven success from over 150,000 Life Sciences users. It is the world leading provider of Customer Relationship Management (CRM) applications, which are built with industry specific capability and Customer Centric Service with a 360-degree view of customers. They empower biotech and pharmaceutical sales professionals with personalized customer intelligence and help close the gap between analysis and execution. The applications enhance segmentation and targeting with integrated analytics while significantly helping to improve productivity and marketing effectiveness by driving consistency across marketing and other customer-facing business processes. All of this leads to improved physician relationships thus contributing to increased revenues.

## THE ORACLE ACCELERATE DIFFERENCE

Oracle has created Oracle Accelerate especially for small and medium businesses and government entities.

- Oracle Accelerate delivers simply priced bundles of applications relevant to your industry segment from across the Oracle Applications product family (e.g. Oracle E-Business Suite, Oracle JD Edwards EnterpriseOne, Oracle PeopleSoft Enterprise and Oracle Siebel);
- Oracle Accelerate delivers rapid implementation tools called Oracle Business Accelerators to help implement solutions faster;
- Oracle Accelerate provides implementation services delivered through Oracle Consulting Services or partners who specialize in your industry segment, to minimize startup time and risk.

Using a fixed-scope approach, Oracle Accelerate substantially reduces the complexity of more traditional, large-scale implementations.

Now you can have the right applications to manage your operations and data, at the right cost—so you can achieve real business value quickly while avoiding the expensive rip-and-replace costs of other inflexible, non-scalable solutions.

## WHY ORACLE ACCELERATE FOR BIOTECH AND PHARMACEUTICAL?

Oracle Accelerate for Small and Medium Biotech and Pharmaceutical organizations offers a comprehensive software solution that drives innovation, improves product quality & safety, supports compliance pressures, and enables customer centricity through automated operations and informed decision making. The Oracle Accelerate Solution for Biotech and Pharmaceutical incorporates best practices while maintaining the flexibility to support your evolving needs.

Oracle Accelerate provides a **comprehensive** and **flexible** solution – giving you a solution that meets your needs today and tomorrow.

- **Complete** – The simplest to the most complex business processes can be managed with one business applications footprint.
- **Integrated** – Take advantage of the leading industry capabilities without having to increase IT resources.
- **Scalable** – Start small, add and change as you need, without fear or uncertainty that you will outgrow your business applications.

Oracle Accelerate is **designed** and **built** for Small and Medium Biotech and Pharmaceutical companies.

- **Rapid Deployment** – Applications, Business Accelerators, documentation, test scripts – all pre-bundled to meet your needs today and tomorrow
- **Best Practices** – Leverage best in class industry best practices developed by Oracle and our partners having worked with thousands of customers
- **Custom Fit** – Bundle solutions—you decide what you need and when you need it and incorporate your business practices during the implementation process.

Oracle Accelerate provides an affordable solution that is **easy to own** with predictable value.

- **Easy to Buy** – Simple and affordable packaged pricing
- **Easy to Use** – Applications and business flows easily configured to do business the way you do business.
- **Easy to Maintain** – Minimal IT overhead required for support. Stay on the upgrade path.

Easy to Own Solutions

with Predictable Value

Industry Focused Solutions

to Meet Your Unique Requirements.

Complete solutions

to Meet Your Needs Today and Tomorrow

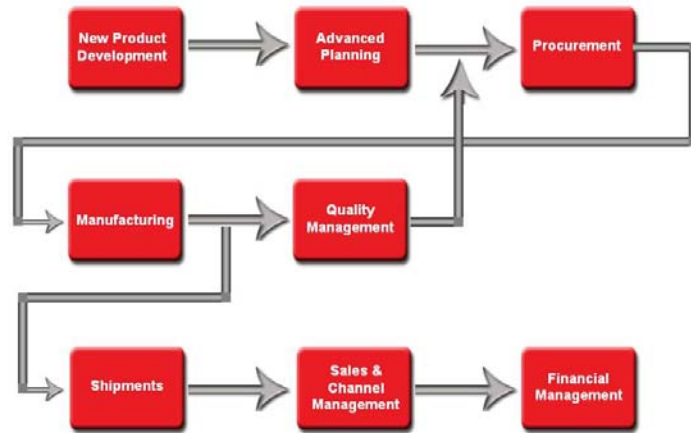
- **Easy to Adapt** – Solutions that allows you to decide what you need and when you need it

“With enterprise small and medium-size business (SMB) spending leading enterprise expenditure, winning the midmarket is a key component to Oracle’s future growth. Since its acquisition of PeopleSoft, Oracle has been quietly making investments in new partnership programs, product development, and branding initiatives around the JD Edwards assets. These initiatives and investments show Oracle’s intent to compete in the midmarket. With key partner successes in the past two quarters, Oracle is demonstrating that JD Edwards is still a viable contender. Existing users should upgrade to EnterpriseOne 8.11 (the latest version) and the upcoming 2006 enhancements for JD Edwards World to take advantage of applications to be built on Project Fusion.”

—IDC,  
April 2005

## BENEFITING FROM INDUSTRY-LEADING BEST PRACTICE BUSINESS PROCESSES AND DATA

Oracle Accelerate for Biotech and Pharmaceutical solution provides a baseline of standard processes, user-friendly setup utilities, master file records, end-user task views, roles, and security profiles. This baseline allows you to save time and money by providing a foundation upon which you can build your solution. The Oracle Accelerate for Biotech and Pharmaceutical solution includes the following Business Processes:



## IMAGINE THE POSSIBILITIES

If you are interested in a rapid, low-risk approach, look no further. Oracle Accelerate solutions are packaged and delivered to be easy to own, industry-focused, and complete; just what you need, nothing you don’t, so you can start at just the right size—and price—for your needs.

**UNLIMITED POSSIBILITIES FOR LIMITED BUDGETS****WHY DO SMALL AND MEDIUM BUSINESSES CHOOSE ORACLE?**

- **Easy to Own** - A low-cost computing platform and rapid implementation reduce cost from day one.
- **Easy to Implement** - Tens of thousands of SMB customers make Oracle a market leader.
- **Easy to Use** - A single integrated software suite unifies systems, streamlines processes, and drives better business performance.
- **Easy to Manage** - A uniform business platform gives customers the freedom to grow, as needed, without expensive reimplementation.

**JUST WHAT YOU NEED – NOTHING YOU DON'T****RELATED PRODUCT AND SERVICES**

The following product and services are available from Oracle:

- Oracle E-Business Suite
- JD Edwards EnterpriseOne
- PeopleSoft Enterprise
- Siebel
- Oracle On Demand
- Oracle Consulting
- Oracle Support

**INFORMATION ACCELERATES**

Oracle is the leading vendor of e-business transformation services, providing technology and professional services to the world's leading e-businesses. Oracle Accelerate utilizes a fixed-scope approach, substantially reducing the complexity of more traditional, large-scale implementations. For customers interested in a rapid, low risk approach, Oracle Accelerate provides the opportunity to leverage world-class functionality at unprecedented entry-level value.

Oracle Accelerate delivers a complete set of applications, rapid implementation tools, and an extensive partner system, so that small and medium businesses can maximize their budgets and achieve real business value quickly. Utilizing a fixed-scope approach, Oracle Accelerate substantially reduces the complexity of more traditional, large-scale implementations.

For Small and Medium Biotech and Pharmaceutical companies, Oracle Accelerate offers a comprehensive software solution that drives innovation, improves product quality & safety, supports compliance pressures, and enables customer centricity through automated operations and informed decision making. The Oracle Accelerate Solution for Biotech and Pharmaceutical incorporates best practices while maintaining the flexibility to support your evolving needs.

For customers interested in a rapid, low risk approach, Oracle Accelerate provides the opportunity to leverage world-class functionality at unprecedented entry-level value. Learn more at:

- For information about Oracle or Oracle's Accelerate Biotech and Pharmaceutical solution, please visit: [www.oracle.com/accelerate](http://www.oracle.com/accelerate)



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