



**SAP White Paper
Life Sciences**

CONTRACT LIFE-CYCLE MANAGEMENT

**A Holistic Approach to the Creation,
Administration, and Execution of Contracts**

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EXECUTIVE SUMMARY

In the expanding, dynamic, and price-driven life sciences ecosystem, it's estimated that over 80% of sales are distributed through indirect channels and purchased through contracts between manufacturers and contract organizations. Contract management complexity abounds as in perhaps no other industry. Consequently, increasing the productivity and transparency of the contract management continuum is paramount to achieving competitive advantage and shareholder value.

Yet the contract management continuum in most life sciences companies is typically neither productive nor transparent. Instead, complexity continues to spiral out of control, largely because of marketing innovations in the life sciences field. Back-end rebates and up-front discount sales schemes often disregard the rule sets of the company's contract management process, compounding not only complexity but risk.

In response, the life sciences industry has evolved a multiplicity of business units, systems, and activities to support the contract management process that have become increasingly separated and distinct — creating the potential for real difficulties and problems in the process. The mistakes that occur can cost the company a fair proportion of the contract margins. Yet these variances persist, partly because these contracts are often managed outside existing systems that are too rigid to accommodate the needs of a fast-changing market.

Meanwhile, growing demands from customers, government regulators, and managed care organizations require sound decision making on product pricing and contracts. Strict compliance with contract obligations is essential to maintaining healthy relationships with suppliers and trading partners, while market forces including regulations that deal with government pricing increasingly expose company portfolios. Amid these pressures, life sciences companies also face an ever-changing regulatory climate.

For most businesses, the contract management process — the very means by which life sciences companies get their products into the marketplace — is more and more obscure. The resulting unpredictability further aggravates profit leakage, exposure to risk, and inadvertent illegalities while reducing sales opportunities and increasing channel conflict. The more unmanageable the process, the more complicated it becomes with every change and update.

To answer these challenges, the leading global companies in life sciences are beginning to assess better ways to manage their contract management systems and processes. They are recognizing the need for an integrated, synchronized, enterprise-wide contract life-cycle management process that is simple, manageable, and predictable. An integrated solution provides the transparency needed to satisfy the auditors' eyes, to balance pricing with go-to-market strategies, and to support sales and finance teams — including the ability to accurately predict margins and earnings per share.

A unified IT platform supporting this solution has the power to standardize and automate all related processes, including communications with suppliers, trading partners, and customers. These processes are aligned to support profitable growth and lower total cost of ownership. A platform providing a consistent process and data model enables common rule sets and managed workflow across the enterprise, ensuring that everyone is working with the same information. It should use the company's existing technology to integrate back-end processes with contract management processes. And it should be highly adaptive to help the company react to market dynamics, using well-documented rule sets to precisely respond to rule changes.

Life sciences companies that can move the right products at the right prices, on the right terms and conditions, are the ones that will thrive. Those that do will streamline business processes and manage workflow so that decision making based on real-time information becomes part of their everyday activities – whether it's approving prices or reacting to contract performance issues. And these companies will continue to seek out enabling technology.

INTRODUCTION

Trends in Contract Life-Cycle Management

Outside of public health and safety, there is probably no single issue of public discourse as multidimensional or emotional as access to healthcare and the rationing of treatment – or said another way, the price of healthcare. With estimates that over 80% of all sales and prices in the United States are stipulated by a commercial or government contract, contract management has emerged as a critical focus area for most healthcare and life sciences organizations. The challenges are significant and confront these organizations everywhere – from business process to legal and systems perspectives.

Growing Complexity

For a large life sciences company, contract price reductions, including back-end rebates, administrative fees, and chargebacks, may, for example, amount to more than US\$1 billion. Even a small variance in chargebacks or rebates can result in huge over-payments – or huge savings, if they are avoided. Just a 2% overpayment variance for a company with an annual contract exposure of US\$100 million, for example, equals US\$2 million in potential savings. Adding to chargeback and rebate liabilities is the growing difficulty of managing government regulations, which exposes companies with inadequate processes and systems to significant fines and penalties that affect profit margins.

Risk Mitigation

In today's contract management environment, the U.S. Sarbanes-Oxley Act and other government pricing and reporting requirements have a major impact on financial controls and disclosures. With a large portion of a life sciences company's contracts typically managed outside of systems and their inherent controls, they are continuously exposed to financial and legal risks. In addition, contract-related liabilities only continue to grow, stimulated by ongoing price pressures from government, managed care, and generic competition. Making informed pricing and contract decisions is therefore critical.

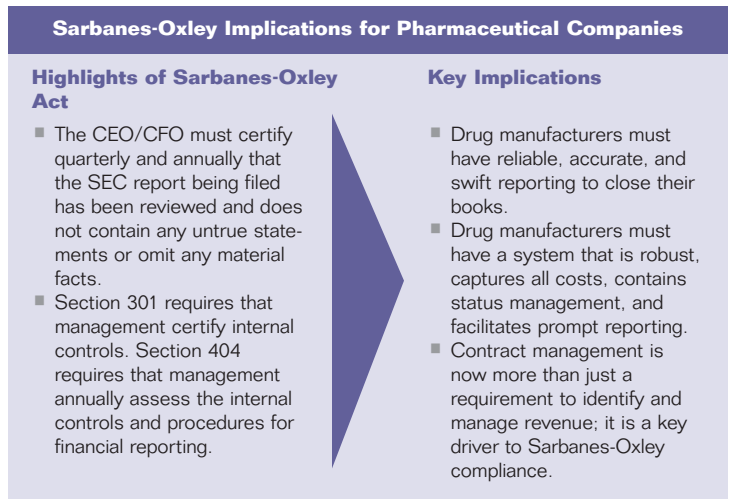


Figure 1: The Implications of the U.S. Sarbanes-Oxley Act to the Life Sciences Industry

Market Pressures

Intensified compliance concerns also increase the focus on pricing and contract management, relative not only to Sarbanes-Oxley but also, in the United States, to emerging Medicaid and Medicare legislation and Office of Inspector General (OIG) regulations. Portfolios are also increasingly exposed, with patent expiries, branded entrants, and the shift toward biologics and biotech-pharma alliances. In addition, intermediary market influences are increasing the strength of traditional customers and expanding the involvement of payers and other new intermediaries.

Customer and Supplier Relationships

A considerable channel conflict has emerged in the life sciences marketplace. Lack of data consistency and nonintegrated contract life-cycle management processes lead to dissemination of misinformation and in turn, to unhappy trading partners and customers. Significant opportunity loss occurs in the inability to collaborate with trading partners to wring efficiencies from the

healthcare system. Today's public policy climate has heightened risks associated with managing complex contracts, compliance, and government reporting (see Figure 2).

Risk	Impact	Result
Government Price Exposure	Compliance with Centers for Medicare and Medicaid Services, OIG, and VA requirements	Under- or over-reporting government prices may result in the following: <ul style="list-style-type: none"> Interest charges, penalties, or fines Overpayment of Medicaid rebates Corporate and personal legal risk
Loss of Financial Controls	<ul style="list-style-type: none"> Inability to execute creative or complex deal structures Inability to manage deal within the system 	Manual processes or outdated system may cause the following: <ul style="list-style-type: none"> Irreconcilable deductions leading to write-offs Excessive or duplicate payments
Sarbanes-Oxley	Improper treatment of deals could impact revenue recognition	<ul style="list-style-type: none"> Improper disclosure in financial reporting Criminal and/or financial risk
Channel Conflicts	Channel/trading partner disputes	Inefficient, non-value-added business processes
Profit Leakage	Large contract exposure may result in, for example: <ul style="list-style-type: none"> 5%–20% or more of gross sales US\$50 million to US\$1 billion liability 	Small variances may cause profit leakage or overpayment, as follows: <ul style="list-style-type: none"> 3%–8% of chargebacks and rebates paid* Noncompliance and enforcement to contract terms further erode margins <p style="text-align: right;"><i>*Source: Accenture</i></p>

Figure 2: Challenges in Contract Life-Cycle Management for Life Sciences Companies

To address these challenges, the trend today is to develop contract strategies that harmonize pricing guidelines, company policies, and contract terms across the enterprise. Life sciences companies are implementing flexible and configurable contract negotiation and management systems supporting diverse rule sets and deal offerings that can vary by customer segment. They are measuring and managing contract commitments and obligations that drive visibility and accountability, enhance profit margins, and increase mind and market share. Using powerful data analysis tools, they are increasing pull-through by capturing business intelligence that provides the essential history of contract information necessary to survive government audits and to reach across operational and tactical systems to build strategic intelligence and optimized price guidelines. They are embedding auditing tools with rigorous validations designed to proactively manage exceptions related to pricing, contracting, sales and marketing, and compliance.

THE QUEST FOR SIMPLICITY

These trends are leading companies to ask what values they can gain from technology. On a company-by-company basis, the answer to that question brings up others: What do you want from your contract management solution? What imperatives would drive the design? Most companies would require predictability, especially of margins and revenues. But they would also demand complete manageability to meet market dynamics, full visibility into processes and information for decision making, the ability to stand under the scrutiny of auditing in every department, and a self-determined solution to control their business future. The quest is for simplicity in processes to make them serve business needs.

However, a snapshot of today's contract management processes shows that picture in reverse. In most of today's life sciences companies, contract management is not a predictable process and is anything but simple and manageable. The complexity of sell-side contract management in life sciences has compounded, creating too many variables. An unpredictable solution can never be manageable.

The snapshot further shows that contract life-cycle management has become obscure, a fundamentally incomprehensible process essentially imposed by market dynamics. The very mechanism that drives revenue and profit margins is undermined. The unintelligible rule sets supporting contract life-cycle management processes prevent the CFO and finance people from accurately predicting margins and revenues. The CFO who is not in control of the revenue recognition rules in the sales contract is putting the business at risk, potentially making statements about revenues gained that do not match reality.

Life sciences companies are losing money because they do not understand the potential of contract pricing and are unable to provide their sales teams with effective tools. Or they are winning sales with low pricing, undermining profit margins.

Channel partners feel the resulting confusion and frustration when faced with inconsistent answers or misinformation, and that drives up complaints and costs. With an unmanageable, poorly defined contract management process, sales teams are prone to buck the system rather than serving the needs of the business and its customers. Further, companies can too easily commit unintended legal transgressions as obscure rules camouflage trading that is outside legal boundaries.

Self-Determination Versus Market Dynamics

Today's contract management environments exist because of the highly intricate relationships between pharmaceuticals and medical device suppliers, their distributor channels, the contract agent, and the final consuming organizations. This ecosystem was not intelligently designed but evolved one organization or buying center at a time — a true product of market dynamics.

Today, the market creates intense competitive pressure, with huge sales being made by contracting organizations that grow ever larger. Sales organizations are forced to continually invent new means to satisfy market needs, using discounts, rebates, or other mechanisms to work with their distribution channels and end customers without regard to the business processes that will be affected. Amplifying that situation are regulations intended to control the dynamics of the ecosystem and insure an undistorted marketplace and fair treatment of end customers. Each regulation change demands new checks and balances in the contract life-cycle management process.

CONTRACT LIFE-CYCLE MANAGEMENT FOR LIFE SCIENCES

Over the years, different business units and organizational functions have assumed responsibility for different parts of contract management, leading to dispersed process ownership. Typically, people in proposal generation are separated from price masters, who are separated from the sales teams, who are separated from the invoicing teams. Where there is distributed ownership, there is no ownership. Furthermore, barriers are sometimes set up between business units within the same organization. A contract management solution must integrate with multiple transaction systems, some of which are external and outside the company's control.

The Transparency to Balance Price with Go-To-Market Strategies

Without control over contract life-cycle management, decision makers must constantly counter pricing pressures with new promotional ideas. But every new promotion results in special terms and conditions that need special coding. And these schemes must be weighed against the regulatory risks and potential audits from different departments that request proof of compliance.

Gaining supremacy over the contract life-cycle management process requires the transparency that can exist only with accurate, available data sources. Such transparency does not result from deploying accidental architecture, but only from an integrated contract life-cycle management process that supports selling processes, auditing demands, and predictable earnings per share. Since financial markets are more interested in margins than revenues, CFOs are faced with the massive challenge of margin predictability in the midst of this tangled web of rebate and discount rules. But with a highly controlled contract management environment, the impact of revenue predictions on margins is understood and the quality of earnings-related predictions is improved.

A complete contract management solution must consider the complexity of the life sciences ecosystem from end to end. The solution must be able to manage the needs of many different customers and contracts with managed care, group purchasing organizations, and government pricing. It must consider the many multifaceted member relationships and multitiered sales channels between wholesalers and hospitals, and between specialty distributors and e-business hubs that connect customers to the supply chain. In addition, every day, it must provide performance-based rebates driven by market share and many other pricing variables.

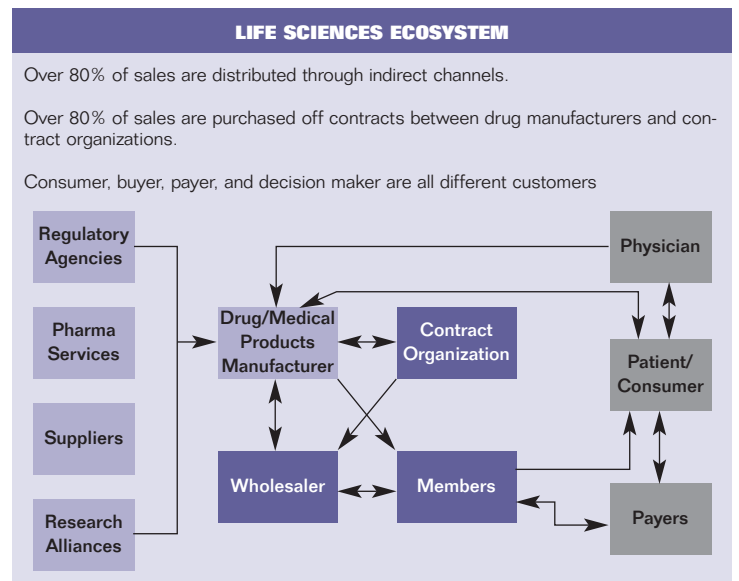


Figure 3: The Life Sciences Ecosystem Supporting Diverse Contracts, Customers, and Relationships

Contract Life-Cycle Management Solution Requirements

In addressing the core aspects of the sell-side contract life-cycle management process, a solution must also address a spectrum of business benefits – from improved revenue management, reduced risk, and improved predictability to enhanced customer and trading partner relationships, improved channel performance, and lower operating costs, to name a few. Achieving this vision moves contract management toward an integrated and synchronized contract life-cycle process spanning the enterprise – with simplicity, manageability, predictability, responsiveness, flexibility, and control as key objectives. But what does that involve? What are the criteria for a complete contract life-cycle management solution?

Industry-Specific Design

The best option is an industry-specific solution that embraces open standards, is built upon a stable platform, can adapt to industry-driven requirements, and protects investments from future technology or regulatory changes. A generic sales, pricing, and contract solution is not the best choice for integrating contract management processes in life sciences. A company should not have to deal with software modules using different technologies or those that have been patched together.

Managed Workflow

Managed workflow provides control across multiple process silos using a consistent process model that not only applies to the vertical silos but also to the horizontal activity of the contract management process. Combining managed workflows with business

process modeling tools, organizations are able to model, execute, and monitor their processes, ensuring that proper controls are in place and everyone supporting the process knows his or her role.

Integration with Existing Technology

Effective contract management is not a question of new technology but of how to deploy existing technology to solve new problems. In general, contract management systems are integrated with a company's back-end processes and systems to support contract management needs. Existing technology must not restrict employees from responding to diverse contract requirements.

High Adaptability

While usability, security, and performance are critical, the paramount concern for a sell-side contract management solution is high adaptability. Because dynamic market and regulatory forces drive contract management processes, the solution must offer high application maintainability and well-documented rule sets so that rule changes and their implications are clearly understood and used.

What are the ramifications of ignoring these contract management and pricing requirements? Expenditures continue without supporting data. Substantial sums are wasted without a focus on process and controls. The ability to meet Sarbanes-Oxley and OIG requirements is weak, and noncompliance with government programs and regulations can result in huge settlements, criminal indictments and civil fines, and five- to seven-year corporate integrity agreements. Systems and processes will not support strategic and tactical business needs, raising questions about the value of contract pricing strategies. In addition, companies that implement point solutions lack end-to-end visibility, with responsibilities fragmented across the organizations, potentially leading to costly errors and dissatisfied customers.

The dynamics of today's economy require life sciences companies to rigorously manage costs and government compliance, as they also attempt to increase market share with innovative sales strategies. To ensure profitable growth in the world of sales contract development and pricing, chargebacks, and rebate management, life sciences companies are responding faster to changing market demands, requiring well-defined goals. But they cannot meet this challenge without an integrated and total contract life-cycle management solution operating on a scalable, enterprise-capable development, integration, and technology platform.

Closing the Loop on Processes

Closing the gap between a company's technical and process capabilities and its business requirements is critical to success in the market today. Systems and processes must be aligned to support stability and profitable growth, lowering total cost of ownership and increasing the flexibility to address the future. The company must be able to decrease its risk of exposure from high error rates and a limited capacity to meet market needs.

As a solution provider to the life sciences industry for more than 30 years, SAP has been evolving its vision toward a complete, closed-loop process for managing all phases of a life sciences sell-side contract. Today, SAP leverages feedback from customers in the ethical, biological, generic, and medical device fields, including 18 of the world's top 20 life sciences companies. Their portfolios of complex contracts, member relationships, and rebates and chargebacks create a dynamic and challenging business environment.

SAP® Technology for Contract Life-Cycle Management

Today, SAP offers a fully integrated contract management solution for life sciences companies, powered by the SAP NetWeaver® platform. The SAP® Contract Management application aligns contract creation and pricing processes with membership and customer information, making it possible to initiate contracts quickly and accurately, post them to membership organizations, and administer the rebates and chargebacks cost-effectively. In supporting the contract life cycle from negotiation through financial reconciliation, the application provides a central, integrated repository for master data. Business processes are thus streamlined and synchronized to facilitate integration with government pricing processes needed to manage regulatory compliance and react to market price sensitivity. With the SAP NetWeaver Business Intelligence component, robust data analytics functions and tools allow sales trend analyses, consolidated financial reporting, and complete margin and profit analyses.

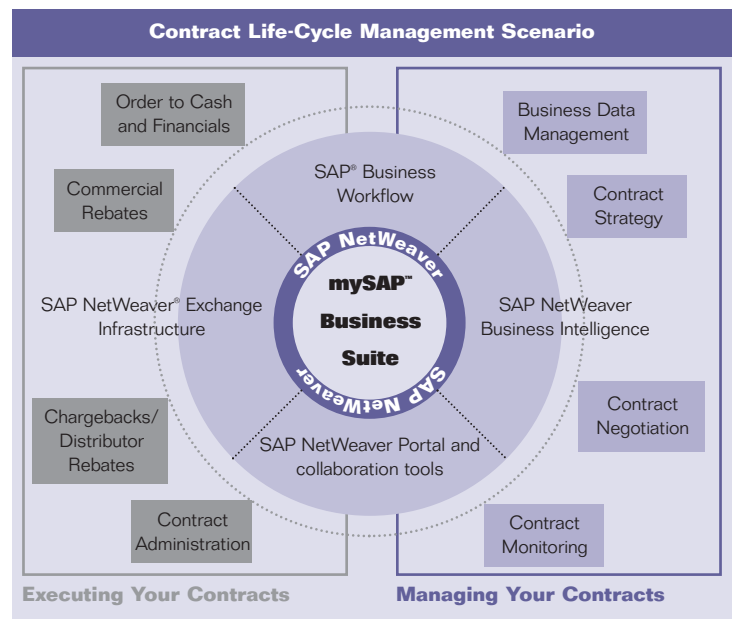


Figure 4: The SAP Contract Life-Cycle Management Scenario

To create a scalable enterprise-level solution, SAP is combining existing SAP software components configured to support contract management processes with those for everyday business needs. The result is end-to-end support from contract strategy definition to negotiation, through deal execution and monitoring. It is the only contract life-cycle management solution built upon a mature development and technology platform.

SAP also recognizes the strategic value and benefits of enterprise-level contract life-cycle management for life sciences to both SAP and its customers. Customers benefit from the following:

- The evolution of SAP’s experience delivering solutions to the life sciences industry – more than 2,000 implementations, of which 90% are validated
- SAP’s increasingly bulletproof technology, with ongoing audits of SAP development by life sciences companies, assuring solution stability
- SAP’s position as the world’s largest enterprise software company, with a US\$1 billion annual R & D effort supporting the comprehensive SAP for Life Sciences solution portfolio
- SAP’s ability to provide natural integrations to essential core business solutions, including enterprise resource planning for sales transactions, business intelligence for superior analytics and reporting, and complete financials and distribution solutions

SAP NetWeaver: The Foundation

In developing the most innovative approach to contract management, SAP takes the point of view that technology must not stand in the way or obstruct progress. The focus must be on resolving the business issues, not on keeping up with technology.

As a result, SAP believes the technological foundation for a contract life-cycle management system should be based on open standards, able to integrate people, information, and processes

within and beyond the organizational boundaries of a life sciences company. SAP NetWeaver provides this foundation with a comprehensive integration and application platform that works with the existing IT infrastructure to enable and manage change.

With SAP NetWeaver, companies can flexibly and rapidly design, build, implement, and execute the new business processes that revolutionize contract life-cycle management, provide a new source of competitive advantage, and drive innovation throughout the organization by combining existing systems while maintaining a sustainable cost structure. As shown below, while SAP NetWeaver provides the technological foundation, enterprise services architecture (ESA) provides the blueprint for building the adaptive business approach necessary to revolutionize contract management and contract execution.

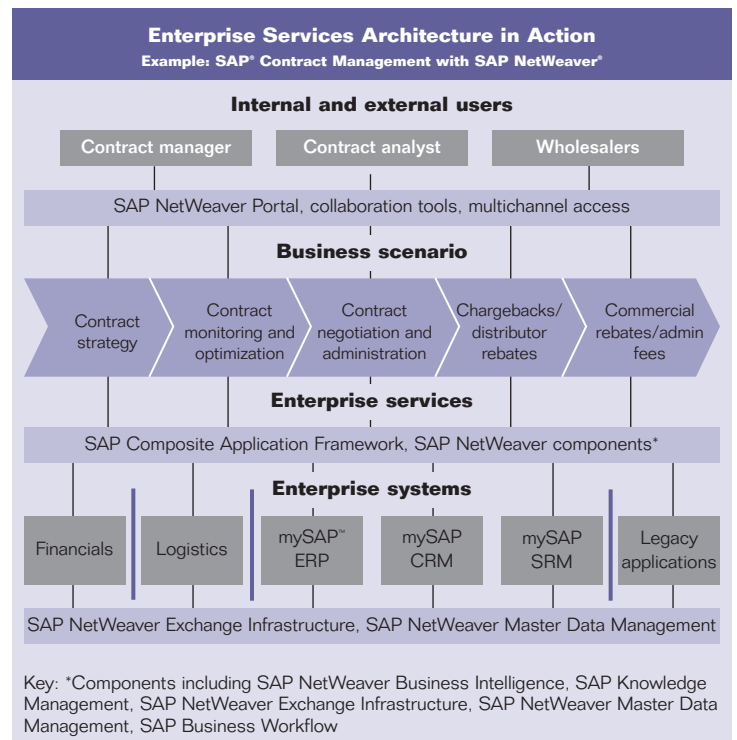


Figure 5: SAP NetWeaver: A Foundation for Contract Life-Cycle Management

Enterprise Services Architecture: The Blueprint for Adaptive Business

Using the ESA blueprint, a company can deploy new solutions on top of existing SAP functionality and enterprise solutions, increasing the value of the current systems while facilitating the development of new processes. With ESA and SAP NetWeaver, a company can enable its information delivery strategy to leverage both existing SAP and non-SAP systems. This architecture allows companies to focus on improving the effectiveness of its business processes, not on implementing advanced technology.

Paradigm	Client-server architecture	Enterprise services architecture
Benefits	<ul style="list-style-type: none"> ■ Distribute and scale ■ Graphical user interface 	<ul style="list-style-type: none"> ■ Leverage existing infrastructure ■ Adaptable business through reassembly of processes ■ End-to-end business scenarios include external business partners ■ Role-based user interaction
Business Application	Functional modules	Component and enterprise services
Technology Platform	SAP® R/3® Basis <ul style="list-style-type: none"> ■ Separation of database and application ■ Web enablement 	SAP NetWeaver® <ul style="list-style-type: none"> ■ Process integration ■ Information integration ■ People integration
Transition	Migration	Evolutionary transition

Figure 6: Enterprise Services Architecture Enables Full Integration of SAP and Non-SAP Software

With ESA and SAP NetWeaver, life sciences companies profit from the following:

- **Innovative new business processes** – The platform powers innovative, industry-specific software and enables SAP partners and customers to deploy solutions that take advantage of existing functionality.
- **Superior business value** – SAP NetWeaver provides a business-focused infrastructure that supports continuous improvement of processes. It minimizes the risk and cost of introducing new processes, because existing systems remain unchanged when adding them to end-to-end enterprise processes.
- **Improved business performance** – SAP NetWeaver helps to aggregate and analyze information across the organization, enabling management to gain the insight needed to make the right decisions.
- **Unmatched user experience** – Solutions built with SAP NetWeaver provide an efficient user experience through a role-based portal interface. With SAP NetWeaver, companies can extend business processes to all employees, partners, and customers.

SAP technology, combined with its robust product suite, enables SAP customers to revolutionize the management of the revenue side of the life sciences industry, managing contract documents in all their aspects – from market analysis and contract strategy, through offer and contract development, to contract administration and fulfillment of chargebacks and rebates.

To learn more about contract life-cycle management for life sciences companies from SAP, visit the SAP for Life Sciences Web site at www.sap.com/industries/lifesciences.

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