

PHARMACEUTICAL Business Strategies for Pharma/Bio Success COMMERCE

A Holistic Approach to Contract Management

How visibility into a contract's lifecycle can save you millions of dollars and limit risk

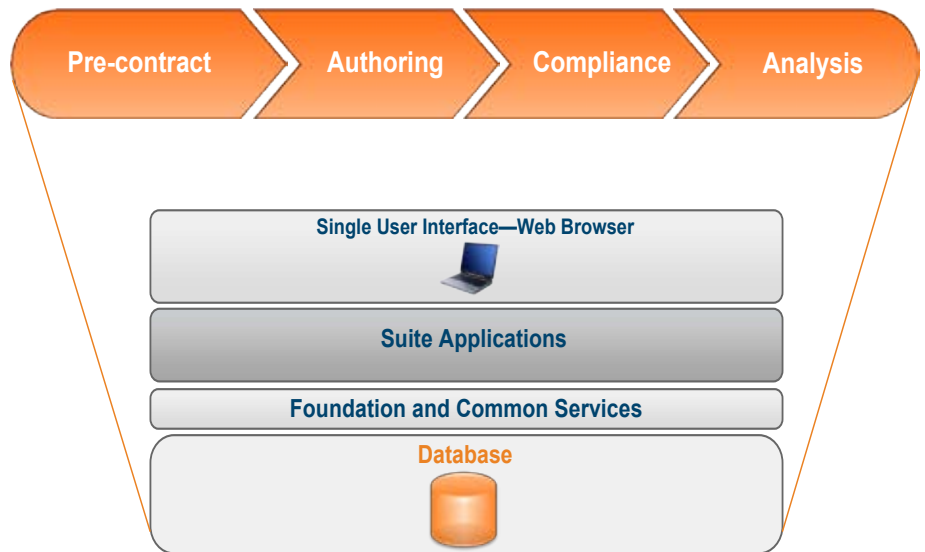
By David Blumberg, I-many

WE'VE ALL HEARD THE STORIES – An account manager hungry to win a critical deal devises a clever twist outside of the standard pricing strategies. Somehow the contract is inked and gets in front of the client before system-wide effects can be calculated. The deal creates a new price floor with implications to best price, AWP (and 7 other acronyms that I'll drop later) and millions of dollars in revenue are lost. Did I say millions? Let me rephrase – hundreds of millions.

As this example shows, the pharmaceutical industry is a complex industry where upstream decisions and errors can cause enormous downstream impacts. It is one of the most heavily regulated sectors in the U.S. and around the world with a multitude of national and local compliance efforts that need to be addressed. Efforts to amend pricing and reimbursement policies efficiently to maximize revenues and ensure compliance are a major drain on resources; requiring millions of dollars and thousands of man-hours. Because of this, pharmaceutical companies have a greater need for a lifecycle approach to contracting and need to rethink how to work within an ecosystem of compliance.

In order to react quickly and accurately to dynamic legislative and market conditions, companies need to develop insight into the impact their contract decisions have on the rest of the business and on the bottom line. They need to know how a new law (for example, pedigree rules in California) will affect how pharmaceuticals are priced, reimbursed or tracked; or how opening up a new method for economically incenting the trade (for example, a manufacturer-wholesaler distribution agreement) will play out. How will new trade policies affect net revenue? How does one translate data stripped out of EDI transactions and disparate file formats into insight regarding the progress of a newly launched brand? What might downstream inventory fluctuations indicate about product diversion or other market behaviors that lead to revenue leakage or increase compliance risks?

Pharma executives struggle on a very fundamental level for true insight into the impacts and results of the end-to-end contracting process. What contracting strategies optimize profit? What constitutes a good return on investment? Which rebate programs



achieve market objectives and which do not? Which trading partners provide the most value? Who and what puts an enterprise at risk and what controls can reduce that risk?

Given the complexity of the industry, its managers would benefit greatly from having intelligence infrastructure in place to model what affect the regulatory or channel changes would have on the contract management lifecycle and ultimately on net sales. About seven years ago, I-many put together a conceptual framework that spanned the entire contract lifecycle. It included pre-contract analysis to help predict the outcomes and downstream impacts of entering into the agreement and functionality to author, route, edit, approve and store contracts. Additionally, it had software to administer, adjudicate, and validate contract claims against disparate sources of transactional data. Finally, the vision included the functionality to look backwards at performance and forward based on trends and predictive algorithms.

Unfortunately, seven years ago technology was evolving rapidly and an obvious choice for an integrated platform had yet to emerge. Additionally, the industry wasn't yet ready to embrace the vision. Departments were siloed, end-to-end approaches were not considered a priority and senior management had yet to grasp the totality of how significant the penalties would be for not getting it

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right—either in terms of the hundred’s of millions in compliance fines or the massive lost revenue opportunity.

Today, the industry finds itself in a very different space. There are tools specifically aimed at the pharmaceutical industry that help it gain insight into past, current and future events that it can use for future strategy and planning. Armed with this intelligence, companies will be able to uncover new revenue-driving opportunities and take better advantage of proven ones..

Current approach doesn’t go far enough

Process automation does occur today – at least in parts. Unfortunately it is rarely found outside of the narrow “revenue management” parts of the process. More than 80% of the top 100 pharmaceutical companies deploy some sort of automated contract-compliance solution. Unfortunately, the capabilities covered by these tools are usually limited revenue compliance (e.g., administration and adjudication) and provide little help in authoring or analytics. The compliance tools help greatly in adjudicating existing complex contracts. They can perform a host of complex validations and process large amounts of transactional data resulting in the application of accurate pricing, associated discounts and rebate qualifications. However, these administration-centric solutions fall short of true end-to-end contract management’s potential. As a result, pharmaceutical companies are failing to see the big picture and are not taking advantage of this technology throughout the entire lifecycle of their contracts.

Both the earlier stages of contract management and the late stages remain only partially automated. The first stage of end-to-end contract management is “pre-contract” analysis. In this stage companies need to understand downstream impacts to the impending agreement (e.g. Best Price implications). Many companies have no consistent automation or meaningful technological augmentation and rely on policy, committees, ad-hoc analysis and gut feel.

The second critical stage of the end-to-end process is “authoring.” In this stage, contracts are composed, routed for approval, “inked” and stored in some type of repository. In our experiences, we see Microsoft Word as the cornerstone of automation in the great majority of companies. Workflow is manual, approval processes range from byzantine to chaotic and workflow is accomplished by “sneaker-net” or e-mail. There is very little automation at work with companies relying on manual updates and tracking. Contracts are stored in all kinds of locations and Sarbanes-Oxley (SOx) compliance can be difficult to achieve.

Likewise, there is little coordination or business intelligence going on at the end of a contract’s lifecycle, making systematic post-contracting analysis virtually non-existent. It is at this stage that companies are missing an opportunity to analyze past events to better formulate future strategy and to project future financial implications (e.g., forecasting financial accruals).

Companies need to develop an efficient and reliable contract management business strategy that encompasses the entire lifecycle

of a contract from the pre-contract and authoring stages through the administering and post-contract analytics stages. Once they take this holistic approach to contract management, pharmaceutical companies will be able to generate valuable insight in their goal of maximizing revenue within the bounds of compliance.

End-to-end contract management business solutions

An efficient contract-management business strategy encompasses the entire lifecycle of a contract from the core functions of contract authoring and administration to analytics and business intelligence. This integrated platform allows data to flow seamlessly from one piece to another as it moves through each phase, automating steps in the process in an effort to ease complexity, ensure consistency and reliability of business information and reduce administration costs. The insight gathered from a holistic approach to contract management can help companies realize new opportunities, clean up unprofitable business practices, forecast business impacts accurate and ultimately, improve the attainment of business objectives while reducing compliance risk.

While there are many partial contract management solutions available today, pharmaceutical companies need to look for a complete solution that is built on a modern technology platform; is tailored specifically for the pharmaceutical industry; has the flexibility and configurability to meet dynamic market conditions; provides valuable insight into past, current and future activities for future strategy development; has a consistent and intuitive interface; and allows companies to migrate to this solution set on their own timetable.

Modern technology platform

In this day and age of modern IT departments, it’s essential to find a solution that utilizes a modern, standards-based technology stack and also has the technological prowess to handle the volume and complexity of current and future contract management needs. Obviously, characteristics such as audit ability, airtight security, robust performance, comprehensive tools for configuration, customization and interfacing with other strategic enterprise wide systems (e.g., SAP) are essential.

It is also important to find a modern platform that has enough power and flexibility in the configuration layers so that the solution is not held hostage to the vendor in the inevitable event of change.

Sarbanes-Oxley, HIPAA, Medicare Part D and the Deficit Reduction Act, pharmaceutical companies can save time, energy and money by making the compliance process easier.

Tailored for the pharmaceutical industry

Selling prescription drugs is unique. It is much different than selling soft drinks, automotive supplies or just about anything you can think of. The industry is heavily regulated—not just in R&D, manufacturing and distribution, but in marketing, sales and compliance as well—and relies on complex financial formulas to set

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pricing and distribution policies. The contracts that we deal with are complex, requiring much experience to author, administer and analyze.

Additionally, the landscape is evolving rapidly with new regulations, trade approaches and contract approaches. While creating a system that can handle basic chargeback processing is not particularly hard, creating a system that can handle the complex government- and managed-markets contracts is very hard. Thus we see a vendor world that has many entrants in the “easy” space and very, very few where the industry nuances create immense complexity.

This poses significant risk for smaller, less complex organizations. The cheap, simple application that they buy today will frequently not grow to meet their needs as their companies evolve and the marketplace around them changes.

That said, it is vital that pharmaceutical companies deploy a contract management solution that is specifically suited for the industry, uses our unique vernacular and includes the distinct functionality front-line employees need on a daily basis. Features that manage complex rebate and chargeback programs, register pricing formulas with the government, authenticate Medicaid status and centrally collect this information for easy, consolidated reporting for compliance are particularly important.

Mine effective and accurate business intelligence

Contract management business solutions are not just instruments for administering pricing and proving compliance. They are valuable analytic tools that can help companies avoid costly mistakes, discover profitable trends and apply this knowledge to future planning. A modern solution needs to be able to seamlessly mine accurate and up-to-date information from all four steps in the contracting process and make it available to a broader set of functions.

By gaining insight into sweeping affects of their past, current and future contracts pharmaceutical companies can adjust corporate strategies in order to better forecast and optimize performance—whether it is achieving less revenue leakage, avoiding a best price violation, creating more accurate financial forecasts, reducing overhead or ensuring compliance.

Flexible, configurable

The pharmaceutical industry is in constant flux, making it important that a contract management strategy can be quickly and efficiently configured to reflect the dynamic marketplace. Regulations are enacted, get tweaked and sometimes die out. In the same vein, new products are being developed routinely, medical protocols change and trade partners evolve. An effective business solution should be able to reconfigure existing contracts per these changes and meld them automatically in all future contracts.

It is here that flexibility and configurability is key. If the language in one document is changed, or if pricing formulas are amended, the solution needs to be able to automatically transmit those changes

throughout the entire database. This ensures that all contracts are accurate and up to date without putting an additional burden on your staff to go through and make the changes manually.

Consistency and integration

A contract management solution should leverage a common user interface that is consistent throughout the lifecycle of the contract. Not only does the language need to be the same, the services be similar and policies be consistent, the solution needs to look, feel and act the same, allowing information to flow much easier throughout the organization.

Each module needs to be built on a common platform that is highly available, secure and scalable. A service-oriented architecture (SOA) industry standard database platform allows data to flow seamlessly throughout the organization freely so that data only need to be captured once and then pre-populated throughout all relevant fields and documents.

Open upgrade path

Finally, your contract management solution needs to give you the ability to start where you want in the process. Not every company is ready to completely automate their authoring process. Other companies may be years away from being able use powerful analysis efficiently. These companies need to be able to choose their own migration path, whether it is done in one fell swoop or completed over time, piece by piece. While the solution needs to be holistic, covering the four processes we discussed above, it also needs to have the flexibility to cover one piece at a time.

We work in a unique industry, with unique consumers, unique oversight, a unique supply chain and unique concerns. It is important that pharmaceutical companies have the analytic business tools and information they need to efficiently meet these unique challenges. A holistic contract management business strategy can help manage the complexity the industry faces, empowering pharmaceutical companies to leverage past, current and future contracts to affect better operations and future strategy. By mining analysis throughout the entire lifecycle of contracts and organizing business information more efficiently, companies can take better advantage of revenue-driving opportunities and act quickly to dynamic market demands, in effect increasing operational performance and limiting much of the risk associated with our industry. **PC**

ABOUT THE AUTHOR

David Blumberg is executive vice president of life sciences and fulfillment services for I-many, a leading contract and transaction compliance management solution provider. Blumberg previously worked at Accenture where he was the lead partner for the pharmaceutical and medical products practice.

