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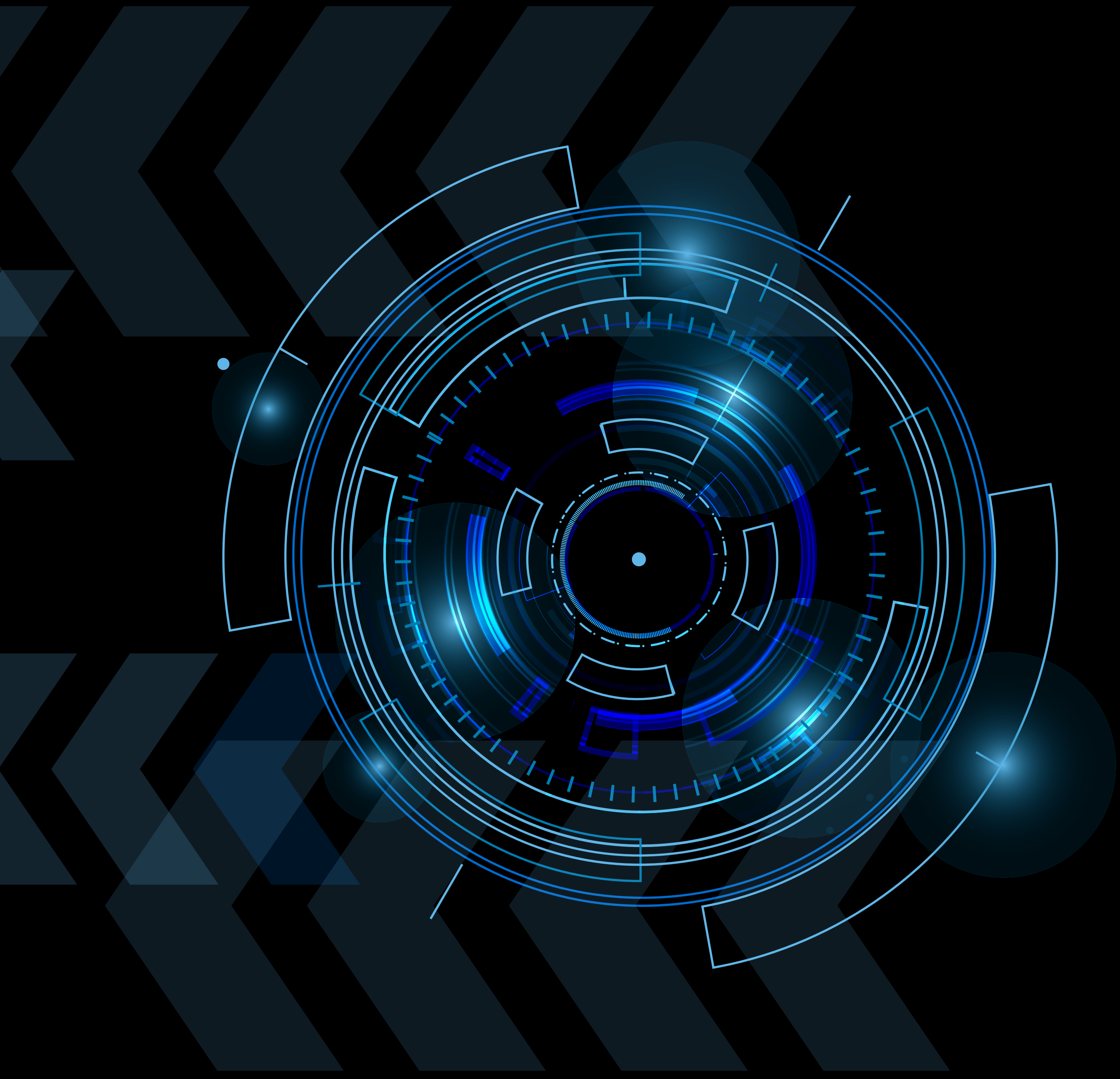

Contracting obligations for procurement of goods and services: An overlooked lever in value generation and risk management for the life sciences and MedTech industry

Companies in the life sciences and medical technology (MedTech) industry have a lot on their plate. The race to advance patient care is taking place amid market volatility, shifting regulations, and evolving patient and provider expectations. With competing priorities to contend with, contracting obligations may not always be top of mind.

In this article, we'll review the kinds of contracting obligations that we commonly see in the industry. Then we'll unpack some of the risks of noncompliance—think potential revenue loss and misallocation of staff—as well as challenges with managing those risks. We'll wrap with a discussion of potential solutions, including those that recent advancements in artificial intelligence (AI) have made possible.

Factors that shape contracting obligations

Life sciences and MedTech companies work with third parties globally along the value chain. These parties provide goods and services such as the following:

Research and development (R&D). Life sciences and MedTech companies are increasingly outsourcing a wide variety of R&D to clinical research organizations (CROs), academia, and other organizations that provide advanced R&D services. These kinds of suppliers can help companies accelerate development while optimizing their R&D costs. However, managing these development cycles is fraught with regulatory and commercial risks, from risk evaluation and mitigation to post-market clinical studies.

Manufacturing. Life sciences and MedTech companies have a plethora of regulatory guidelines and rules to follow when contracting with another party in the manufacturing process—be it a raw material supplier, a contract manufacturer, or an acquisition of a manufacturer. Managing global obligations for these diverse and complex laws and regulations (e.g., good manufacturing practices, Foreign Corrupt Practices Act, False Claims Act) are not only time-consuming but entail hefty penalties and reputational risks if not managed effectively.

Marketing and distribution. A wholesaler buys products in bulk and distributes them to pharmacies. A pharmacy benefit manager (PBM) markets products in return for discounts or incentives. Companies also may sell directly to government agencies domestically (such as the US Veterans Administration) or abroad. Such variability in the supply chain can lead to leakage in rebates and clawbacks.

These and other business relationships involve contracts that typically have two categories of obligations:

Commercial. Commercial obligation management can potentially prevent millions of dollars of spend leakage due to variation in negotiated rates and actual billed rates. It can also help companies avoid delays in milestone-based payments, study submissions, and eventually in the drug launch—all of which have an effect on the bottom line.

Regulatory and other noncommercial. Managing these obligations effectively can help companies mitigate costly penalties, product withdrawals, and reputational risks.

What's at stake for life sciences and MedTech

The consequences of a compliance issue can be significant. Consider what happens when a Food and Drug Administration (FDA) inspection turns up a potential production problem and responds with a Form 483 citation. This isn't an uncommon occurrence. From October 2021 through September 2022, the FDA reported issuing 538 citations for devices, 466 for drugs, 126 for bioresearch monitoring, and 61 for biologics.[1] The reasons range from failure to document or follow procedures to problems with equipment to scientifically unsound laboratory controls. The FDA follows a similar system when the results of clinical trials aren't reported in a timely manner: warning letters followed by 30 days to address the violation, then further escalation if the violation persists. Fines may exceed $10,000 per day, and even criminal prosecution isn't off the table.

Compliance issues can be just as costly outside of the regulatory realm. A late or incorrect payment can lead to penalties and slow down research through clinical trials. Beyond that, failure to follow negotiated rates can result in lost revenue from sales contracts with customers and excess spending on contracts with suppliers. Another example is the notice period to terminate or stop an auto-renewal. Many life sciences and MedTech companies have accidentally renewed something they didn't need—or paid cash for something they never used—simply because they failed to track these clauses in their contracts.

Obligation risks are hard to manage because terms, dates, and other critical details vary from contract to contract, making them a challenge to track across thousands of agreements. Organizations often end up pulling resources from higher-value activities to conduct time-intensive, manual regulatory compliance checks. Even so, inefficiencies in the contracting process such as poor visibility and insight into complex deals lead to missed margins and commercial under performance.

Leading practices to achieve compliance

So, what does it take to improve compliance with contracting obligations?

A shift in mindset

Businesses tend to focus on getting a contract signed, with management of the post-signature phase often becoming an afterthought. This can negatively affect compliance with contractual and regulatory obligations. Contracts need to be understood as a strategic business asset with value that can be won or lost from one end of the life cycle to the other.

A well laid-out process

Companies should take a close look at their practices. Effective management of contracting obligations depends on a process that gets the right people involved at the right time throughout the contract life cycle, from initial request through ongoing monitoring (see illustration).

Obligation management challenges and solutions

Challenge	Potential solution
Manual identification of obligations	Rules-driven discovery of obligations
Unclear ownership of obligations	Rules-driven recognition of assigned owners for each obligation and its fulfillment
Information housed in different systems	Integrations that bridge the gap between the commercial pricing and terms in the contract and those that are in the purchase orders and invoices
Lack of insight into action on obligations	Dashboards showing obligations and performance on appropriate actions
Scattered, inconsistent tracking of obligations	Centralized governance of contracting obligations

Leading processes for managing contracts

1. Contract request
Request for a contract by the business and/or additional stakeholders

2. Contract creation
Contract creation, initial authoring, and internal approval

3. Negotiation & execution
Negotiation with supplier, redlining, and signature

4. Archive & repository
Contract storage in a central repository (includes legacy migration

5. Data management
Maintenance of contract metadata and other master data (supplier, customer)

6. Template & clause management
Development and maintenance of standard contract template and clauses, plus associated processes (approval mass amendment, governance)

7. Compliance/obligation management
Contract process governance and controls

8. Performance & monitoring
Proactive tracking of contract status through dashboards/reporting, Key performance indicators and notificationsa

Obligations management as an integral part of a contracting process aided by automation

Technology-enabled contract life cycle management has become central to managing supplier obligations during the contracting process. The process itself has several moving parts, none of which work in isolation. But they do involve multiple departments, which means they must be well synchronized to automate and streamline obligations.

As an example, let's look at what needs to happen to manage obligations with a CRO supplier. Different departments—think procurement, legal, and the appropriate business unit, among others—would need to coordinate on:

- Vendor onboarding
- Due diligence
- Contract drafting, complete with tagged regulatory and milestone-based commercial obligations
- Bidirectional linkage of each contract to downstream transactional processes
- This is easier said than done. Companies must break their departmental silos and work together to enhance their intermingled processes, then automate them through sophisticated contracting technologies.

Contracting technologies now have integrated AI to transform their obligation management capabilities. AI analyzes the contracting data captured as part of the contract life cycle management workflow, along with the contracting language itself, then uses the data for obligation management and reporting. This includes automated identification and capture of key data fields (like agreement dates, terms, and counterparty information), flagging of contractual obligations and assessing negotiated risk, and automated alerts and reminders to obligation owners based on this extracted data.

Stakeholder engagement

In a well-managed program of contract process governance and controls, control owners are responsible for making sure specific contracting obligations are present and complied with. However, the program itself is a coordinated effort (see sidebar, "Obligations management as an integral part of a contracting process aided by automation"). It requires users to adopt contract life cycle management (CLM) technology to author, modify, and approve contracts—not to mention stay on top of obligations—in a collaborative manner.

Artificial intelligence

AI capabilities can boost regulatory and noncommercial compliance by identifying obligations and keeping track of them. The technology can be set up to automate obligation schedules to send alerts and reminders at the right time and frequency so users can take appropriate action. Extracted obligation data can also be used to validate against invoices to facilitate proper performance and compliance. Along the way, AI can corroborate the data it extracts with what it has learned in the past so it can automatically handle routine, high-volume contracts (like nondisclosure agreements) while freeing specialists to focus on complex agreements (like master service agreements).

Systems integration

By integrating an AI-enabled CLM system with purchase order and other rebate management systems, companies can create a tight connection between contractual data and transactional data. This improves commercial compliance by giving users line of sight into information about rate cards, statements of work, and other obligations negotiated as part of the contract. Integration can also make compliance easier by removing redundant workflows.

Leveling up your compliance game

Compliance with contracting obligations is a critical component of effective contract management. It helps companies avoid overspending on suppliers while helping them capture what customers owe. At the same time, it significantly reduces the financial, operational, and reputational risks of noncompliance. And by following leading practices for managing contracting obligations, life sciences and MedTech companies can set themselves up to capture the extended benefits of improving the contracting process end to end.

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- Operations and spend management
- Contract life cycle management
- M&A transactional support
- Legal department operations
- E-discovery
- Talent acquisition, retention, and mobilization

We can free you to focus on strategic priorities; enhance the speed and quality of issue identification; and use data to drive faster, more informed, holistic decision-making.

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Contacts

Scott Read
Principal
Deloitte Transactions and Business Analytics LLP
sread@deloitte.com

Jaspreet Anand
Vice President, Service Delivery
Deloitte Transactions and Business Analytics LLP
jaanand@deloitte.com

Brent Griffith
Managing Director
Deloitte Consulting LLP
bgriffith@deloitte.com

Cassandra Forbes
US Legal Business Services
Deloitte Tax LLP
caforbes@deloitte.com

Endnotes

1 US Food & Drug Administration, "Inspection observations," accessed September 19, 2023.

2 US Department of Health and Human Services et al., "Civil money penalties relating to the ClinicalTrials.gov Data Bank," August 2020.