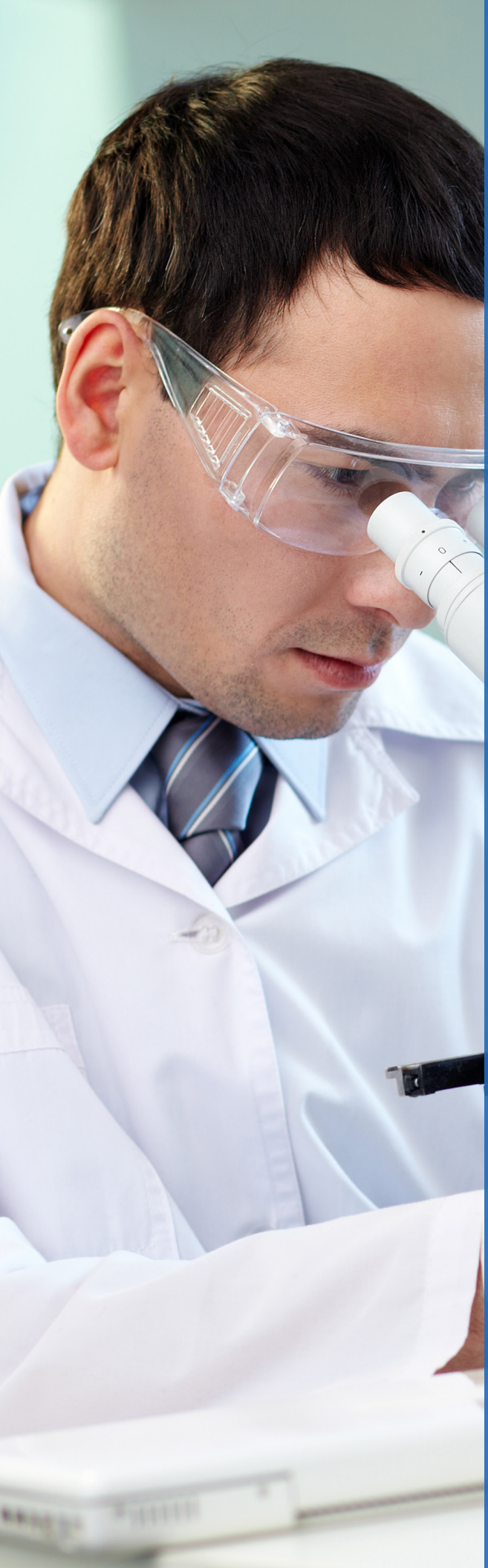

Streamline Regulatory Compliance in Life Sciences with Digital Transaction Management

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Executive Summary

The U.S. Department of Justice has collected upwards of $17 billion in settlements from the healthcare industry since 2009, including more than $2 billion from a single life sciences company.[1] As part of those settlements, more than half of Fortune 500 pharmaceutical and medical device companies are operating under corporate integrity agreements (CIA) with the U.S. government.[2]

A CIA outlines the ethical obligations a company agrees to in exchange for being allowed to continue participating in federal healthcare programs. CIAs are lengthy contracts—50 to 100 pages—detailing new procedures and protocols that must be meticulously adhered to in order to avoid further penalties. New procedures include the establishment of new regulatory roles and committees, comprehensive quarterly and annual reports, exhaustive record keeping, cumbersome review processes, and seemingly endless approvals.

Repercussions for non-compliance with CIA obligations range from $1,000-per-day fines to the removal of products from the market. Compliance has become an unwieldy mission-critical business process for the industry, and digital transaction management (DTM) is poised to solve the ensuing complexities of communications, approvals and record maintenance.

As evidenced in their annual letters to stakeholders, Fortune 500 pharmaceutical and medical device companies are strengthening enterprise-level quality and compliance with federal and international regulations. This paper identifies best practices for leveraging DTM for CIA compliance and the impact such technologies are already having on forward-thinking Fortune 500 companies.

1 http://www.justice.gov/opa/pr/2013/December/13-civ-1352.html
2 https://oig.hhs.gov/compliance/corporate-integrity-agreements/cia-documents.asp

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The Risk

Scope of Today's Problem

Leading life sciences companies aim to improve health outcomes around the world by delivering breakthrough treatments while complying with safe manufacturing techniques. When quality is compromised, that mission to deliver breakthrough treatments and the lives invested in these efforts are put at risk.

U.S. regulatory bodies are increasing oversight of mission-critical research and development, promotion and distribution activities. They have given the life sciences industry the incentives to develop better practices for demanding regulations. Total settlements for regulatory noncompliance since 2009 have exceeded $17 billion.

One of the largest healthcare settlements in US history took place in November 2013. Johnson & Johnson reached a $2.2 billion settlement with the U.S. Department of Justice for marketing prescription drugs for unapproved uses.[3] In addition, the company was paying kickbacks for prescribing and promoting these drugs.

Fines only disclose one aspect of the consequences for noncompliance. Failure to comply with applicable regulatory requirements may subject companies to additional sanctions, such as rejections of new product applications, withdrawals of product approvals, suspensions of clinical trials, warning letters, product recalls, product seizures, suspension of operations, injunctions, civil penalties and criminal prosecution.

A common thread in many violations is that individuals did not act upon early signs of misconduct, according to Stuart Delery, Assistant Attorney General, in his remarks at the CBI Pharmaceutical Compliance Congress.[4] Therefore, companies found to be noncompliant are also required to enter into corporate integrity agreements (CIA) with the federal government.

Nearly half of the Fortune 500 pharmaceutical and medical device companies have entered into CIAs as part of settlements since 2009. For instance, an additional component of Johnson & Johnson's settlement is a five-year CIA that requires major changes to the way Johnson & Johnson and its pharmaceutical subsidiaries do business. Changes, outlined in greater detail below, include extensive record keeping, submission of annual reports and the addition of independent review organizations.

3 http://www.justice.gov/opa/pr/2013/November/13-ag-1170.html
4 http://www.policymed.com/

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The Challenge

Example CIA Compliance Requirements

Looking at Johnson & Johnson's 101-page CIA gives a depiction of what other pharmaceutical companies face with regards to settlements for noncompliance with federal regulations, including the following.[5]

New Compliance Roles: The company must establish a Chief Compliance Officer (CCO) to be a member of senior management. The CCO must be focused primarily on compliance and make quarterly and annual reports. An independent compliance expert must also be retained to review the compliance program.

New Compliance Committees: The organization must also establish committees comprised of board members, senior executives and non-executives. The committees hold quarterly meetings, review reports and annually adopt a resolution to be signed by each member. The resolutions summarize the committee's review and oversight of compliance with federal healthcare program requirements, FDA requirements and CIA obligations.

New Policies and Procedures: In addition to increased oversight, the CIA requires the company to make significant procedural changes.

- *Inquiries Database:* Track all requests for product information; record the date and name of the inquiry reviewer.
- *Healthcare Provider and Educational Relationships:* Maintain records of the manner and circumstances for meetings or events with healthcare providers, fee-for-service agreements and all related expenses; disclose records of sponsorship or grant funding and third-party educational activity.
- *Promotional Plans and Training:* Develop, implement and review call plans and sample distribution plans for promotion and sales; review the plans on an annual basis as well as for each instance of FDA approval.
- *Research:* Submit a list of all research activities and related documentation to be reviewed; register clinical trials and report results within specified time frames following the completion of a study.

5 https://oig.hhs.gov/fraud/cia/agreements/Johnson_Johnson_10312013.pdf

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The Challenge

Quarterly and Annual Reviews, Certifications and Communications: The CIA requires the company to establish and prove transparency into business operations.

Digital transaction management (DTM) is the solution to compliance with complex CIAs. DTM eases the aspects of compliance related to extensive approval processes, notifications and proof of records attached directly to signed documents. Life sciences companies have been using DTM for ease of CIA compliance since 2012.

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Conclusion

Signatures are everywhere and add a level of complexity that existing systems and solutions cannot manage. Obtaining signatures on paper is highly inefficient and fraught with errors, putting companies at risk of non-compliance. DTM serves the emerging needs of today's sophisticated life sciences companies.

Even without a CIA, global companies operating on foreign soil must understand the potential consequences of failure to adhere to international regulations and update their compliance programs to account for local variations in enforcement standards. The year 2013 saw the largest healthcare settlement ever paid, and companies need to ensure they do not become the next cautionary tale. With DTM, companies not only ensure compliance with stringent regulations but also improve transparency, operational efficiency and speed to results across their organizations.

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Required Documentation

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