

# LIFE SCIENCES & PHARMACEUTICALS



## Managing Risk & Compliance in a Complex Supply Chain

The global supply chain for life sciences and pharmaceutical companies has become significantly more complex over the past fifteen years as increased global competition has driven the need to reduce costs, find new markets and harness emerging technology to improve efficiency and execution. As a result, best in class companies increasingly rely on their suppliers and partners to manage what was once core business. What's more, significantly increasing regulatory mandates and reporting requirements at the corporate, supplier, ingredient, and component level represent a complex, fluid regulatory environment with massive risk and cost of non-compliance.

Given this landscape, it is not surprising that many life sciences and pharmaceutical companies found managing global suppliers and product-quality issues to be among their most challenging global initiatives. Recent industry events, such as the contamination of batches of heparin, demonstrate that a lack of control in the global supply chain can lead to patient harm, product recalls, loss of brand integrity, and significant financial liability for a company. Current global regulations state that companies that design and manufacture pharmaceutical products must ensure that all components, raw materials, and product from suppliers meet predetermined specifications, and that suppliers and their operations are properly monitored and controlled.

> **Aravo has built the industry's leading solution to address these issues for pharmaceutical and life sciences firms.**

And it isn't just about product safety. The US Foreign Corrupt Practices Act (FCPA) implements rules and penalties regarding the use of bribes in the conduct of business, even on the part of trading partners, and other countries aren't far behind. Given this regulatory environment, the ability to identify, manage and track key regulatory standards and compliance across the supply chain is a business imperative.

### KEY INDUSTRY REGULATORY ISSUES

#### Food and Drug Administration Amendments Act (FDAAA)

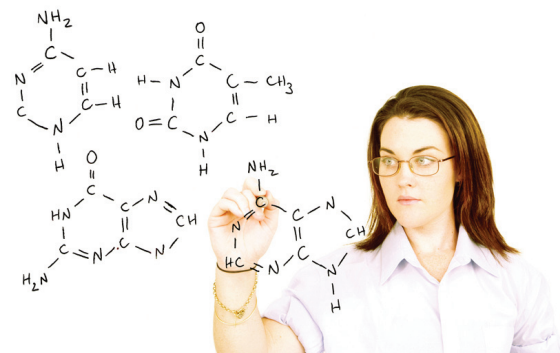
This law, enacted in 2007, allows more comprehensive reviews of potential new drugs and devices, including dramatically intensified supplier scrutiny and vendor oversight. Under the new FDAAA of 2007, the US Congress authorized the FDA to fine individual executives \$16,500 for each violation (e.g., 483 finding); this is in addition to multi-million dollar fines levied on the corporation as a whole.

#### Foreign Corrupt Practices Act (FCPA)

The Foreign Corrupt Practices Act prohibits companies from paying bribes to foreign officials and political figures for the purpose of obtaining business, and applies not only to a company's employees but also to its agents, contractors, investors and suppliers. The FCPA consists of two provisions: the anti-bribery provision, and internal records and process standards which require that companies keep accurate records and maintain clear, accurate, and adequate controls with employees and trading partners (including suppliers, intermediaries and subsidiaries) to protect against improper payments or influence.

### KEY BENEFITS

- > Comprehensive regulatory compliance
- > Brand protection
- > Automated risk mitigation
- > Reduced fines and compliance costs
- > Enhanced visibility
- > Streamlined processes
- > Improved time to market
- > Optimized supplier performance



## Current Good Manufacturing Practices (cGMP)

Good Manufacturing Practices (GMP) are the part of quality assurance that ensures that drugs are consistently produced and controlled to meet quality standards.

cGMP regulations require companies that design and manufacture pharmaceutical products to ensure that all components, raw materials, and products from suppliers meet specifications, and that suppliers and their operations are in a state of control.

## EU Pharma Directive 2004/27/EC

EU Pharmaceuticals Directive (2004/27/EC) requires marketing authorization holders to use drug substances that have been manufactured in accordance with cGMP. These requirements are identical to the ICH guidelines imposed in the US and Japan. In working with suppliers, the directive requires companies to do the following: Contact suppliers and ask for details of the actual manufacturer and any sub-contractors, brokers and distributors used; Find out whether these companies have been inspected by any regulatory authorities, and whether inspection reports or GMP certificates can be accessed; Carry out audits of all of the companies in the supply chain; Draw up Technical Agreements with the manufacturers to ensure that they do not change any parts of the supply chain without informing the marketing authorization holder.

## Food Safety Enhancement Act of 2009

The Food Safety Enhancement Act of 2009 Title II applies to drugs as well as food. Specifically, the provisions which affect pharma suppliers include: Requiring all importers of drugs, devices, and foods to register with the FDA annually and pay a registration fee; Prohibiting any entity from delaying, limiting, or refusing inspection; Prohibiting the submission of any report to the FDA that is false or misleading.



## SOLUTION SUMMARY

Aravo Solutions for Life Sciences & Pharmaceuticals is the industry's leading SaaS solution for managing the entire lifecycle of your complex, diverse global suppliers. Aravo helps your procurement, legal and finance teams easily and quickly manage your exposure to regulated/mandated compliance requirements, as well as lower your cost of compliance. It provides a consistent due diligence process across your extended enterprise – managing supplier policy, credentials, and compliance documentation in a single, globally available, repository. With built-in compliance templates, support for compliance audits, configurable workflows to track credential renewals and new regulatory requirements, and compliance ratings to highlight the most at risk supplier relationships, Aravo ensures you can minimize supplier risk across your supply chain.

In addition, to provide added competitive advantage in your markets, Aravo Solutions for Life Sciences & Pharmaceuticals accelerates new supplier discovery and on-boarding processes, delivering a 360 degree view of supplier relationships and performance across tiers, and providing the single source of truth for all supplier information. Aravo helps keep you ahead of supply chain demands, reduce costs, avoid regulatory failures, increase productivity, and quickly take advantage of today's fast moving global supply base opportunities.



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## About Aravo

The world's best-run businesses utilize Aravo's SaaS Supplier Information Management platform to reduce the cost of managing suppliers by up to 72% and to transform their supplier on-boarding, compliance, enablement, and risk management challenges into competitive advantage. General Electric, Goldman Sachs, Accenture, and Deutsche Bank rely on Aravo to manage information and processes for over 1.5 million global suppliers. Aravo is based in San Francisco, with offices in Chicago, New York, and Ahmedabad, India, and is backed by over \$50 million in investment from Cisco Systems, Big Sky Partners, and the Charles Schwab family. For more information regarding Aravo's award-winning solutions please visit <http://www.aravo.com> or view our blogs at <http://www.2sustain.com> and <http://atrisk.net>

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## KEY FUNCTIONALITY

- > **Supplier/Trading Partner Profiles**  
Aggregate all supplier and trading partner information, including profiles, contacts, facilities, contracts and relationship level, in Aravo's single system of record.
- > **Compliance Surveys**  
Utilize pre-loaded questionnaires from Aravo or create your questions, and quickly build new assessments. Ratings calculations and risk scores populated from assessment results. Configurable formulas based on internal and external drivers.
- > **Compliance Certifications**  
Manage compliance to standards associated with supplier and trading partner relationships by ensuring receipt of required certification documents (e.g. acknowledgement of receipt of FCPA policy). Enable suppliers and internal stakeholders to complete their assigned assessments with no prior training, adding question-specific comments and attaching supporting evidence as needed. Automated reminder and escalation emails to appropriate users as certification due dates approach.
- > **Compliance Scoring**  
Perform business impact analyses against suppliers to auto-calculate criticality, which determines the appropriate assessments for the supplier relationship. Additionally, manage compliance to standards associated with suppliers relationships by business unit, geographic location, service/commodity provided, etc.
- > **Compliance Reporting**  
Reporting functionality provides clear visibility into high-risk areas of your business, the status of supplier assessments and your organization's overall compliance exposure. Maintain permanent audit histories and data repository for all Federal reporting needs.