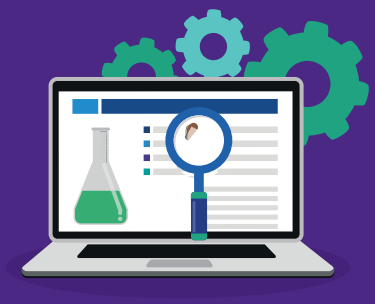
Managing life sciences channel partners



Improving distributor monitoring and compliance

Third-party distributor compliance and monitoring programs have become increasingly complex as global life sciences companies continue to grow their businesses in the international markets. Even the best executed contractual agreements require companies to understand their business partners' compliance environment and continuous oversight of high risk activities. KPMG provides a variety of services for life sciences companies to address the regulatory, legal, and operational risks associated with third-party distributors. Through distributor reviews or audits, KPMG helps companies to assess their compliance programs and identify related risks by evaluating real-time performance against regulatory guidelines, industry standards, and best practices. As part of this assessment, KPMG outlines the current state, structures, and activities of the company's distributor monitoring and compliance programs to identify gaps and areas for improvement. As a global leader in risk and compliance advisory, KPMG is committed to assisting our clients in establishing industry-leading compliance mechanisms that prevent, detect and respond to the full spectrum of third-party risks across various global regions.

KPMG conducted an internal survey of **over 15 distributor audit programs** executed by life sciences companies of different scale to obtain insights into the approaches related to distributors oversight, common risk areas and mitigation actions, and considerations for enhancement.

Key Survey Facts

$500M—$1B

25–100 locations

Typically perform annual audits of 1–10 of their distributors

Pharmaceutical and Medical Device clients with revenues ranging from

$1B—$5B+

Over 150+ locations

Typically perform annual audits of 10–20+ of their distributors

Focus areas of distributor audits include:

- Compliance;
- Anti-Bribery & Anti Corruption ("ABAC");
- Financials;
- Training; and
- Third Party Management.

Manufacturers

— **Lack of training**

– Manufacturers do not provide adequate trainings to their distributors and employees, which lead to a lack of understanding of the compliance risks.

— **Lack of due diligence**

– Infrequent and inadequate due diligence processes raise the risk of the manufacturer doing business with potentially noncompliant business partners.

— **Lack of appropriate contract clauses**

– The absence of ABAC language in contracts raises regulatory risk and exposure to further investigation.

– The absence of audit clauses in contracts limits the manufacturer's ability to review its arrangement with its business partners and ensure compliance.

— **Rebate overpayments**

– The manufacturer risks paying its distributors above the contracted rate due to the lack of timely review or reconciliation by the manufacturer.

Common Findings

Distributors

— **Lack of standardized policies and procedures**

– Distributors do not have formal policies or procedures to govern key business processes, which lead to process gaps, non-compliance, and inefficiencies.

— **Lack of supporting documentation for record retention**

– Distributors' business activities and value transfers are not supported by sufficient documentation, which limits the ability to verify accuracy and completeness.

— **Lack of business justification**

– Distributor does not maintain adequate justification for expenses incurred, which limits visibility into the reason and appropriateness for the expense.

— **Lack of required approval**

– Distributors do not obtain required approvals from manufacturers or internal management personnel (e.g., use of sub-intermediaries), which increases the risk of noncompliance among the parties.

— **Excessive distributor margins**

– Distributors may receive margins higher than intended or reported back to the manufacturer, which impacts the final prices to customers.

Common Recommendations—Manufacturers

— **Policy Development and Training**

– The development of formal policies and procedures, and trainings will establish clear guidelines to help mitigate risk and improve compliance.

— **Contractual, Documentation, and Record Requirements**

– Executing agreements with distributors that contain appropriate ABAC and audit language is essential in creating a comprehensive compliance program.

— **Monitoring Program**

– Establishing a formal monitoring program will help substantially reduce compliance risk.

— **Due Diligence**

– Performing due diligence on business partners will help mitigate financial and regulatory risk.

— **Policy Enhancement and Training**

– The results of compliance audits can help identify opportunities for improvement to existing policies, procedures, and trainings to ensure continued and future compliance.

— **Enhance contractual, documentation, and record requirements**

– Monitoring existing agreements with distributors for appropriate and updated ABAC and audit language is an important part in the compliance process. Identifying any gaps can help improve future agreements with distributors.

— **Enhanced monitoring and due diligence process**

– Improving the monitoring of distributors through automated tools and dashboards as well as frequent compliance audits can help improve the efficacy of a manufacturer's compliance program.

No Program → **Mature Program**

Common Recommendations—Distributors

— **Policy Development and Training**

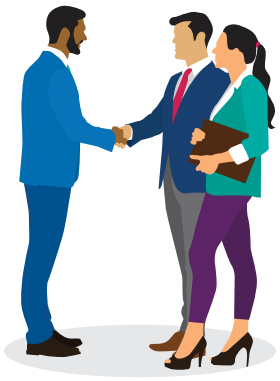
– The development of formal policies, procedures, and trainings can establish clear guidelines to help mitigate risk and improve compliance.

— **Documentation and Record Requirements**

– The implementation of processes and systems to ensure that all business activities are appropriately recorded and supported by adequate documentation and justifications is essential in creating an environment of compliance.

— **Approval Process**

– The creation of a comprehensive approval and due diligence process for sub-intermediaries plays a critical role in mitigating inappropriate expenditures/ business activities of sub-intermediaries and ensuring continued compliance.



KPMG can reach beyond the unique complexities of third-party agreements to develop monitoring and audit programs for high risk business partners, such as:

— **Travel Agencies**
— **Tender Agents**
— **Foundations**
— **Clinical Research Organizations ("CRO")**

Why KPMG?

700+ offices in 154 countries

207,000 professionals

>6,000 Healthcare/Life Science-focused

Provide services to the top **25** **global life sciences companies**

50% of thetop 20 HC systems

The KPMG difference:

— KPMG Forensic can act as anindependent party, utilizing a fullyintegrated approach for in-depthreviews of distributor operations,risk assessments, and corrective actions.

— **Integrated international teams** with extensive industry knowledge and insights into the emerging risks across various regions.

— **Demonstrated performance** with the global leaders in life sciences and technology

— **Cross-cultural versatility** to operate effectively across the globe

— **Cutting-edge technology and data analytics** capabilities to develop customized innovative solutions for the executives and stakeholders to timely identify and manage the risks in a dynamic business environment

— Understanding of the **complexity** and nuances of the variety of distributor arrangements in the life sciences industry

— Extensive experience from performing an average of **10 reviews** per year for clients

— Professionals **with multidisciplinary strengths** in life science operations, legal, compliance, and technology that draw from a diverse set of skills

— A **non-adversarial approach** that presents facts to facilitate resolution and protect vital business relationships

— **Unrivaled support** to clients through developing robust risk assessment process, developing ongoing monitoring programs and enhancing compliance governance on global, regional and local levels.

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