

Life Sciences Due Diligence Case Studies

Risk of political exposure, kickbacks, conflicts of interest, and regulations unique to foreign jurisdictions are just a few of the concerns that keep life sciences compliance professionals awake at night. Identifying risks while remaining agile and competitive in international business requires nuanced contextual knowledge and judgment. Human-led due diligence is an essential tool for cutting through the noise to distinguish critical risks from unsupported allegations.

REGIONAL CASE STUDIES

Middle East

When a standard pre-renewal due diligence exposed allegations of corruption against an existing agent, PSA quickly transitioned ongoing inquiries into an active investigation. Following additional inquiries and media research in Arabic, PSA identified and recovered supporting documentation that verified the allegation. We then traveled to a 3rd country to obtain statements and receipts from those involved. Our action led to the debarment of the agent and supported the disclosure of our findings to US regulators.

Europe

PSA conducted investigative due diligence in Europe on a high-risk, but essential, counterparty with a history of corruption concerns. PSA explored all available reporting in English and local languages, discreetly interviewed previous employees, and spoke directly with those involved in previous enforcement proceedings. Armed with this detailed understanding, PSA began mapping the current organization, its management, incentives, processes, and controls. As a result, we were able to demonstrate the company had taken effective steps to amend its management, culture, and had put in place sufficient controls to permit our client to engage with them under certain conditions.

Africa

PSA's research in West Africa established a potential distribution partner that was well-placed to support an expansion of the client's products into the region. The research established the distributor's bona fides, confirmed their access and capability, and a commendable track record of working for other similar companies in the region.

TOPICAL CASE STUDIES

HCP Vetting

PSA was approached by a pharmaceutical company with 2,000+ HCPs in East Asia, some of which had PEP concerns. PSA was able to develop and apply a robust, cost and time-appropriate scope of work to sufficiently vet HCPs and remediate false positives.

Agent and Distributor Vetting

PSA assisted in the ground-up establishment of a due diligence program for a medical device company under pressure to demonstrate effectiveness in the early stages of a deferred prosecution agreement (DPA). Working with the client's legal and compliance leaders, PSA brought in an appropriate platform partner and developed a risk assessment methodology for the client's 3rd parties. PSA was able to identify and immediately initiate due diligence on the highest-risk counterparties first, thereby enabling the application of a defensible risk-based approach.

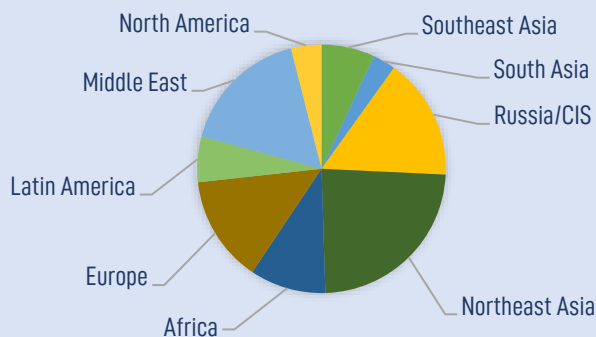
Whistleblower Response

PSA responded to allegations of fraud and bribery in the Chinese distribution networks of a global medical device company. Responding from PSA's Shanghai office, we were able to swiftly engage in discreet human source inquiries and records-based research to assess the veracity of the claims, and then expand our search to quickly identify the mechanism and parties responsible.

Disclaimer: To safeguard our clients and their interests, important details regarding our previous experience have been changed to intentionally obscure the nature of the assignments and the Parties involved. Similarities to any real person(s), companies, or events is purely a coincidence. In the event that we state a Party is guilty, it is understood that the Party rejects this assertion, and has refuted this statement.

Global distribution of life sciences industry investigations and due diligence reports:

Life Sciences companies make up 20% of PSA's clientele. They order reports in every region of the world. In 2023 PSA provided services in 151 countries on six continents.





Pacific Strategies & Assessments

Established in 2000, PSA is a specialist risk consultancy delivering critical information to our clients through our Due Diligence, Investigations, and Advisory services. We operate where our clients do business, with regional offices staffed by investigators and responders who have extensive in-region experience gained from professional

backgrounds in corporate investigations, government intelligence and law enforcement. With a disciplined focus on information collection, we have a 23-year track record of supporting businesses in conducting assessments of complex operating environments.



Due Diligence

Our DD products are tailored to our clients' needs and based in deep understanding of best practices and regulatory guidelines. We scale from desktop research to on-the-ground investigations with multiple process-based due diligence options.



Investigations

PSA has a proven record in supporting companies in complex, international investigations. Our investigative abilities can be scoped to accommodate a variety of engagements, including whistleblower response, fraud investigations, and asset tracing.



Advisory

PSA provides strategic guidance to firms to address specific concerns. We tailor services to support clients on a variety of complex issues, including complex disputes, country-specific operational risks, emerging regulatory issues, and point-specific human risks.