

CONTROLLED SUBSTANCES COMPLIANCE

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Now, more than ever, Drug Enforcement Administration (DEA) Registrants across the entire controlled substances supply chain must be proactive in their internal assessments and external engagement with government regulators. DEA Registrants play a vital role in preventing diversion and maintaining a closed system of distribution.

Our experts outline the appropriate steps to ensure compliance with the Controlled Substances Act (CSA) and Code of Federal Regulations (CFR) and help avoid the financial and reputational risk that can result from subsequent enforcement actions.

It should be noted that the majority of DEA Registrants are law-abiding and have appropriate anti-diversion protocols in place. However, there is often a discrepancy between delineated protocols and their actual implementation. Regular, robust anti-diversion assessment and appropriate improvement and the development of policies that ensure compliance with the CSA and CFR will help avoid the financial and reputational risk that can result from enforcement actions. Proactive external engagement with government regulators and investigators is also critical to enhance communication, receive clarity regarding nuanced regulatory requirements, and minimize the litigation risk associated with government investigations.

SERVICES INCLUDE:

- Assess diversion control program objectively and ensure compliance with the CSA and CFR
 - Detailed risk assessment to identify and prioritize the organization's diversion risk
 - Overall program assessment; program improvement; and monitoring support
- Evaluate Suspicious Orders Monitoring System (SOMS)
 - SOMS improvement and subsequent monitoring
- Development of appropriate diversion compliance training for all employees
 - Tailored to specific roles and responsibilities
- Customized background investigations for the pharmaceutical industry
- Due diligence investigations
 - Existing customers
 - New customers
 - Potential business partners and/or mergers

- Development of "Know Your Customer" protocols
- Physical security evaluations
 - Assessments and recommendations based upon CSA and CFR requirements
- Investigations
 - Assist with potential government investigations
 - Undercover investigations involving sensitive CSA related issues
- Brand protection and anti-counterfeiting solutions
- Onsite account visits (distributors; manufacturers; pharmacies; physicians; clinics and other DEA Registrants)
 - Detailed assessments to assist with regulatory and business decisions
- Announced and/or unannounced "mock" DEA inspections to focus on frequently cited DEA violations, for example:
 - Failure to set up a system to detect suspicious orders
 - Failure to report to the Automation of Reports and Consolidated Reporting System (ARCOS)
 - Failure to report theft and loss
 - Failure to maintain complete and accurate records
 - Failure to document transfers between Registrants
 - Failure to account for losses
 - No Biennial Inventory
 - Making security changes without notifying DEA