CONTROLLED SUBSTANCE COMPLIANCE & SHIPPING EXPERT COMMUNITY

Key Information

Contact details:
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Project website:

The goal of our community is to improve the understanding and interpretation of controlled substance and shipping legislation worldwide.

High level of compliance is vital to maintaining public trust in life science R&D. The work of the Controlled Substance Compliance & Shipping Expert Community keeps its members up-to-date with current developments in best practices, legislation, and regulations.

Controlled substance legislation has changed rapidly in recent years as legislators respond to societal issues and concerns. Remaining compliant in this environment is an ever-growing challenge, and consequences for breaches can be severe.

Cross-border shipping is also in a very dynamic and legislated environment and ties in very closely with aspects of Controlled Substance logistics. Pharma companies must ensure that shipments are fully compliant with both national and international requirements. Mistakes cause delayed or rejected shipments, which in turn have a negative impact on pharmaceutical R&D timelines.

This long-standing expert community focuses on tackling the challenges we face, developing solutions, communicating with regulations, and learning from each other to stay current and compliant with legislation governing controlled substance and shipping activities.

Who should join?

The expert community is made up of major pharmaceutical companies and specialist software providers. This community provides an open and safe environment for members to benchmark and share experiences in various areas of focus related to controlled substance and compound shipping legislation and regulations worldwide.

Recent topics include:

Barriers to research The UK's Advisory Council on the Misuse of Drugs recommended revising de-minimis limits for research involving synthetic cannabinoids. The collaborative approach and expertise of the CSCS expert community make it an ideal platform for communicating technical advice and advocating change to governmental organizations.

The International Narcotics Control Board Highlighting risks and trends of precursors in illicit drug manufacture, emphasizing collaboration on controls and tools under the 1988 Convention.

Pharmaceutical Research and Manufacturers of America (PhRMA) Addresses U.S. Controlled Substances Regulations and the state-federal law conflicts affecting the pharmaceutical landscape.

Suspicious Order Monitoring (SOM) IQVIA presented the proposed changes in SOM regulation and comments received by the DEA.

Specialty logistics service providers White-glove/ Tier 1 shipping providers, role and responsibilities, and the types of shipments handled.

Inventory management systems Presentation of controlled substances inventory solutions. Members benchmarked their inventory management processes.

Inspections and audits Regulatory inspections, internal audit programs, license applications, and renewals. This led to a repository summarizing major jurisdiction legislation, inspection focus, exemption, threshold.

Benchmarking exercise A large exercise of how pharma handles logistics and compliance.

Dangerous Goods (DG) Transportation by road and air, including responsibilities of a DG safety advisor (DGSA) and country-specific requirements.

DEA's Controlled Substances Destruction Alternatives to Incineration (ANPRN) We responded to the DEA's proposed rule changes (March 2024, DEA-2023-01-48) on destruction of controlled substances.

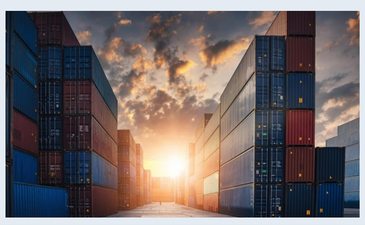
Unlocking Efficiency and Compliance: Shipping Tooling Focus group Working on end-to-end tooling requirements for a more efficient shipping landscape.

Thanks to our funders who are making this project possible; without their help, this community would not exist or collaborate.

Call for input:

We are working on an upcoming topic on **R&D Goods Valuation for Cross-Border Shipments**.

If you can share information on the methodologies used in your company for valuation of DNA, cells, plasmids etc, please get in touch:
Birthe.nielsen@pistoiaalliance.org



Pistoia Alliance: Collaborating to lower barriers to R&D innovation

The Pistoia Alliance is a global, not-for-profit alliance of life science companies, vendors, publishers, and academic groups that work together to lower barriers to innovation in R&D.

Our members collaborate as equals on open projects that generate significant value for the worldwide life science community.

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