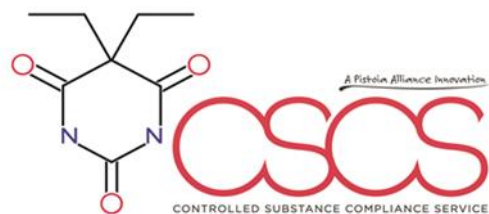


Controlled Substance Compliance & Shipping Expert Community



Key Information

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Goal of the Expert Community

To improve the understanding and interpretation of controlled substances and shipping legislation around the world

Sponsors/partners



What we do

High levels of compliance are vital to maintain 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 shipments are fully compliant with both national and international requirements. Mistakes cause delayed or rejected shipments which in turn have 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 legislations governing controlled substance and shipping activities.



Unlocking Efficiency and Compliance: Join the new Shipping Tooling Focus group:

R&D units navigate a maze of shipments monthly, spanning domestic and global territories. From sample management to clinical and lab samples, the complexity is immense.

In the absence of tailored solutions, pharmaceutical companies resort to in-house systems to oversee the coordination, trade, and dangerous goods aspects of this process. This decentralized approach often leads to inefficiencies, potentially exacerbating trade compliance and safety risks associated with consignments.

Collaborate for change:

Your insight is invaluable. Together, let's shape a safer, more efficient shipping landscape. Reach out to cscs@pistoiaalliance.org and be part of developing the requirements for a new tooling solution.

Who should join?

The expert communities are made up of major pharmaceutical companies and specialist software providers. This community provide an open and safe environment for members to benchmark and share experience in various areas of focus related to controlled substance and compound shipping legislation and regulations around the world.

Recent topics include:

Changes to HS nomenclature & mislabeling issues

Barriers to research The UK's Advisory Council on the Misuse of Drugs recommended to change de-minimis limits for research organizations with compounds which fall under the synthetic cannabinoids definition.

The International Narcotics Control Board on trends and risks of precursors and collaboration with industry & international governments in controls, tools used, and the 1988 Convention and Equipment control in illicit drug manufacture.

Pharmaceutical Research and Manufacturers of America (PhRMA) on the evolving landscape of U.S. Controlled Substances Regulations including conflict between state and federal laws.

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 by these service providers.

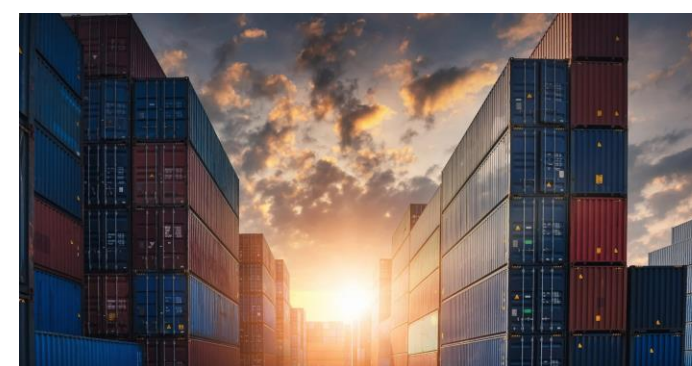
Inventory management systems BIOVIA presented their solution for inventory management, focusing on the controlled substances application. Members benchmarked the inventory management processes.

Inspections and audits Regulatory inspections, internal audit programs, license applications and renewals. This resulted in the formation for the group of a repository for summary legislation / inspection focus / exemption / threshold for major jurisdictions.

Benchmarking exercise The group undertook a large exercise on how pharma manages logistics and associated compliance.

Dangerous Goods (DG) Transportation of DG by road and air. We also examined the role and responsibilities of a DG safety advisor (DGSA), including specific countries 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.



Join the Pistoia Alliance Controlled Substance Compliance & Shipping Expert Community

If you would like to join the CSC & Shipping Expert community, please get in touch with us:

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www.pistoiaalliance.org
 [@pistoiaalliance](https://twitter.com/pistoiaalliance)

