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

ChemAxon

Scitegrity

MERCK

Pfizer

gsk

To join the steering committee, we ask for a $7K yearly contribution

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 group keeps its members up-to-date with current developments in best practices, legislation and regulation.

Controlled substance legislation has changed rapidly in recent years as legislators respond to societal issues and concerns. For example, enhanced suspicious order monitoring requirements in response to the opioid epidemic, and 'super generic' definitions of the mid 2010s in an attempt to manage the rapid increase in synthetic cannabinoid analogs. 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. Since the start of the pandemic there have been many additional challenges in transporting Pharmaceutical R&D materials. Pharma 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.

The Community focuses on tackling the challenges we face, developing solutions, influencing regulations, and learning from each other to stay current and compliant with legislations governing controlled substance and shipping activities

The CSC & Shipping Expert Community has existed since 2013 making this one of the Pistoia Alliance's longest ongoing groups.

Biggest challenge for our members in CSC & Shipping compliance:

- The proper translation of the wording of regulations to the appropriate (sub)structural queries, is key to the accurate detection of controlled substances.
- Keeping current with the changing requirements worldwide and maintaining an effective and efficient approach to maintain compliance.
- Engaging with regulators and gaining an understanding of how regulators operate and devise improved approaches to CS compliance.
- Interpretation of ambiguous regulations. Where there is ambiguity in legislation, trying to get meaningful and timely engagement from regulators to understand exactly what is meant and how this applies to scientific research.
- Navigating and improving transport delays resulting from Global Logistic Barriers (i.e., Covid-19 and Brexit)

Activities 2021/22

Brief overview of the main activities in 2021/2022**Changes to HS nomenclature & mislabeling issues -** Expert Group members Scitegrity presented on the Harmonized System that handles nomenclature changes and ChemAxon presented challenges in communicating with customs regarding mislabeled information.

ACMD 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.

Brexit updates – Updates on the changes to Brexit-related regulations.

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

Pharmaceutical Research and Manufacturers of America (PhRMA) presented to the community on the evolving landscape of U.S. Controlled Substances Regulations at both federal and state levels and gave examples of conflict between state and federal laws and ongoing uncertainties.

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

Specialty logistics service providers – Our members discussed white-glove/ Tier 1 shipping providers, responsibility of trade complacence data 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 – The Compliance Group, Ireland presented controlled drugs requirements in Ireland, Italy, and UK focusing on their audit and inspection experience**.** The community shared its own experiences in 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.

US Section 301 – Prof Henry Gao from Singapore Management University and expert on Chinese law and international trade gave his views on the future status of the US/China tariffs that currently are in place.

Who should join?

The expert communities are made up of major pharmaceutical companies and specialist software providers. Knowledge and experience sharing is entirely voluntary. 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.

The community works as a team to tackle the challenges and strive to stay current with the changing environment.

If you would like to join the CSC & Shipping Expert communities, please get in touch with us CSCS@pistoiaalliance.org

Pistoia Alliance: Lowering 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 sciences community.

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