Controlled Substance Compliance & Shipping Expert community

Improving the understanding of controlled substances and shipping legislation around the world

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Controlled Substance Compliance & Shipping Expert Community (CSCS)

Community manager
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Problem Statement:
Legislation relating to Pharma R&D is changing rapidly; each change adds complexity and widens controls. Remaining compliant is an ever-growing challenge and consequences for breaches are severe. Compliance is also important in shipping. Customs, cold chains, dangerous goods and infectious material legislation all make R&D shipping complex.

Value Proposition:
High levels of compliance are vital to credibility of and public trust in life science R&D. The CSCS Expert Community provides a forum for Compliance professionals, researchers, compound and shipping managers to share best practices and update their awareness of new legislation.

Project Member:
The expert communities are made up of pharmaceutical companies and specialist software providers, sharing their knowledge and experiences on a voluntary basis.

Project champions:
Nicolas Fur & Ania Hajdukiewicz, Novartis, (Shipping)
Jessie Bin Song, Merck, (Controlled Substance Compliance)

Steering Committee:
GSK
Pfizer
NOVARTIS
MERCK
Chemaxon
$7K per year ensures a seat on the Steering Committee
Scitegrity

Project Deliverables:
- Round Table Discussions and Seminars
- Discussion and Collaborations with Expert Speakers, independent and quasi-judicial monitoring bodies

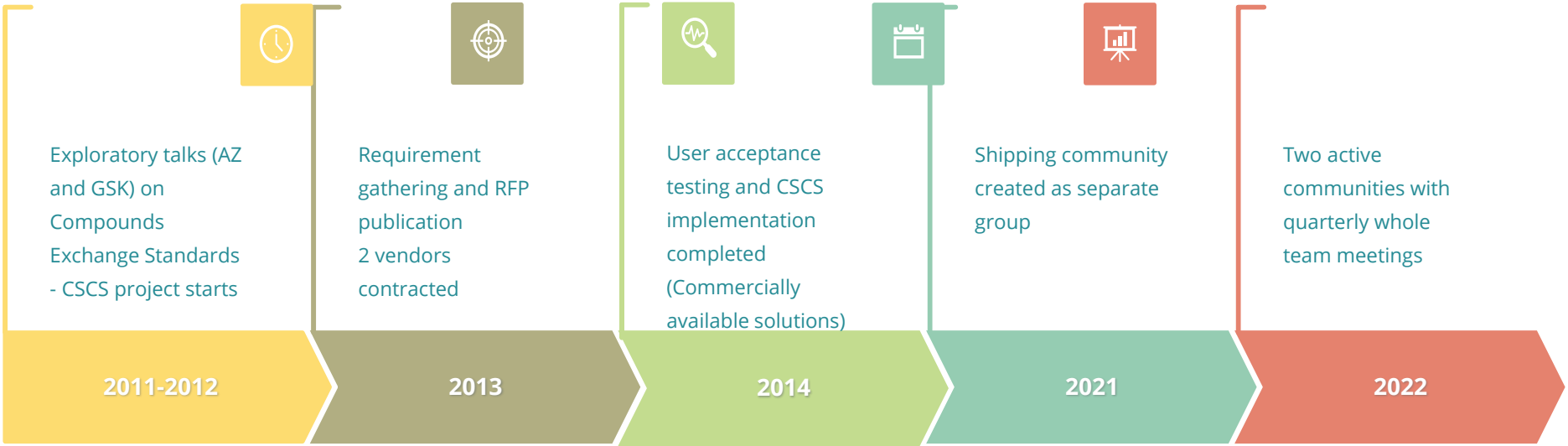
Agenda

- How do the community operate
- CSC activities: communicating with regulators
- Shipping group: activities & call for input

Collaborate.
Innovate.
Educate.
London 2024

CSC & Shipping History

Pistoia Alliance



Pre-project
An Expert System combined with a Controlled Substance Knowledgebase to determine if a substance is controlled

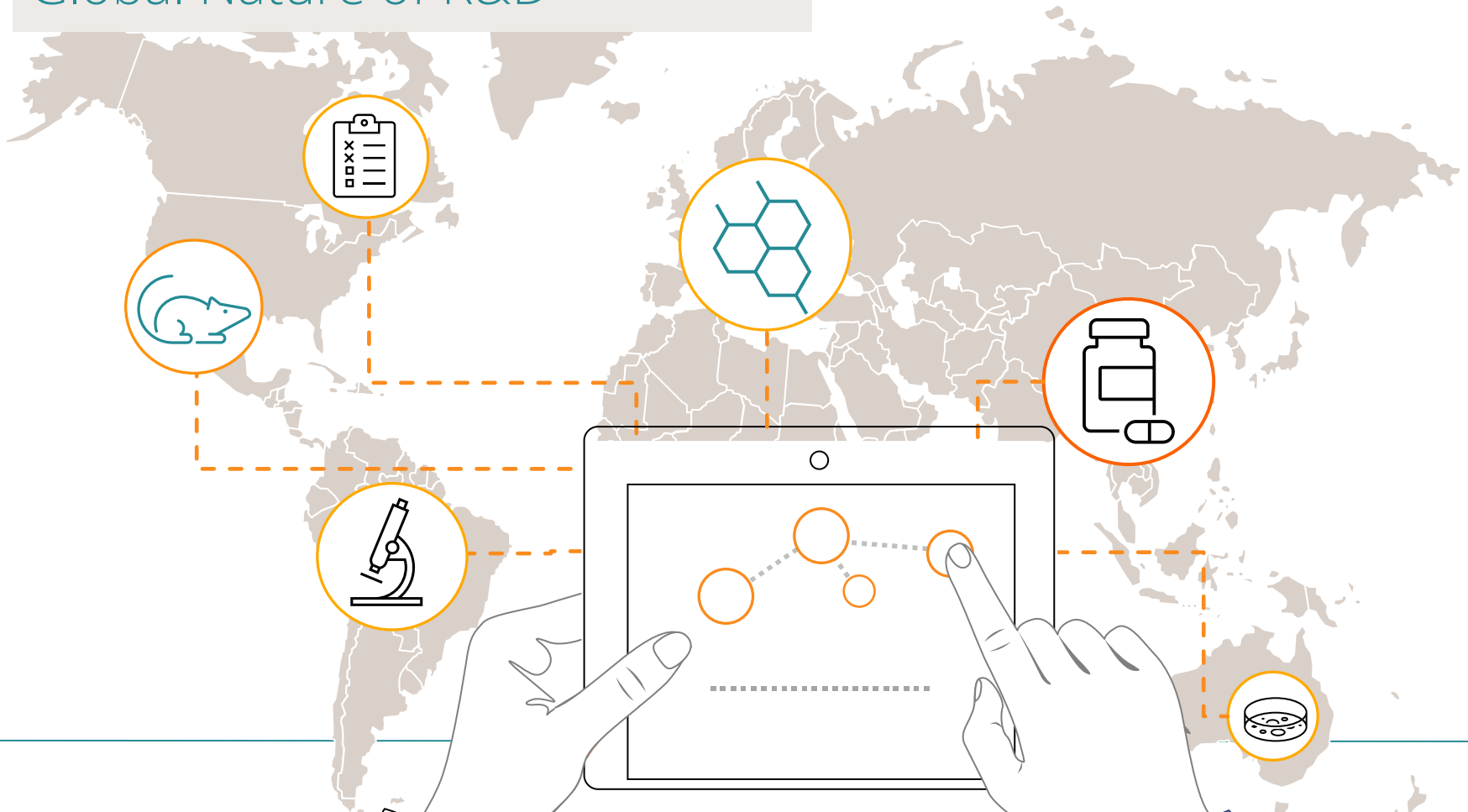
Project Process
Chemaxon and Patcore: Compliance Checker
Scitegrity: CS2

2 Expert Communities
>20 members from different pharma companies

CSC - Mission

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

Global Nature of R&D



Myriad of legislation

Controlled Substances Act

United States anti-drug law

The Controlled Substa
the statute establishin
which the manufactur

German Federal Narcotics Act

Drug laws in Germany are governed by the German Federal Narcotics Act [1] [2] [3] The
act defir

Misuse of Act 1971

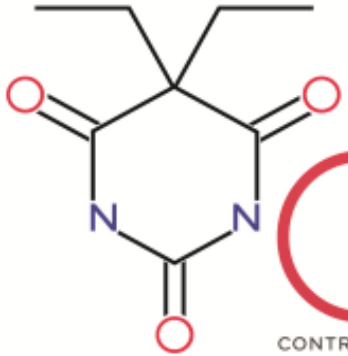
UK legislation

The Misuse of Drug
Act of the Parliame
action in line with t

Federal Agency and Health Prod

Belgian government agency

The Federal Agency for Medici
Belgium is responsible for
new medication in Belgium
Xavier De Cuyper is Genera



A Pistoia Alliance Innovation

CSCS

CONTROLLED SUBSTANCE COMPLIANCE SERVICE

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Arrêté du 22 février 1990 fixant la liste des substances classées comme stupéfiants

Dernière mise à jour des données de ce texte : 23 mai 2021

NOR : SPSM9000498A

Accéder à la version initiale

RÉPUBLIQUE FRANÇAISE
Liberté
Égalité
Fraternité

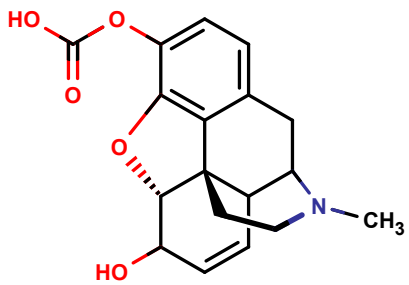
It was all going so well

In the past:

Legislation was based around specific structures and some small generic examples.

Examples has to be interpreted and transformed from legal wording into scientific nomenclature to be useful,
i.e. words into chemical structures

Morphine

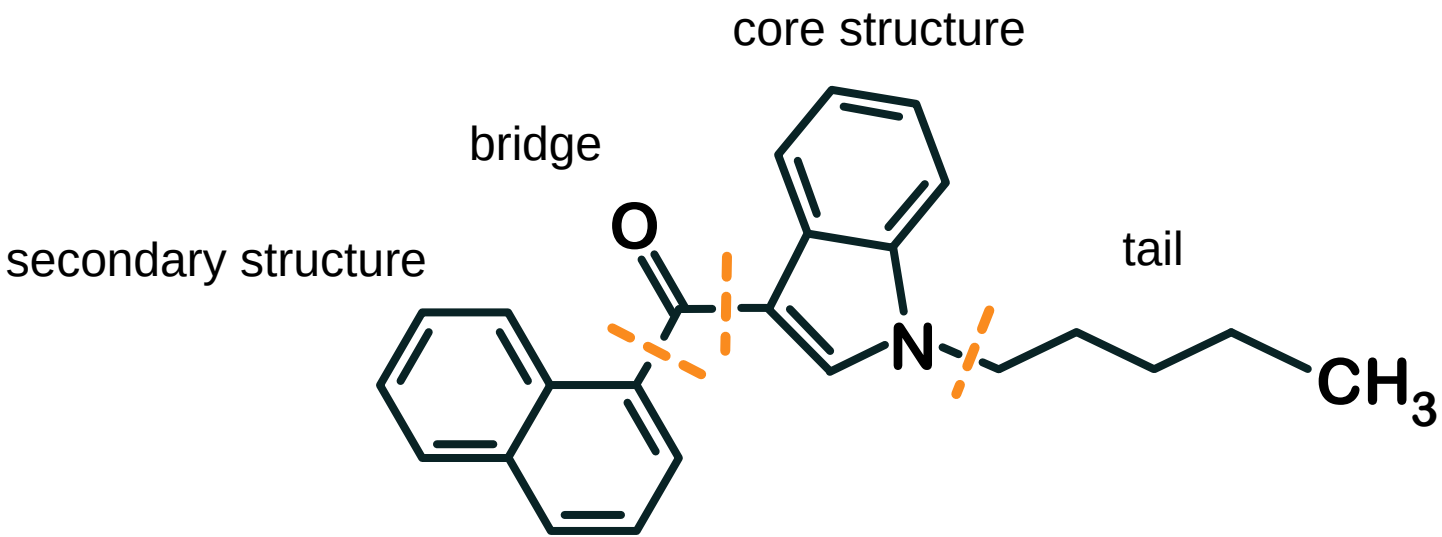


ACMD Report

Addresses ‘Third Generation’ synthetic cannabinoids
An expanded generic definition…

‘Simply increasing the number of generic controls to cover the broad range of psychoactive cannabinoid structures which are being identified using a similar approach to the existing controls would require an extremely long list of additional paragraphs. It is therefore proposed to adopt a different approach, based on defined modifications of a ‘model’ compound, 1-pentyl-3-(1-naphthoyl)indole (‘JWH-018’)’

https://www.gov.uk/government/publications/third-generation-synthetic-cannabinoids
* ACMD: Advisory Council on the Misuse of Drugs



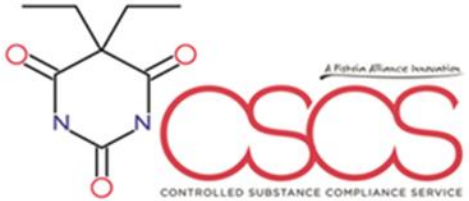
JWH-018

An Unprecedented Change

From	To
Listing substances on a named basis	Structure based generic definition
Clarity & manageable licensing process	Uncertainty & unprecedented scale
Industrial strategy: efforts to improve UK environment	New barrier to investment and research

Tackling the Issue:
Working with our Partners

Pistoia Alliance



Chemaxon

Scitegrity

We are a glob … arriers to innovation in Controlled Substance Compliance & Shipping Expert Community

The Association of the British Pharmaceutical Industry

BRITISH PHARMACOLOGICAL SOCIETY

ROYAL SOCIETY OF CHEMISTRY

The House of Commons and the House of Lords

Nick Hurd The Minister of State, Home Department

I beg to move,

That the draft Misuse of Drugs Act 1971 (Amendm
laid before this House on 4 June, be approved.

I am sure that Members of the House will have notice
made by the draft order is based on scientific and tec
therefore distinct from other amendments to the Mis
have recently been brought forward for debate. In th
record my thanks to the Advisory Council on the Misu
advice on the matter and for its continued work, whi
order.

STATUTORY INSTRUMENTS

2019 No. 1323

DANGEROUS DRUGS

The Misuse of Drugs Act 1971 (Amendment) Order 2019

Made - - - - 8th October 2019
Coming into force - - 15th November 2019

At the Court at Buckingham Palace, the 8th day of October 2019

Present,

The Queen's Most Excellent Majesty in Council

In accordance with section 2(5) of the Misuse of Drugs Act 1971(**a**), a draft of this Order has been laid before Parliament on the recommendation of the Advisory Council on the Misuse of Drugs and approved by a resolution of each House of Parliament.

Accordingly, Her Majesty, in exercise of the powers conferred on Her by section 2(2) of that Act, is pleased, by and with the advice of Her Privy Council, to order as follows:

971 (Amendment) Order 2019

Share

15 July 2019
Volume 799

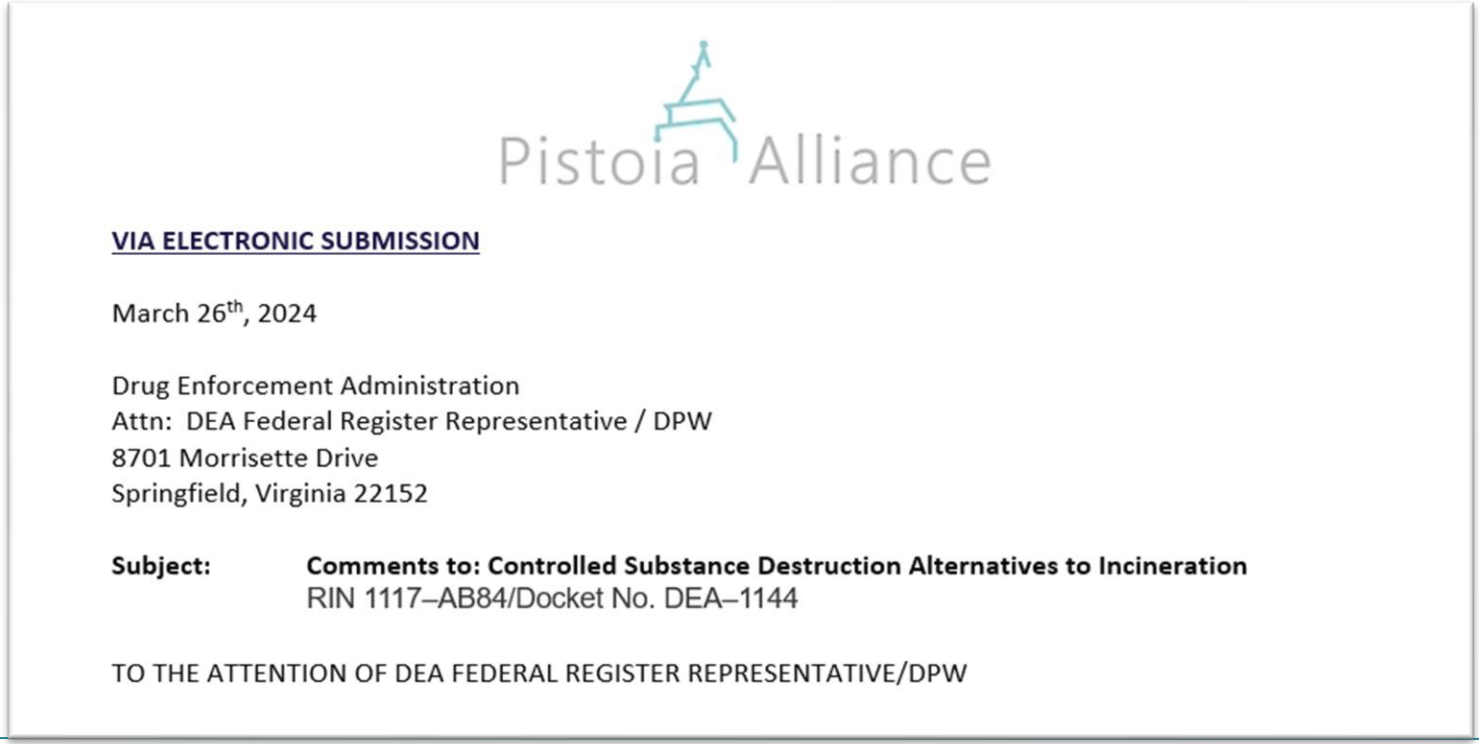
ugs Act 1971 (Amendment) Order 2019.

islation Scrutiny Committee

ness Williams of Trafford) (Con)

nts to the Misuse of Drugs Act 1971 in that it is based on changes to scientific and technical detail in existing legislation and does not introduce further controls on compounds

DEA's controlled Substances Destruction Alternatives to Incineration: Responding to proposed rule changes



Pistoia Alliance

VIA ELECTRONIC SUBMISSION

March 26th, 2024

Drug Enforcement Administration
Attn: DEA Federal Register Representative / DPW
8701 Morrisette Drive
Springfield, Virginia 22152

Subject: **Comments to: Controlled Substance Destruction Alternatives to Incineration**
RIN 1117–AB84/Docket No. DEA–1144

TO THE ATTENTION OF DEA FEDERAL REGISTER REPRESENTATIVE/DPW

Shipping community - Mission

Our commitment is to participate in speeding up drug discovery effort by shipping in an efficient and compliant way while dealing with a constantly evolving regulatory space and high material variety.

Mutual Goal: Cycle time and Quality

Key parameters

- Temperature restrictions
- Compliance aspects
  - Compliance checks, classification
  - Declaration and permits: Customs, FDA, HMRC,USDA, Fish and Wildlife, DEFRA, CDC
- Time to prepare and transport the shipment
- Routing – Should/Must use preferred LSP
- Incidents - Requestor, Shipper, Carrier

Compliance considerations

Key parameters

All shipments have to be in compliance with local and international regulations.

- HS Code
- INCO Terms
- Valuation
- Permits and Licenses
- Country of Origin
- Denied Party Screening
- Dangerous Goods
- Material Description (a catch all element)

How do we reduce those Barriers?

Goal: Materials arrive in a timely manner and in the same condition as when the shipment left the site of departure

Challenges: Nature of the materials produced for research and evolving requirements

Reducing Barriers:

- Awareness to the Process to the People who Contribute to the Process
- Awareness to the Compliance Elements Critical to the Process
- Voice your needs and problems

CSC & Shipping Activities

Enhancing best practice

Discussions and speaker program

- (PhRMA)Pharma research CS Regulation landscape
- Inventory management system (Biovia)
- James Felman Defending analogue cases
- Roundtable discussions and Bench-marking with members
- Biocair - Brexit
- Specialty logistics service providers
- US section 301 China tariffs
- Brexit 2022
- INCB Trend precursors and industry collaboration
- Suspicious order Monitoring (SOM)/ IQVIA
- Licenses and inspections in different countries
- Colin Clarke (Avantor), international shipping
- Changes to HS nomenclature and issues
- Dangerous Goods (DG), road and Air. DGSA

Horizon scanning, encourage input to public consultations

- Fentanyl generic and US GAO consultation
- Barriers to Research. UK ACMD
- Monitoring legislative changes (Scitegrity, ChemAxon)
- HS Classification tools
- DEA's Alternative to incineration response

Call to Action – Pistoia Alliance R&D Shipping Expert Community organizing a focus group

- **Objective:** Discuss obstacles in R&D Shipping Coordination IT Systems
- **Scope:** Covers Sample Management/Compound Management, Clinical, and Lab Samples
- **Participants:** All Pharma R&D including 3rd party CROs and CMOs
- **Challenges:** Lack of off-the-shelf solutions, decentralized approach leading to inefficiencies
- **Opportunity:** Collaborate to identify solutions

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.

How can I join?

- A company must be a member of the Pistoia Alliance
- Each company may send as many participants as they wish to the meetings
- You can join one or both expert communities
- Details on how to join: cscs@pistoiaalliance.org

Questions