CSCS Expert Community

Improving the understanding of controlled substance legislation around the world.

CSCS Expert Community lead – Andreas Schumacher
CSCS Expert Community manager – Claire Bellamy

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CSCS Expert Community

The Controlled Substance Expert Community provides a forum for industry compliance officers and compound managers to share best practice in controlled substance compliance and update their awareness of new legislation.

Our members include major pharma and specialist software providers.

Steering Committee

Scitegrity  ChemAxon  Pfizer

gsk  GlaxoSmithKline  NOVARTIS  MERCK

Project Members

Lilly  Roche  binocularvision™  MERCK
Legislation is changing rapidly and it has become much more complex to stay compliant.

Markush structures were widely adopted in the 2000s and define an area of chemical space. There is ambiguity in many definitions, but this approach generally results in a manageable number of controlled substances.

Recently countries have started to define super-generics. These capture significantly more compounds in pharma libraries and are much more difficult to interpret.
How does the group work?

Whole team meetings with invited speakers are held on-line quarterly. Members are widely spread across Europe, North America and China. Extra meetings are occasionally called if needed.

The steering committee is made up of a single representative from each organisation. It meets quarterly, to steer the group’s activities and hold more detailed discussions.

Andreas Schumacher (Novartis) is the chair of the group and oversees the strategy. Claire Bellamy is the coordinator.
CSCS Activities

**Enhancing best practice**

**Previous discussions and speaker program**

- The opioid crisis in the US: proposals and policy considerations - PhRMA
- Chinese controlled substance legislation – Millipore-Sigma
- Tariff coding - Scitegrity
- International Drug regulation. - Simon Elliot, WHO
- US drug regulation, an expert witness perspective - Prof DeCaprio

**Regulators**

- Horizon scanning, encourage input to public consultations
- Monitoring progress of bills such as SITSA
- UK Misuse of Drugs Act amendment 2016
- Monitoring legislative changes e.g. Belgium and Poland

**Sponsor and status**

- John Katko
  - Sponsor, Representative for New York's 24th congressional district. Republican.

**Home Office**
Confluence project discussion area

- Useful links to legislator websites
- Discussions
- Subgroup output
- Interesting news items
How do I join?

A company must be a member of the Pistoia Alliance.

Participating companies are requested to contribute a subscription. At present, this is set at $6K per year. It is used for coordination costs and face-to-face meetings.

Each company may send as many participants as they wish to the meetings.

Details of how to join are available from claire.bellamy@pistoiaalliance.org or john.wise@pistoiaalliance.org