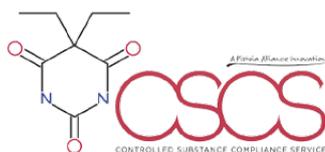


Managing Multi-site Controlled Substance Compliance



Novartis scientists collaborate across multiple facilities and ship research compounds between the US, China, Switzerland and Singapore on a daily basis. CSCS is used to check all samples prior to production and again before shipment.

Novartis' small molecule research and chemistry groups have adopted a solution built on the Pistoia Alliance's Controlled Substance Compliance Service (CSCS) to streamline the process of compliance checking when shipping compounds between sites. Being able to use a single consistent CSCS solution to interpret local legislation at multiple facilities around the world is vital to remaining fully compliant.

Centralised solution

Many pharma companies rely upon their research scientists to check that the substances they individually make or purchase are not controlled. The overhead of carrying out these checks can slow down their research, and the complex legislation can lead to different individual interpretations, particularly when shipping compounds cross-border. Failure to comply with the legislation can have serious legal, financial and operational consequences.

There is an additional need to check compounds purchased from third-party vendors, for example when buying screening compounds for lead optimization projects. Vendors provide their own compliance information but the regulations are complex and, without the use of a common standardized approach, each vendor has to make their own

interpretation. Novartis regularly sees cases where a compound is found to be controlled but the vendor had no flag or comment indicating that this was the case.

To assist scientists in making accurate and consistent interpretation of the legislation, thus maximising compliance, it is advisable to develop and maintain a centralized internal database to log controlled substances. Scientists need to be able to check the database before manufacturing or ordering a compound to see if it is controlled by relevant legislation. Realising that many other pharma companies were probably doing the same, Novartis identified the need for an advanced common solution that could ease the process of maintaining compliance across the whole industry.

Regional compliance

Countries around the world have differing legislation on controlled substances. Scientists shipping material between labs in different countries need to be aware of the rules that apply at the destination as well as those that apply to their own facility.

Figure 1: Illustration of the regional compliance legislation heatmap.



"CSCS gives us access to a single source of information around controlled substances that is as authoritative or complete as it is possible to get at this moment in time."

Daniel Baeschlin,
 Director Compound
 Management, Novartis

Maximise compliance

With limited resources available to perfect an internal database and regularly scan the compliance literature and legislation, Novartis joined the Pistoia Alliance's CSCS project in order to work collaboratively on a shared solution. By way of the CSCS project the various pharma partners could encourage software vendors to develop commercial compliance-checking products with an economy of scale that would not be possible to achieve in isolation.

Pro-active checking

In addition to enabling scientists to carry out quick and consistent compliance checks of their own, Novartis is now able to use their CSCS solution to scan registered substances in their ELN at regular intervals to keep track of what has been produced or ordered, and pro-actively identify anything controlled.

When a potentially controlled substance is identified – even if the control applies

Controlled substance compliance is not an option. Novartis understand that a consistently applied technical solution such as CSCS gives the best possible chance of maintaining full compliance. It enables the creation of a comprehensive centralized system that allows for compliance at a much greater level of confidence than before.

to a different location – the corresponding scientist is notified to make them aware of what they can and cannot do, and how this may restrict their collaboration with researchers at other locations. A scientist can then take the appropriate action to modify their experiment plan at an early stage, before expending too much resource on it, if the notified restrictions would prevent it from completing as originally intended.

“The first phase of the project saw the creation and delivery of commercial CSCS solutions with the support of the Pistoia Alliance team. This worked very well and achieved all the key deliverables. We were impressed not only by the project management and the way it was kept to time and budget, but by the openness of all the project members.”

Quan Yang,
Global Lead and Director
for Biology Information
Systems, Novartis

Consistent interpretation

Not all controlled substance legislation is clear and there are often ambiguities that are open to interpretation. This grey area has the potential to create conflicting opinions on the status of a compound in any given jurisdiction, a problem that becomes particularly visible when working with smaller compound vendors who may be less aware of the restrictions that apply in other countries.

The companies that joined the Pistoia Alliance CSCS project were at various

Pre-competitive collaboration

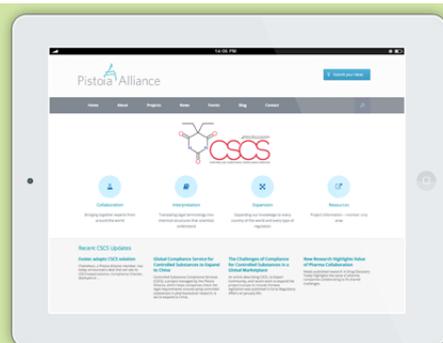
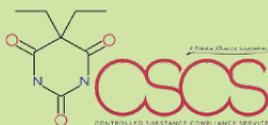
Using the Pistoia Alliance as an honest broker to exchange ideas and solutions between interested parties was extremely helpful. It can be a challenge to free up internal resources to work on a pre-competitive project, but by sharing the effort and financial support for CSCS with other project members, Novartis was able to help drive the project forward and achieve its own internal goals on time as well as the shared goals of the project team.

stages of advancement in implementing their own technical solutions to this problem. They understood that developing standard solutions to be deployed by pharma and vendor companies alike would enable the CSCS project to deliver significant value to the industry as a whole. Such solutions would enable grey areas of legislation to be tackled using a uniform approach with all key players in agreement as to what is and is not controlled.

With a CSCS solution now deployed across all its research sites, Novartis is confident that it remains up-to-date and in compliance with all relevant controlled substance legislation, and by working with the Pistoia Alliance it has achieved this with only a fraction of the resources that would have been required had it developed the solution itself.

More information on CSCS

<http://www.cscs-experts.org/>
contact@cscs-experts.org



Pistoia Alliance: Lowering barriers to R&D innovation

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.

