

Controlled Substances Program at Novartis Institutes for BioMedical Research

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Novartis Institutes for BioMedical Research (NIBR)

- NIBR is Novartis' global pharmaceutical research organization
- Focused on discovering and developing innovative new medicines to cure disease and improve human health
- >6,000 scientists, physicians and business professionals around the world

Why does Novartis have a Controlled Substances Program?

- Work with a broad range of chemicals and pharmacologically active chemical compounds, some of which may be regulated as Controlled Substances (CS)
- Controlled substances fall within *varied* regional, national and international legislation and agencies that regulate their whole lifecycle including synthesis, acquisition, storage, handling, usage, transport, and disposal or destruction



Maintain
compliance
while allowing
research to
progress

Comprehensive approach

Globally aligned program under Operational Compliance

- Registered and licensed use of approved CS
- Monitoring of all materials coming into, stored, and leaving Novartis to prevent unlawful use and diversion

Registered use of controlled substances

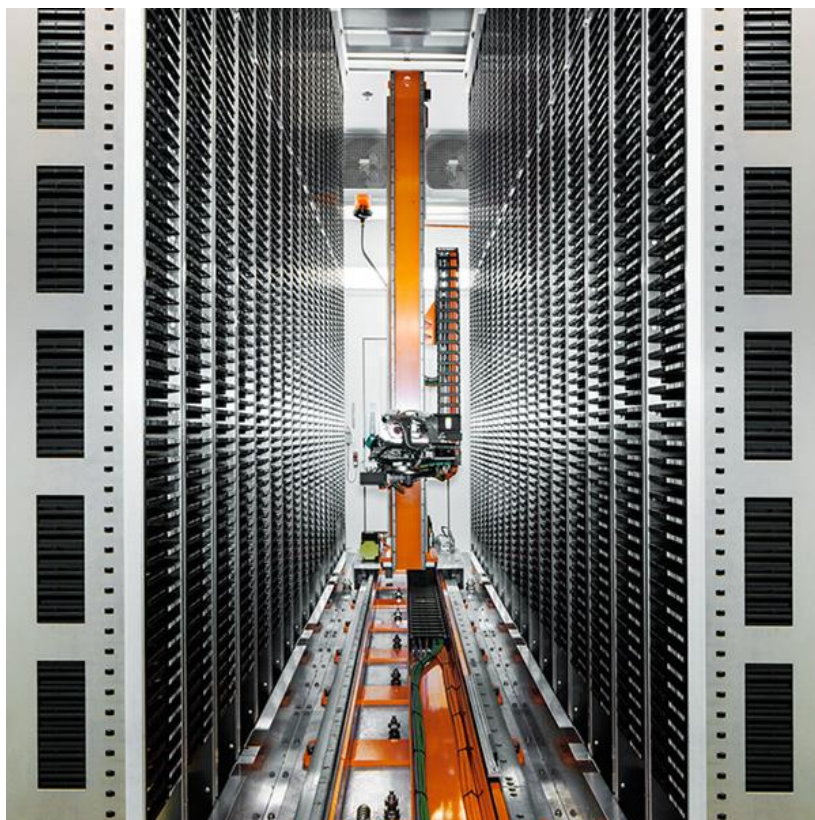
- US example: licensure with MDPH, CA DOJ, and US DOJ DEA
- Defined list of approved materials under US and State Schedules
- Policies and processes in place covering procurement, storage, handling, usage, transport, and disposal
 - Security and diversion prevention
 - Training
 - Documentation
 - Auditing

Surveillance of materials to prevent unlawful use

- Chemical purchases
- Incoming compounds, including blinded material
- Design and syntheses of materials
- Chemical inventories and compound libraries
- Transport of chemical matter

How do we monitor all these channels?

- Operational Compliance team working closely with cross-functional partners and researchers – awareness, pro-active outreach, policies, program support, enforcement
- Use of ChemAxon Compliance Checker on electronic lab notebooks, inventories, libraries, requests
- Use of ChemAxon Compliance Checker Service for NDA work
- Currently, manual and semi-automated processes using Compliance Checker



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Questions?

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Thank you