GLOBAL

INDUSTRIAL CHEMICAL REGISTRATION E-GUIDE

charles river

Why Go Global?

The regulatory requirements and legal responsibilities involved with registering your chemical, polymer, or pharmaceutical intermediate are complicated. Achieving registration is costly and time-consuming. Why settle for just one market?

Strategic program design can help you to satisfy country-specific data requirements in your current and future key markets, extending your return on investment:

- Avoid unnecessary or duplicate testing
- Ensure data can be used in multiple countries/regions
- Increase cost-effectiveness of your program
- Meet regulatory timelines and prepare for the future

Where to Start?

What is required? Independent of jurisdiction, registration requirements depend on similar points:

Is the substance already listed

- On a national inventory?
- On confidential inventory?
- As exempt from registration?

What is the annual tonnage you want to import or manufacture?

- Now?
- Next year?
- In several years?

What is your role in the supply chain?

- Manufacturer?
- Importer?
- Formulator?
- Distributor?

Consider This

Every country has specific data requirements; some of these may overlap. Careful planning can help you to avoid unnecessary, duplicate testing.

- What are the core data requirements?
- What additional studies might be triggered?
- Where should studies be conducted?
- What is the best order in which to initiate registrations?

More to Consider

Read-across:

- EU: Might be possible for data required from 10 tonnes/year onwards
- China: Not accepted

Are available data scientifically valid and sufficient for GHS purposes?

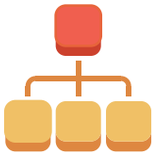
- If not, consider re-testing
- China GHS: check whether 5,000 mg/kg endpoint is included in your study
- Studies performed in other countries should be performed according to GLP when used for EU REACH

Evaluation by authorities after submission:

- Japan, China, Australia, USA, Canada: evaluate all dossiers
- EU: when passed completeness check, one obtains a registration number (authority evaluation may happen later)

What's Involved

The following steps are part of any successful registration strategy; planning a broader registration scope at the outset maximises your investment of time and capital.



Project Coordination

Ensuring all studies and dossier work run in the right order avoids losing time.

Pre-registration consultancy meetings with Authorities

Having good relations with Authorities and an ability to communicate in their native tongue is invaluable. If necessary, work with trustworthy local subcontractors to ensure the correct approach.

Study Monitoring

Determining which country-specific (e.g., China, Japan) studies need to be performed locally and identify trustworthy local providers.

Full Regulatory Package

Performing hazard assessment, classification and labelling (GHS), QSAR, read-across, grouping, risk assessment and risk refinement, and producing the Safety Data Sheet.

Consultancy

Addressing all questions that arise during the process.

A Global Strategy for Your Substance

Define Regulatory Strategy and Project Team + **Data Gap Filling** + **Dossier Preparation** = **Successful Application**

Define your markets, perform a data gap analysis for setting testing strategy.

Identify missing studies in your substance data portfolio which need to be performed.

Prepare dossiers in respective formats, C&L, QSAR modelling, hazard, exposure, and risk assessment.

Get your registration number, permission to market, post-submission activities and support and peer review documents.

Charles River Track Records

Global Industrial Chemical Registration

Country	In-house vs. subcontracted	Appoximate number of projects (2007/2017)
Canada	In-house	>15
USA	In-house	>65
China	Sub-contracted	>30
Japan	Sub-contracted	>25
Phillipines	Sub-contracted	>15
South Korea	Sub-contracted	10
Australia	In-house	>35
New Zealand	In-house	3
Switzerland	In-house	10

Charles River Track Records

EU REACH

Description	Appoximate number of projects (2007/2017)
Lead dossiers (incl. non-phase-in dossiers)	>400
Member dossiers	>500
Full CSA/CSR	>250
(ELINCS) Tonnage updates	>60
Intermediates (incl. reviewing SCC)	>30
E-SDS preparation	>65

The Charles River Team

As your partner for global registrations, we have the world-wide regulatory expertise to understand complex requirements and the local connections to perform the necessary studies to achieve registration in multiple markets. As a full-service CRO, we are uniquely positioned to

Assist >

With thorough data gap analysis for commercialising your substance in defined countries/regions worldwide.

Perform >

Missing studies in your substance data portfolio.

Support >

New chemical notifications and registrations.

Contact Us

To get your registration with all data required can take quite some time, resulting in no market until registered/notified. Don’t delay. Contact us today:

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