

Increase submission rates and avoid costly delays



Clarivate™



Your trusted partner in planning CMC (chemistry, manufacturing, and controls).

Cortellis CMC Intelligence™ is a comprehensive database that organizes global CMC regulations and highlights any variances in local practices to provide:



Content coverage for both biologics and small molecules dosage forms.



Curated submission procedures with estimated and official timelines.



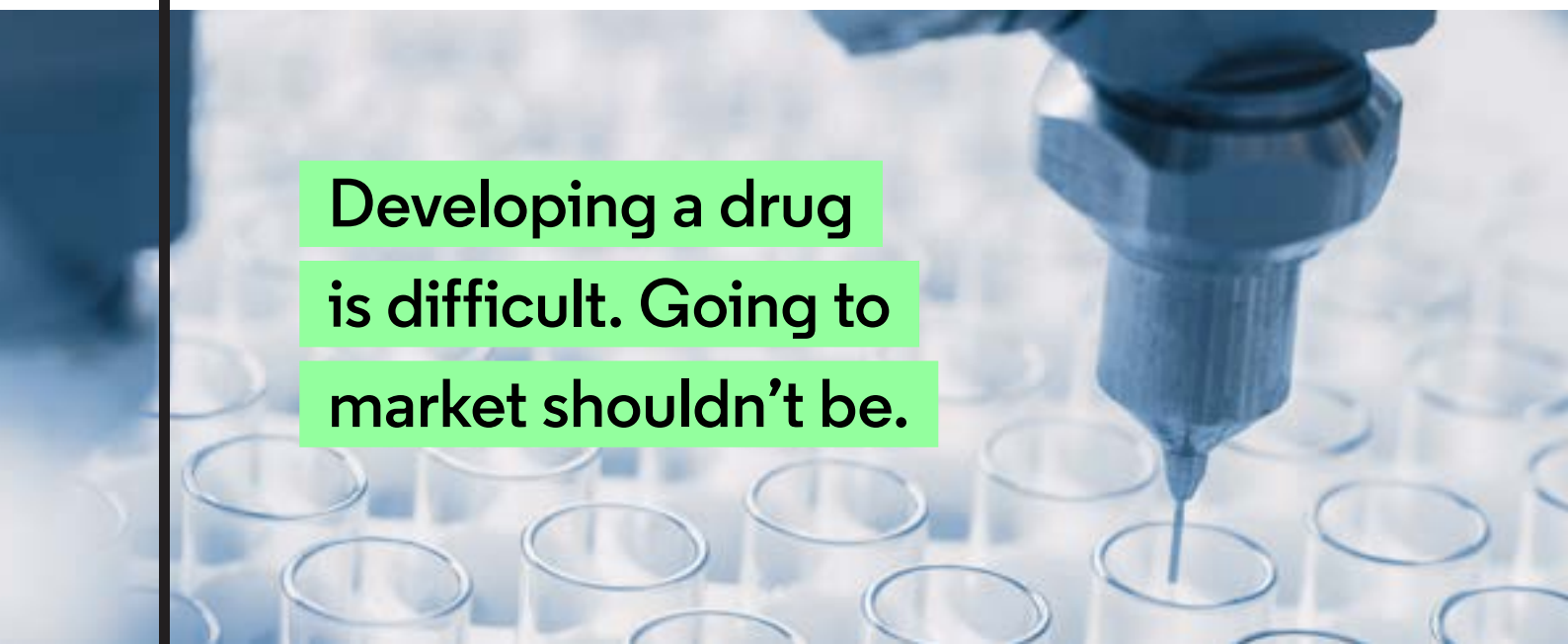
Automate the process of CMC regulatory monitoring through user configured alerts.



Detailed summaries (in English) from experts in local regulatory practices paired with reference source documents to provide a complete picture.



Efficiently compare regulations across countries, territories, and organizations — including the ability to export vital comparison tables.



**Developing a drug
is difficult. Going to
market shouldn't be.**

Trust a CMC solution, compiled by specialized industry experts, to prepare your dossiers accurately and swiftly.

Robust data:



5K+

source documents



64

territories, countries, and regions for biologics content



900+

links to Cortellis Regulatory Intelligence, providing access to expanded detail



137

countries, territories, and organization specific regulations for small molecule content





Content covers



Small molecules:

- Cream
- Drops
- Inhaler
- Liquid injectable
- Liquid oral
- Powder
- Solid oral
- Solid, modified release
- Spray

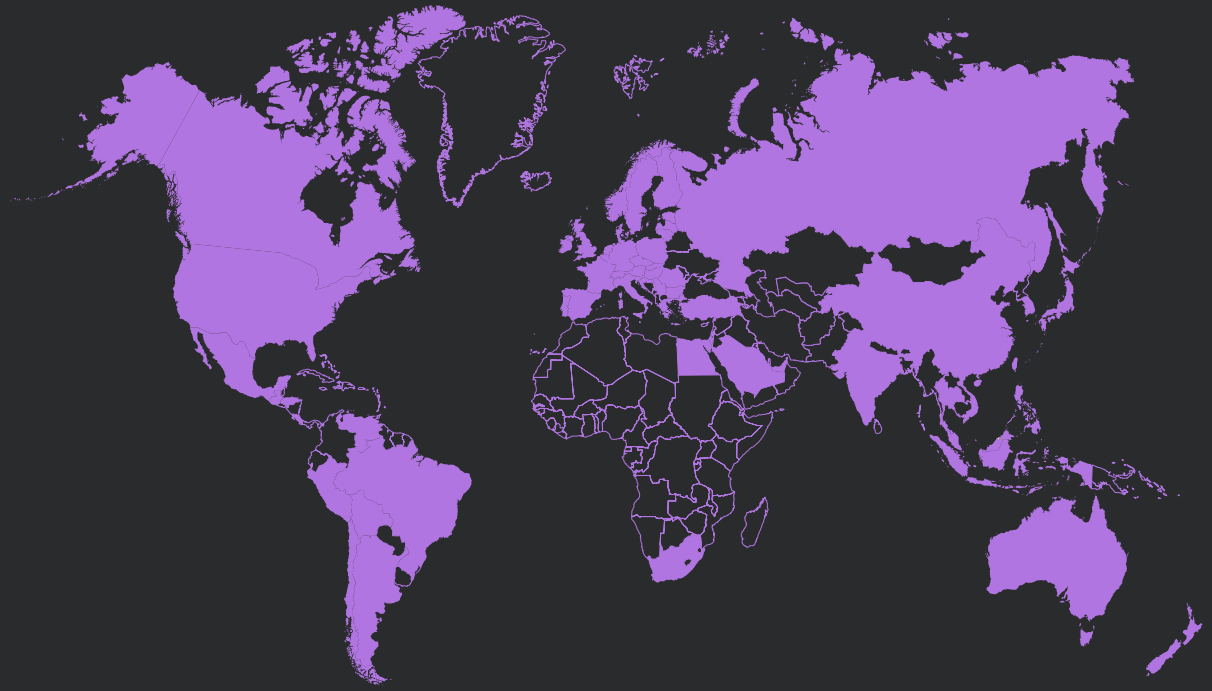


Biologics:

- Biosimilars
- Blood derivatives
- Cell therapy
- Drug – devices combination products
- Gene therapy
- Monoclonal antibodies
- Recombinant hormones and proteins
- Vaccines
- Tissue Therapy



Find information on how to tackle post-approval changes for **61 countries**.



Coverage includes:



Administrative changes



Extensions of marketing authorizations



Flowcharts for change pathways



Quality changes

- Manufacture
- Container closure system
- Stability
- Finished product
- Excipients
- Control of active substance
- Design space and post approval management protocols



Fee details



CTA quality amendments



Documentation requirements for variations



Compare detailed national regulatory authority derived official CMC regulations and local expertise-based local practices across countries in English.



Streamline your internal practices of monitoring global CMC regulations all in one place through the updates navigation button to quickly view the latest changes to that regulatory agency of your country of interest and see how those source documents impact key requirements.



Visually compare summary requirements across countries and export to facilitate audits.



Identify common and divergent requirements across countries of interest to better inform key decisions.



Leverage detailed workflows for post-approval regulatory submission procedures with expected timelines.



Create custom alerts to provide notifications when country or content specific to your areas of interest have been updated.

About Clarivate

Clarivate is a leading global information services provider. We connect people and organizations to intelligence they can trust to transform their perspective, their work and our world. Our subscription and technology-based solutions are coupled with deep domain expertise and cover the areas of Academia & Government, Life Sciences & Healthcare and Intellectual Property. For more information, please visit clarivate.com.

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