

Cortellis CMC Intelligence

Increase submission rates and avoid costly delays

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

Planning the chemistry, manufacturing and controls (CMC) module for regulatory submissions is a costly and time-consuming process that, when completed incorrectly, can lead to extended deadlines and unplanned costs. Cortellis CMC Intelligence is a comprehensive database that collates and organizes official CMC regulations and local practices in a single platform to provide:



Daily updates to new or existing source documents



Detailed summaries (in English) of local regulatory practices and reference documents



Comparison tables organized according to ICH eCTD structure



Curated submission procedures with estimated and official timelines

Leverage high quality, comprehensive data supported by extensive domain knowledge and expertise

Robust data



130+

modules for country, territory, and organization specific regulations



800+

source documents with citations



25+

product and regulatory related filters based on eCTD structure



170+

links to Cortellis Regulatory Intelligence, providing access to expanded detail

Expert team



Curation by CMC professionals who are also native language speakers



Deep knowledge of key issues and trends impacting your submissions



Manual report curation ensures attention to detail and high quality



Geographically diverse with global breadth and local depth



"Information is nicely presented and searchable ... so it's much faster to find and doesn't need much explanation when sharing with colleagues."

Regulatory Intelligence Manager, global biopharmaceutical company

Unlock the hidden insights in data

Increase the chances of approval and avoid rejected applications using a comprehensive, organized, accurate and centralized source of CMC regulations, including official requirements, local practices, systematized comparisons and submissions procedures.



Detailed reports

Reduce time spent identifying and tracking all official CMC requirements and local practices using comprehensive, organized reports.



Comparison tables

Efficiently compare regulations across countries, territories, and organizations – all from a single point of database access.



Source documents

Quickly link to all official documents – including those available in Cortellis Regulatory Intelligence – for a comprehensive view.

Access trusted intelligence intergrated across the R&D lifecycle

Make data-driven decisions with speed and certainty across the development lifecycle with the Cortellis suite of life science intelligence solutions – including customized consulting services delivered to your specific requirements. Only Cortellis provides the insights needed to accelerate innovation with confidence.

R&D continuum



Discovery & preclinical development

Clinical development & regulatory compliance

Portfolio strategy & business development

Generics strategy & development

Data | Insights | Consulting | Services

Make better decisions and accelerate innovation

Contact a representative to learn how Cortellis CMC Intelligence can accelerate innovation for your organization, or visit clarivate.com/cortelliscmc