



Cortellis CMC Intelligence

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

In an industry in which it can take many years and sometimes hundreds of millions of dollars to develop a life-saving product, it shouldn't be so difficult to finally bring that product to market. Especially when this product is a drug that could potentially alleviate so much pain and suffering in this world.

One of the major hurdles in launching a new drug is the approval of chemistry, manufacturing and control (CMC) data, which is necessary in order to begin clinical trials and obtain final drug marketing authorization in each country. Failure to prepare this data correctly can lead to drug approvals taking much longer than planned, resulting in extended timelines, unplanned costs and testing, loss of forecasted revenue and most importantly, patients without medicines.

Preparing the data requires a large, detail-oriented process that can take several months to complete. This workload is increased exponentially when a company intends to sell a drug on a global scale, as each individual country can have different manufacturing requirements as well as different levels of difficulty in order to obtain this information.

Compiling CMC data – By the numbers:

- 14.8%** The proportion of total R&D expenditure in 2017 spent on CMC activities*¹
- \$432M** The expected spend on CMC activities for a company with a \$2.9B R&D budget**¹
- 11.3 %** The percentage of first cycle NME applications rejected between 2000 and 2012 due to CMC-related issues²

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This is why Clarivate Analytics created Cortellis CMC Intelligence (CMC). With CMC, you gain easy access to comprehensive CMC-related regulatory requirements for 130+*** countries and organizations, all in English. CMC allows regulatory professionals to review all information in one place, leading to increased efficiency and accuracy.

The result is increased confidence that when you submit your dossier, whether it's to one country or the world, you won't have to do so again.

Cortellis CMC Intelligence can be used to:

- Gain visibility on CMC requirements for clinical investigation or commercial use as stipulated by local regulatory authorities, including those in low and middle income countries, and by organization that fund drugs and have their own set of requirements (e.g., The Global Fund)
- Reduce the need for local consultants
- Eliminate the need for an internal CMC database that must be continuously maintained
- Facilitate timely delivery of economical high-quality drug products
- Avoid delays in product registration
- Reduce high product development costs

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- Reduce the number and frequency of deficiencies in dossiers submitted for WHO prequalification
- Optimize product development plans
- Accelerate product introduction
- Increase the value of source product for API and finished dose manufacturers

Who can benefit from Cortellis CMC Intelligence:

- Regulatory affairs professionals
- Regulatory intelligence professionals
- CMC regulatory officials
- Quality assurance officers
- Business development professionals

For information about Cortellis CMC Intelligence visit [Clarivate.com](https://clarivate.com)

References:

1. 2018 CMR Factbook from Clarivate Analytics: Drawn from the 2018 R&D Investment Metrics Programme
2. <https://jamanetwork.com/journals/jama/fullarticle/181779>

*Based on a survey consisting of 17 different contributing companies (11 Major, 6 Mid and Other).

**\$2.9B was the average R&D budget for the 17 large and mid-sized companies in CMR

***At final build