

Case study | Concept Foundation

# Understanding local CMC requirements in low-resource countries

Supporting generic drug submissions in low- and middle-income countries.

Concept Foundation is an international not for profit organization, working on improving access to sexual and reproductive health (SRH) medicines and technologies in low- and middle-income countries (LMIC). The foundation provides extensive regulatory support to manufacturers, including developing regulatory strategies with manufacturers of SRH medicines and technologies with a focus on LMIC markets.



# "With [Cortellis CMC Intelligence] it's easy for me to know which information is correct and have the reference for it."

**Wallada Im-Amornphong,**  
International Regulatory Affairs Manager, Concept Foundation

## Gaining visibility into specific CMC requirements

International Regulatory Affairs Manager at Concept Foundation, Wallada Im-Amornphong, provides generics manufacturers with support preparing CMC dossiers for regulatory submissions in Asia and Africa. She's currently focusing on a drug application in five different countries, with variations across dossiers. To support the manufacturer she's working with, she prepares summary reports using Cortellis CMC Intelligence™ to verify local requirements.

## Ensuring successful applications



### Saved time

Wallada Im-Amornphong has reduced the time it takes her to prepare a summary report from over a week to just one to two days, by accessing requirements on Cortellis CMC Intelligence.



### Simplified review

By eliminating the need to review multiple sources, she has freed up valuable time to focus on conducting further research where needed.



### Easy data access

Easy access to high-quality and verified data has given the foundation increased confidence in applications and reduced the risk of delays and rejections.



### Approved drug submission

The drug submission the foundation is currently working on has passed the application screening process in the countries where it has been submitted.

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[clarivate.com/cortelliscmc](https://clarivate.com/cortelliscmc)