

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



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.



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



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



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

To learn how Cortellis CMC Intelligence can accelerate innovation for your organization visit:

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