

MANAGING CMC FOR GLOBAL ACCELERATED MARKETING APPROVALS

Pradip Ghosh-Dastidar
International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)
USA
Pradip.Ghosh-Dastidar@bms.com

In an increasingly complex global regulatory environment, proper planning and where possible, timely engagement with Health Authorities have the potential for up front resolution of potential CMC review issues. Such Health Authority interactions may facilitate faster dossier review and subsequent marketing authorization approval. In this session, a case study of a global new marketing application will be presented. Additionally, a discussion will explore the challenges, including time and resources, associated with in-country testing, which many countries require for imported products. The IFPMA position on waiver of redundant in-country testing will be presented. Success in receiving complete or partial waiver of in-country testing can be achieved, provided it is properly justified and supported by quality systems and controls in place at all stages of the manufacturing and supply chain to assure that products remain fit for their intended use.