

CMC STRATEGIES TO EFFECTIVELY MANAGE CMC DATA CHALLENGES AND ENSURE REGULATORY COMPLIANCE IN JAPAN

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The amount of Chemistry, manufacturing, and controls (CMC) information needed varies according to formulation type, drug category and jurisdictions. And Japanese regulatory landscape is often perceived as having complicated processes, stringent drug approval standards, language and culture barrier, which are considered by many to be the most challenging in the world. It's very important to understand Japan specific regulatory requirements and preemptively identify CMC data challenges to enable accelerated drug development and approval in Japan. The propose is to identify the priority measures and controls that companies should have in place to build quality into procedures for compiling flawless regulatory submissions and to reduce review time by minimizing regulatory queries, appropriately deal with CMC data challenges. Scientific, robust and adaptive CMC development strategy is essential when dealing with PMDA-interactions, submission conformance or compliance and overall probability of success of the Japan-NDA. Key considerations for formulating and implementing a successful regulatory strategy are: Understanding of marketing authorization application process, key stages, PMDA review and expectations; CMC requirements in Japan focusing on rationalization for setting scientifically sound specifications, stability program, correct interpretation of stability data and shelf life claim as specification and stability are of immense importance in the development of safe and efficacious formulations; CMC review and GMP compliance and; how to utilize prior explicit and tacit knowledge on CMC requirements from successful approvals or PMDA quality consultations meetings, tactical planning, alternative approaches to justify data lacking in CMC package and to ensure the requirements are met to PMDA approval process.