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Insight on PMDA's regulatory procedures, key stages, timing and CMC requirements for bio-therapeutic products in Japan

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The intention of this is to provide a basic understanding of the legal regulatory systems, marketing authorization application, PMDA review process, key stages and timing and CMC requirements in Japan with focus on biological drugs products for human use. PMDA has some stringent CMC data requirements which make Japan a very unique and highly regulated market in the world. Japan's regulatory environment is significantly more complicated compared with other countries. The level of accuracy and details required by Japanese regulatory authority is sometimes even greater than US FDA/any other regulatory agency. . The precondition for this is a national marketing authorization. Global pharma companies would often complete their development for US/EU markets before thinking about Japan. It is clearly an important part of the drug development process and needs to be considered Japan in parallel with work targeted for other major regulatory authorities (US and EU). In context, there is another significant consideration, approval for a drug product in the US/EU is a well-understood and documented process whereas, Japanese approvals have often been more complicated, unclear and time consuming. Here, the author has studied various unique features and challenging regulatory framework for biopharmaceuticals products including regulatory procedures, registration, authority review, compliance and approval and key focus on CMC requirements. Propose is to identify the priority measures and controls that companies should have in place in order to build quality into procedures for compiling flawless regulatory submissions and to reduce review time by minimizing regulatory queries. This also gives an idea to overseas manufacturer for development of bio prescription drug for Japan market and also provide brief checklist of precise requirements.

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