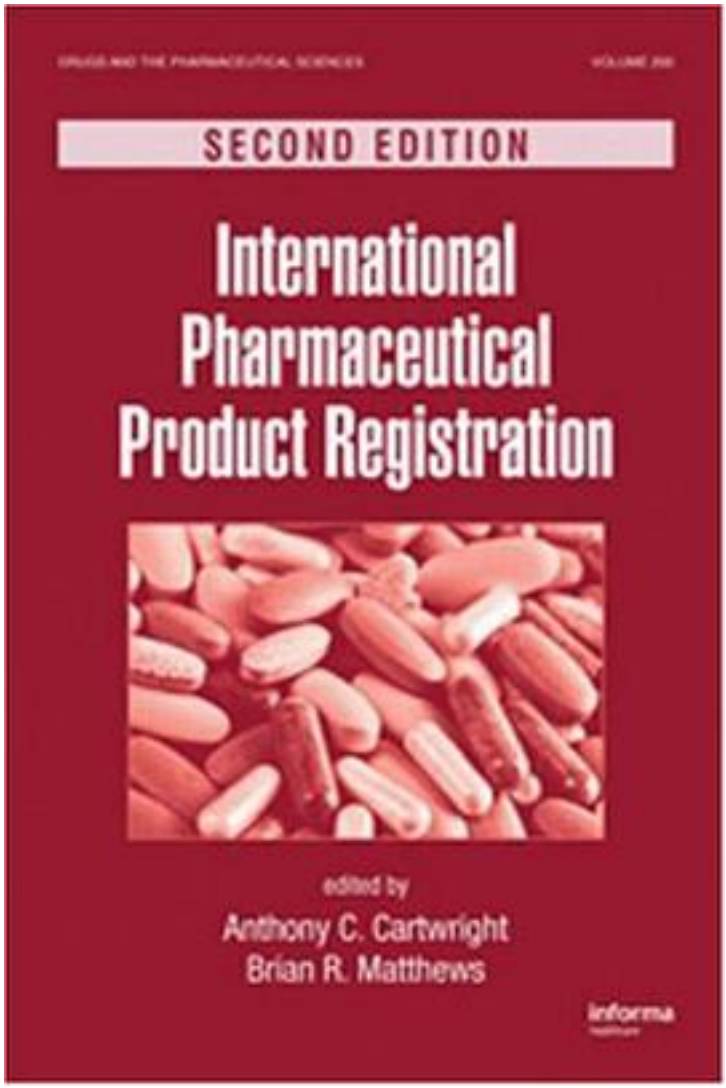
International Pharmaceutical Product Registration



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Top international regulatory experts, scientists, and clinicians deliver the much-needed information that regulatory affairs professionals and drug development scientists need for registering new products. With harmonization discussions and negotiations in full swing between the major regulatory agencies and pharmaceutical trade associations in the US, Japan, and Europe, this Second Edition is an essential guide for all who need to be kept abreast of developments since the first edition. Key benefits include: ICH GUIDELINES-established at the International Conference on Harmonization (ICH) in the areas of Quality, Safety, Efficacy, and Multidisciplinary, which need to be taken into account are discussed, in detail PROGRESS ON HARMONIZATION-including the increased cooperation between agencies, based on ICH, as well as accepted derivatives of the Common Technical Document (CTD), that can lead to time and cost-savings in the product registration process CONTRIBUTIONS FROM 45 EXPERTS-with broad expertise and knowledge of the scientific and technical requirements involved in drug regulation provide authoritative advice and viewpoints you can trust BENEFITS OF OUTSOURCING RESEARCH AND CLINICAL TRIALS-made possible by the existence of internationally accepted guidelines, gives you access to well-trained physicians and a larger, more diverse sample market at a lower cost

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