International Cooperation, Convergence and Harmonization of Pharmaceutical Regulations: A Global Perspective

Pierre-Louis Lezotre
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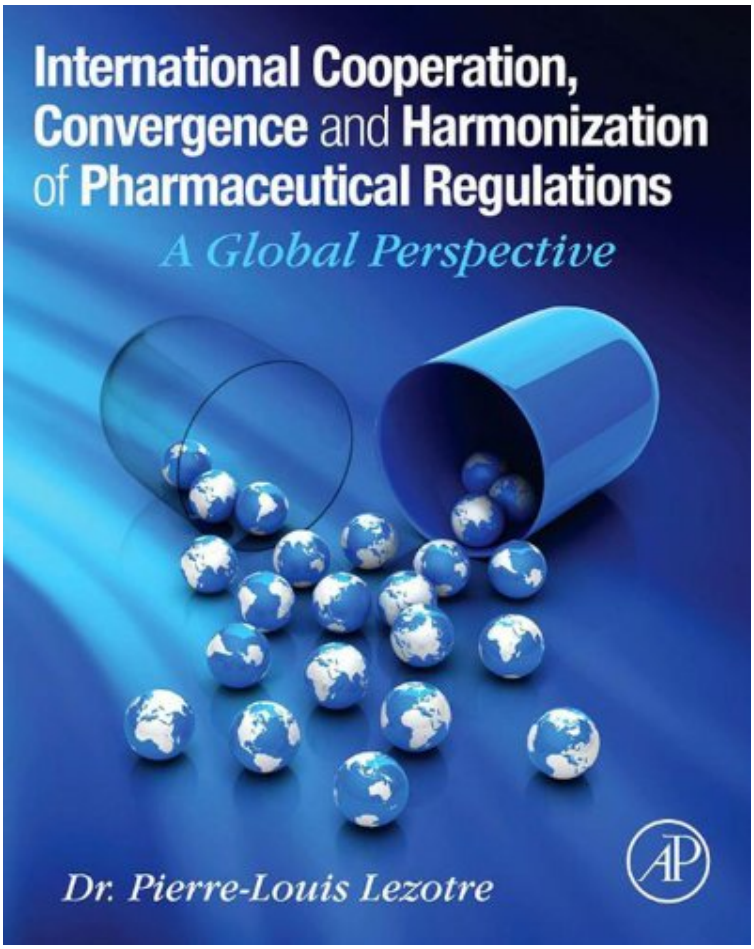

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Pierre-Louis Lezotre : International Cooperation, Convergence and Harmonization of Pharmaceutical Regulations: A Global Perspective before purchasing it in order to gage whether or not it would be worth my time, and all praised International Cooperation, Convergence and Harmonization of Pharmaceutical Regulations: A Global Perspective:

International Cooperation, Convergence and Harmonization of Pharmaceutical Regulations: A Global Perspective provides the current status of the complex and broad phenomenon of cooperation, convergence and harmonization in the pharmaceutical sector (Part I), thoroughly evaluates its added value and its critical parameters and influencing factors (Part II) in order to recommend actions and measures to support the next steps for cooperation, convergence

and harmonization (Part III). All of these recommendations in the book support the establishment of a better coordinated global pharmaceutical system which represents the best realistic alternative to fulfill the objective to establish a global coalition of regulators and to respond to an increased demand to further cooperation in the pharmaceutical sector. This proposed framework, which leverages all of the ongoing positive cooperation initiatives and uses as foundations all of the numerous harmonization projects developed over the years, presents advantages for all stakeholders and would definitively have significant added value to the promotion and protection of global public health.The status of all major worldwide harmonization and cooperation initiatives (at bilateral, regional, and global levels)The value of cooperation in the pharmaceutical sector and the driving factors behind harmonizationThe proposition of a structure for the global pharmaceutical system and timely recommendations for enhancing international cooperation, as well as further discussion and policy changes in this area

ldquo;hellip;thoroughly covers the current state of international cooperative initiatives, underlying principles, why cooperation is important, and productive objectives for the futurehellip; This book has been selected for The First Clinical Research Bookshelf Essential reading for clinical research professionals.”--Journal of Clinical Research Best Practices, July 2014From the Back CoverGlobalization is a reality of the 21st century.nbsp; The development, manufacture and distribution of medicines have been internationalized.nbsp; This increased globalization has fundamentally changed the environment for regulating medicines and created unique regulatory challenges for all stakeholders.nbsp; The regulatory paradigm has indeed changed from national to international and international pharmaceutical norms and standards are more important than ever before.nbsp; International cooperation, convergence and harmonization of pharmaceutical regulations has become the only clear choice to meet the fundamental human right to have access to high quality, safe and effective medicines in both developed and developing countries. In this context, many cooperative initiatives have been established at the bilateral, regional and global levels and harmonization efforts have been enhanced.nbsp; All of these initiatives have taken a variety of forms, from informal cooperation to full integration of regulatory systems. International Cooperation, Convergence and Harmonization of Pharmaceutical Regulations: A Global Perspective provides the current status of this complex and broad phenomenon of cooperation, convergence and harmonization in the pharmaceutical sector (Part I), thoroughly evaluates its added value and its critical parameters and influencing factors (Part II) in order to recommend actions and measures to support the next steps for cooperation, convergence and harmonization (Part III).nbsp; All of these recommendations in the book support the establishment of a better coordinated global pharmaceutical system which represents the best realistic alternative to fulfil the objective to establish a global coalition of regulators and to respond to an increased demand to further cooperation in the pharmaceutical sector.nbsp; This proposed framework, which leverages all of the ongoing positive cooperation initiatives and uses as foundations all of the numerous harmonization projects developed over the years, presents advantages for all stakeholders and would definitively have significant added value to the promotion and protection of global public health. This book features: The status of all major worldwide harmonization and cooperation initiatives (at bilateral, regional, and global levels)The value of cooperation in the pharmaceutical sector and the driving factors behind harmonizationThe proposition of a structure for the global pharmaceutical system and timely recommendations for enhancing international cooperation, as well as further discussion and policy changes in this areaAbout the AuthorDr. Pierre-Louis Lezotre specializes in global regulatory strategy, and is recognized for his passion and expertiseon international cooperation, convergence, and harmonization of regulations for pharmaceuticaland biotechnology products. He has worked in different cultural environments and lived inboth Europe and the United States.Dr. Lezotre studied biology (University of Sciences, Saint-Etienne, France)and drug development (University of Pharmacy, Montpellier, France) from1992 to 1998. He then received his Master in Regulatory Sciences in 1999 (Universityof Pharmacy, Lille, France). He also recently completed his PhD in Law with honors (DoctoralSchool of ldquo;Law, Politics and Management,” University of Law, Lille, France).Since 1998, Dr. Lezotre has worked for several international pharmaceutical and biotechnologycompanies, with increasing levels of responsibility. He has served as a regional andthen global regulatory leader for small molecule and biologic/biotech programs in variousstages of research and development (from early discovery to life cycle management). Hesuccessfully led many global regulatory teams in supporting global registrations of majorproducts and numerous development projects in several therapeutic areas, includingdermatology, urology, neurology, and pain. He has been responsible for communicationswith worldwide Drug Regulatory Authorities and has also worked with external partners/companies through co-development agreements and business development programs.Dr. Lezotre has recently been invited to teach courses on international regulation in theRegulatory Sciences programs of the University of Southern California (USC).