



# Global Regulatory Systems: A Strategic Primer for Biopharmaceutical Product Development and Registration

By Dr. Henrietta Ukwu

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CenterWatch introduces the most concise, yet comprehensive resource available on the major global regulatory systems including the most relevant and pertinent regulatory facts and guidelines consolidated into one, must-have and easy-to-read resource. This strategic road map takes the reader through a dynamic and complex landscape while providing a fundamental understanding and application of global regulatory principles to ensure successful product development and registration.

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### Editorial Review

#### Review

This informative, organized and well written text could be the new primer for the global regulatory environment. It should be on the bookshelf of every product development company. --Laurie Halloran CEO, Halloran Consulting Group

Dr. Henrietta Ukwu provides an insightful perspective and breadth of experience on the worldwide regulatory systems that are critical to the success of clinical trials management. Global Regulatory Systems is an expansive and unparalleled manual for regulatory professionals that describes and helps navigate the complex and ever-changing global regulatory processes. --Emilio A. Emini, Ph.D. Chief Scientific Officer, Vaccine Research Pfizer

Regulatory professionals are routinely asked a variant of the 'can we do this' question. The task of answering this is nearly impossible without an understanding of global regulatory guidance and practices. Therefore, it is essential that every regulatory professional is armed with a framework for reference. Global Regulatory Systems: A Strategic Primer for Biopharmaceutical Product Development and Registration provides a broad, yet concise and detailed, summary of the major regulatory topics that invariably shape drug development programs, both operationally and strategically. --Gregory Dombal Managing Director, Halloran Consulting Group

#### About the Author

Dr. Henrietta N. Ukwu, M.D., FACP, FRAPS, an internist and infectious disease physician, is a biopharmaceutical industry executive with extensive global regulatory experience across many biopharmaceutical therapeutic platforms and all regions. Currently, she is senior vice president and head of global regulatory affairs for PPD Inc.

Beginning her pharmaceutical industry career at Merck & Co. in 1992, Dr. Ukwu became vice president and head of vaccine worldwide regulatory affairs in 1998, and vice president of global regulatory policy in 2002. She joined Wyeth Pharmaceuticals in 2004 as vice president of global regulatory affairs, with responsibility for all therapeutic areas across all platforms vaccines, biologics and pharmatherapeutics. In 2009, she became vice president of worldwide regulatory affairs for Pfizer Inc.

Dr. Ukwu has led regulatory efforts for vaccines, biologics and pharmatherapeutics platforms in the U.S., Canada, Europe, Asia Pacific, Latin America, Middle East, Africa and the WHO. She has been responsible for overseeing strategic product development and registration plans, regulatory interactions with Boards of Health, human subject protection for clinical/pre-clinical development, rigorous regulatory standards and successful registration of new drugs/biologics. She has been involved in many product development activities and has directly led the successful original regulatory development, filings and approvals of 14 new products. Dr. Ukwu has built strategic regulatory teams, led major initiatives to drive regulatory excellence and made significant contributions to developing and enriching the regulatory profession.

A Fellow of both the American College of Physicians (FACP) and the Regulatory Affairs Professional Society (FRAPS), Dr. Ukwu is an adjunct professor at the Graduate School of Pharmacy, Division of Quality Assurance and Regulatory Affairs, at Temple University in Pennsylvania. She has received numerous awards for her outstanding contributions to medicine, science and industry. She has authored professional and scientific publications, and has given many lectures, keynote speeches and presentations.

Dr. Ukwu is married to Dr. Isaac Ukwu. They have three children Victor, Yvonne and Henry.

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