

# Pharmaceutical Legislation of the European Union, Japan and the United States of America – An Overview

Barbara Jentges, PhD, Editor



Updated and Expanded  
Second Edition

New Chapter on Post-Approval  
Changes

New Chapter on CTD Regional  
Requirements

Expanded Chapter on Drug  
Master Files



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# Pharmaceutical Legislation of the European Union, Japan and the United States of America – An Overview

Second Edition

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PDA has reprinted Table 2: Partial Changes to Approved Matters that Require Prior Approval and Table 3: Minor Changes to Approved Matters that Require Notification (Chapter 5) and Figure 1: Template of the Application Form, Table 1: Summary Table of Attachments, and Table 2: Table of Contents for Module 1 Administrative and Prescribing Information (Chapter 6) with permission of JIHO, Inc.



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