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"Fundamentals of EU Regulatory Affairs, 8th edition"

By Pamela A. Jones, editor, 2017, 46 pages, Regulatory Affairs Professional Society, $395.00

Review by Norman M. Goldfarb

"Fundamentals of EU Regulatory Affairs, 8th edition," covers a broad range of EU regulations. EU regulation of medicinal products, medical devices, and in vitro diagnostics is changing rapidly. The book is current through September 2017, including pending changes to legislation.

Most chapters start with a list of applicable laws, directives, regulations and guidances, and then covers the salient features of the current regulatory landscape. Obviously, a work of this scope cannot go into great depth, so the book focuses on providing a solid foundation for each topic. If a library has space for only one book on compliance with EU regulations, this might be the one.

The book includes 43 chapters by 37 contributors in six sections:

- General Information
- Drugs
- Medical Devices
- Medicinal Products
- Foods
- Other Product Classifications
- Resources

The 198-page Medicinal Products section includes 14 chapters:

- Overview of Authorization Procedures for Medicinal Products
- Adaptive and Alternative Pathways
- Preclinical Testing and Good Laboratory Practices
- Medicinal Product Clinical Trials
- Registration Procedures for Medicinal Products
- Quality Systems and Inspectorate Process — Pharmaceuticals
- Generic Medicinal Products
- Nonprescription Medicinal Products
- Market Authorization for Products Derived from Biotechnology
- Pharmaceutical Postauthorization Requirements and Compliance with the Marketing Authorizations
- Pharmacovigilance
- Regenerative Medicine Regulation: Cell Therapy, Gene Therapy, and Tissue Engineering
- Human Tissue Regulation
- Vaccines

The book includes eight new chapters

- EMA and Other EU Regulatory Bodies

- Overview of Drug and Biologic Regulatory Pathways
- Preparing for EMA and Other Agency Meetings
- Regulatory Strategy
- Preclinical Testing for Medical Devices
- Adaptive and Alternative Pathways
- Medicinal Product Clinical Trials and Good Clinical Practices
- Regulatory Resources

Reviewer

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