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European Medicines Agency and the Regulation of Medicines in the European Union; Introduction; Approval of Drugs in Europe; The European Medicines Agency: Its Role and Activities; Ema Support In The Early Stages Of Drug Development; The Centralized Procedure AT WORK; Assessment overview; Single Assessment Report; Patients in the Scientific Review Process; Transparency and the Centralized Procedure; EMA-FDA Cooperation; Cooperation in the Product Life Cycle Cooperation in Inspections Benefits of International Cooperation; References; Chapter 4: Human Clinical Trials and Drug Approvals: Transnational Issues; Introduction; Taking Clinical Trials Abroad; Overlapping Legal and Regulatory Requirements; Legal Landscape in the United States: FDA Oversight of Clinical Trials; Legal Landscape in the EU: EU Clinical Trial Directives and Regulation; International Legal Landscape: International Clinical Practice Standards; National and Local Legal Standards; Practical Considerations in Conducting Global Trials Deciding Whether to Conduct the Foreign Clinical Trial Under an IND Identifying Experienced Contractors and Contract Research Organizations; Managing Idiosyncratic Foreign Sites and Investigators; Conclusion; Further Reading; Chapter 5: Falsified and Substandard Medicines in Globalized Pharmaceutical Supply Chains: Toward Actionable Solutions; Globalization's Influence on the Pharmaceutical Supply Chain; The Effects of the Global Market for Falsified and Substandard Medicines; Barriers to Global Solutions for the Problem of Falsified and Substandard Medicines Combating Falsified and Substandard Medicines through Regulatory Cooperation

Sommario/riassunto

Food and Drug Regulation in an Era of Globalized Markets provides a synthesized look at the pressures that are impacting today's markets, including trade liberalization, harmonization initiatives between governments, increased aid activities to low-and middle-income countries, and developing pharmaceutical sectors in China and India. From the changing nature of packaged and processed food supply chains, to the reorientation of pharmaceutical research and funding coalesced to confront firms, regulators, and consumers are now faced with previously unknown challenges. Based on the 2014 O'

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