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The pharmaceutical and biotech industries are the most regulated in the world due to the nature of the product. Patient safety is central to all decisions, processes, procedures, guidance and regulations. Regulatory agencies such as the MHRA and EMA are in place to ensure new and existing products meet stringent safety requirements.

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Ruthanne Vendy, RAC, a Senior Principal Specialist at R&Q, was selected to be a contributing author to the Regulatory Affairs Professionals Society's (RAPS) Fundamentals of EU Regulatory Affairs, Ninth Edition, which was recently updated to cover the upcoming implementation of the European Union's new Medical Devices Regulation (EU MDR) and In Vitro Diagnostics Regulation (EU IVDR), and the subsequent impact for manufacturers, Notified Bodies, competent authorities, and other stakeholders.

R&Q's Ruthanne Vendy Contributes to RAPS Fundamentals of ...

Regulatory Affairs Professionals Society vii Table of Contents Section I: General Information Chapter 1 FDA and Related Regulatory Agencies.....1 By Mitchell S. Berger, MPH, JD, RAC and Barry A. Berger, JD, MBA

Parties to cross-border disputes arising anywhere in the vast Portuguese-speaking world – a community of more than 230 million in a space that offers a wide array of investment opportunities across four continents – increasingly seek Portugal as their preferred seat of arbitration. A signatory to all relevant international conventions, Portugal has proven to be an ‘arbitration-friendly’ jurisdiction. This volume is the first and so far only book in English that provides a thorough, in-depth analysis of international arbitration law and practice in Portugal. Its contributing authors are among the most highly regarded legal names in the country, including scholars, arbitrators, and practitioners. The authors describe how international arbitration proceedings are conducted in Portugal, what cautions should be taken, and what procedural strategies may be suitable in particular cases. They provide insightful answers to questions such as the following: What matters can be submitted to arbitration under Portuguese law? What are the validity requirements for an arbitration agreement? How do the State courts interact with arbitration proceedings and what is the attitude of such courts toward international arbitration? What are the rules governing evidentiary matters in arbitration? How is an arbitration tribunal constituted? How are arbitrators appointed? How may they be challenged? How can an international arbitral award be recognized and enforced? How does the Portuguese legal system address the issue of damages and what specific damages are admitted? How are the costs of arbitration proceedings estimated and allocated? The book includes analyses of arbitration related to specific fields of the law, notably sports, administrative, tax, intellectual property rights (especially regarding reference and generic medicines), and corporate disputes. Each chapter provides, for the topics it addresses, an examination of the applicable laws, rules, arbitration practice, and views taken by arbitral tribunals and state courts as well as those of the most highly considered scholars. As a detailed examination of the legal framework and of all procedural steps of an arbitration in Portugal, from the drafting of an arbitration agreement to the enforcement of an award, this book constitutes an invaluable resource for parties involved in or considering an international arbitration in this country. The guidance that it seeks to provide in respect of any problem likely to arise in this context can be useful to arbitrators, judges, academics, and interested lawyers.

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