

Drug Development Process and Global Pharmaceutical Marketplace

Much more so than when the last edition of this book was written, pharmaceuticals¹ are global in impact, their regulation, and market.

This volume focuses on the assessment of the safety of new drugs. In the broadest sense, this means it must address not only the traditional “small molecules” that have dominated the field for the last century and the large therapeutic molecules derived from biotechnology sources but also vaccines, biologics such as blood and blood products, and excipients. The globalization of the regulation of the safety, efficacy, and manufacture of their products comes from the success of the ICH (International Conference on Harmonisation) process. But, as will be seen, the same globalization of the industry and continuous our advance of science have also led to market diversification of the types and use of drugs and, with this, a fragmentation of regulatory drug safety evaluation requirements which has made things more complex rather than simpler.

¹The term *pharmaceuticals* is here used in the broadest sense of man-made therapeutics: small molecules and large pills and vaccines, blood products, and, as must be, their attendant components (excipients, impurities, and all) to different degrees and in different products.