Pharmaceutical Medicine and Translational Clinical Research. Divya Vohora and Gursharan Singh (eds). Academic Press, an Imprint of Elsevier, 125 London Wall, London EC2Y 5AS, UK. 2018. xxvii + 497 pages. Price: US$ 125.

The authors of this book have carried out a detailed and comphrensive review of all the major stages of drug discovery starting from the laboratory till the final approval and launch of the new drug product in the market, along with ramifications to get the necessary statutory clearance from the governing authorities.

Seldom do the readers get an opportunity to understand the various steps involved in drug research and the authors should be complimented for taking us through the long journey of a drug molecule, from the confines of the laboratory to the market place.

The details encompass selection and preparation of potential candidates for screening on laboratory animals, submission of data for obtaining new product approval from US FDA, registering for patents, meeting the needs for local marketing clearance, etc. The laws prevalent in India and other countries in the world are clearly outlined.

The new modern concept of pharmacogenetics which is an interaction between genes and drugs, i.e. how genetic make-up of an individual affects the pharmacokinetics PK and pharmacodynamics PD of any drug, has been clearly outlined. This could very well be the next-generation concept of treatment, as it would bring about greater benefits and efficacy to a patient's illness.

The regulatory procedures followed in the US and in UK are well known to the manufacturers, whereas not many are aware of the registration procedures to be followed in European Union (EU) countries. The requirement for product registration in EU countries is well documented. Audit systems and procedures for GMP and GCP are also outlined.

Intellectual Property Rights (IPR), Patent Law Protection, Copy Right and Trade Marks, which are prime requirements for safeguarding speciality products, are important for a foreign manufacturer and these are adequately covered.

Generic market in India is very large and the section biosimilar has been described. It is important to note that generics are expected to be identical or bioequivalent to a brand name drug in dosage form according to US FDA guidelines. Only when bioequivalent studies are carried out with verifiable results available, can the claim be substantiated.

Japan, which has an important pharmaceutical market, could have been included in the book.

As stated in the Foreword by G. N. Singh (Drug Controller of India), the book is a handy reference document for personnel working in this field of activity. Besides, there are a large number of other representatives who are engaged in pharmaceutical business, including overseas companies and investors who are looking at India as an important centre to increase their turnover.

It would be useful if the chapters in the book could be regrouped and republished with the same references for further reading, to cater to this category of readers. This would increase the readership and add to the pharmaceutical business.

Drug discovery from the laboratory to the market place involves a long journey of more than 11–12 years and is an expensive proposition. It is estimated that over US$ 350 million is incurred on research of a new drug, and the success rate of a new drug turning to be a block buster is very low. Besides, at times, companies are required to withdraw a drug from the market because of serious adverse reactions, which involves significant loss to the discoverers.

Hence very few drug companies venture into this business; most of the large companies have merged to larger conglomerates and not more than half a dozen units are in basic drug discovery now. Patent law and protection of IPR are major concerns for the companies and unless the rules are favourable, they may not venture into new business in India.

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