Book review

Drug development perspectives considerations, challenges, and strategies

Nuggehalli Srinivas. Published by HNB Publishing, New York, 2010. 328 pp, price \$99.97, ISBN: 978-0-9664286-9-8

The falling productivity of the global pharmaceutical industry is a matter of record and a concern for those both within industry and in the life science sector more broadly. Seeking to reverse this trend, industry is looking much more widely for sources of innovation, moving away from a centralized closed innovation model. As a result those in drug development are tending to work in much smaller groups on novel targets with individuals taking much wider responsibility for multiple aspects of early drug development. A book that provides a broad overview with relevant examples is potentially very valuable to those working in this environment. Dr Srinivas has over 20 years experience in many phases of early drug development and has published widely. In this book he has selected five areas for detailed review: bioanalysis, allometry, CYP metabolism, PK simulations, drug combinations and genetic polymorphisms. Selection of these topics seems to have been driven by the availability of suitable examples. An introductory section on why these have been selected and how they fit into an overall drug development plan would have been helpful. Each chapter follows the same general plan: an introduction, a series of detailed examples, and a concluding summary section. The summary sections at the end of the chapter are the best feature of the book and provide useful practical and strategic insights. Unfortunately some of the detailed examples seem to reflect the information available on the subject drug rather than addressing specific aspects relevant to the chapter. As a result some of the key messages are lost in the detail. The introductory sections are rather short and serve more as a summary of the information in that chapter rather than an overview of the topic. This is a particular weakness as the topics are highly selected and readers new to drug development will need more information on the other tools or techniques available to address the question in hand. For example the chapter on allometry discusses the strengths and weaknesses of this technique but has very little information on what other

options are available for human PK prediction. This is important because allometry is no longer widely used as the primary method for human PK prediction. It may be beyond the scope of this book to discuss detailed alternative examples but an outline of key concepts such as the minimal anticipated biological effect level (MABEL) would provide important context for readers.

Overall this book provides a useful reference for those seeking specific examples to illustrate identified issues in drug development but it lacks the broad overview and guidance for it to be used as a practical guide to drug development.

Competing Interests

There are no competing interests to declare.

Duncan Richards

Clinical Director, Academic DPU, GSK R&D, Cambridge

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CORRESPONDENCE

Dr Duncan Richards, Clinical Director, GSK Academic DPU, Addenbrookes Hospital, Hills Road, Cambridge CB2 2GG, UK.
E-mail: duncan.b.richards@gsk.com