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"The Science and Business of Drug Discovery: Demystifying the Jargon"

Edward D. Zanders, 2011, 397 pages, Springer, $189

Review by Norman M. Goldfarb

"The Science and Business of Drug Discovery: Demystifying the Jargon" is an engaging, comprehensive and straightforward review of drug discovery and development. The book is ideal for anyone who wants to understand how their work fits into the overall scheme or needs to communicate with people from other specialties. Despite the book's vast scope, it includes non-superficial insights like the following two examples:

> One problem with testing drugs in animals is that the results do not always correlate with those obtained later in human subjects. This issue of concordance has been reviewed by discovery scientists, academics and regulators, who have surveyed human toxicities relating to 150 compounds (Olson et al. 2000). The toxicities were picked up in 71% of tests using rodents and non-rodents (63% non-rodents alone, 43% rodents alone). Of all toxicities detected in animals, 94% occurred within one month of testing.
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> Every time a new drug-related scientific breakthrough is featured in the media, it is nearly always qualified by the phrase "but it will be many years before a treatment is available for patients." This is obviously true because of the preclinical and clinical hurdles involved, but it is also dispiriting; there is a general feeling, among those involved, that processes could be improved and regulations made more efficient. One study of phase III cancer trials organized by the Eastern Cooperative Oncology Group (ECOG) in the USA gives an idea of the scale of the problem (Dilts et al. 2008). By studying 16 trials in detail, the group concluded that it took as much, or more, time to activate a trial (ranging from 435 to 1,604 days) as it did to conduct the study itself. Since more than 481 distinct processes were required, including 61 major decision points, this is not too surprising. To make the point even more forcefully, a process diagram capturing all the interactions, if printed out in 8-point type, would measure a staggering 5 by 50 feet. This may, for all I know, be quite normal when designing an airplane, but frankly most people would rather wait a bit longer for a new jumbo jet than for a new cancer treatment. Anyone who contributes to a multidisciplinary project in any field will feel a shudder of recognition after discovering why the timelines were so extended. This was because of the need for review boards and agencies from multiple locations who were all expected to operate with identical procedures and approaches, an almost impossible objective. The biopharmaceutical industry, regulators and clinicians are all aware of the problem and are making attempts to streamline processes and even question the value of some types of trial. There is also a strong financial incentive to speed up clinical trials, since every month of delay causes revenue loss to the sponsoring company as the patent life of the drug ticks away. It is not unreasonable to suggest that the topic of clinical trial efficiency is very near the top of a list of concerns felt by the biopharmaceutical industry.

The book includes 20 chapters:

- Introduction
- Introduction to Drugs and Drug Targets
- Background to Chemistry of Small and Large Molecules
- Laying the Foundations: Drug Discovery from Antiquity to the Twenty-First Century
- Drug Discovery Pipeline Overview
- Target Discovery
- Medicinal Chemistry
- Biotherapeutics
- Screening for Hits
- Process Chemistry and Formulation
- Preclinical Development
- Clinical Trials
- Regulatory Affairs and Marketing Approval
- Diagnostics and Personalized Medicine
- Pulling It All Together: A Drug Development Case History
- Commercial Aspects of Drug Development
- Challenges and Responses
- Technology Transfer Executives
- Recruitment Executives
- Pharmaceutical Translators and Interpreters

The book is available in bookstores.

Reviewer

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