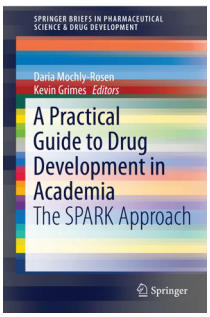
TRANSLATIONAL RESEARCH

Drug discovery from the inside



A Practical Guide to Drug Development in Academia, The SPARK Approach

Edited by Daria Mochly-Rosen & Kevin Grimes

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Drug discovery is, by necessity, a team sport. The path to a marketed compound is long, wildly convoluted and even more wildly expensive, and the range of expertise needed to navigate it is beyond any one person's ability. Most of the time, it's beyond the abilities of teams of hundreds of people, which is unfortunate as the overall failure rate in the clinic is still hovering around 90%.

Given this reality, it's a good thing that so many people are still willing to try their luck. There are compensations, of course: the financial rewards can be great for a successful therapy, and the rewards of bringing new hope to sick patients are not to be underestimated, either, even if they don't show up on the income tax forms. Anyone making a new discovery in academic medicinal chemistry, pharmacology or molecular biology can find themselves wondering whether their work might not be the start of something big. Drugs have, after all, come from any number of unlikely places—why not this one?

But at this point, they will find themselves looking out over one of the biggest gaps between academic science and industrial science ever to exist. This is bad enough, but even worse is the fact that not everyone realizes that this canyon stretches out in front of them at all. Some sort of optical illusion makes the end result—a new drug or even a new drug company—seem much closer than it really is. The problem is that everyone doing drug development at a biopharma company started out in academia, whether as grad students or postdocs, whereas most academic scientists have never experienced industrial research. It's to this large group that *A Practical Guide to Drug Development in Academia* is addressed. As an industrial medicinal chemist myself, I'm happy to report that it is a valuable look into that unknown landscape and may well end up saving many people a great deal of time, money and heartache.

The editors, Daria Mochly-Rosen and Kevin Grimes (both of Stanford's School of Medicine) have experienced the industrial transition firsthand and since 2006 have run workshops at Stanford for others trying to do the same. This book, a distilled version of those sessions, details the major steps of a drug discovery and development effort, from the first stirrings all the way to clinical trials, licensing and/or company formation. Anyone reading it will emerge far better informed about the whole process and will have the benefit of a great deal of extremely sound advice. I found myself nodding in agreement all the way through because this book is full of points that need to be made.

Many of these points come in the form of highlighted paragraphs headed 'What Surprised an Academician'. I found these particularly valuable as it's one thing to be told by someone from the drug industry about how tricky drug development is but quite another to hear it from someone who's found out the hard way. These sections, when they address large-scale issues, are what family counselors call 'tough love'. As an example, many academic discoveries really do need to be put on much firmer ground before they can be the start of an industrial effort. Reproducibility of the idea under various conditions, therapeutic relevance and workable (and patentable) chemical matter are just some of the issues. The research standards for publication in a good journal (or for a grant renewal) really are much less stringent than what the US Food and Drug Administration (or potential investors) will expect to see. Not everyone will enjoy hearing this sort of thing, but it's still more fun than wasting everyone's time and money.

But the smaller-scale issues are well worth hearing about as well because they tend to highlight scientific specialties that (for the most part) just don't exist in academia. Formulations scientists and scale-up chemists are two of these. They're irreplaceable parts of any small-molecule drug development team, but very few people outside industry will have ever encountered anyone from these areas at all as they don't fit well into academic departments. There are no degrees granted in Advanced Scale-up Technique; all the best people doing it have learned their skills on the job. And while no book can substitute for this sort of experience, just knowing the outlines of what's involved (and why it's important) goes a long way. A lot of hard-won knowledge is laid out here in a brief but informative way. Every topic is well referenced, with citations from both the primary literature and relevant resources from the internet.

I would actually welcome it if this book's intended audience were broadened even more. Younger scientists starting out in the drug industry would benefit from reading it and getting some early exposure to parts of the process that they'll eventually have to understand. Journalists covering the industry (especially the small start-up companies) will find this book a good reality check for many an over-hopeful press release. Even advanced investors who might want to know what really happens in the labs will find information here that might otherwise be difficult to track down in such a concentrated form.

Academia and industry need each other. Industrial research thrives by keeping a close eye on the pioneering work that the best academic research centers generate. And those academic labs, if they're ever going to translate such discoveries into new drugs, need the experience, specialization and resilience of the best industrial organizations. Watching the two groups argue with each other, then, is like watching a fight between a car's engine and its wheels. The industrial drug researchers who have gone into academia over the last 10 or 15 years are one factor helping to bring the two groups together. This book (and the efforts that led to it) could be another. ■

Competing financial interests
The author declares no competing financial interests.

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