
Leading Pharmaceutical Innovation

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Leading Pharmaceutical Innovation

How to Win the Life Science Race

Third Edition

 Springer

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Preface

The life sciences have never been an easy industry, and they are about to become even more treacherous to navigate. New technologies speed up innovation, new competitors emerge from both new geographical corners of the world and formerly distant segments at home, and customers become more sophisticated and more demanding. The healthcare sector is becoming a pressure cooker, and pharmaceutical companies are right in the middle of it.

We have been investigating the healthcare sector and leading pharmaceutical companies for more than a decade, and here are just some of the shifting patterns that we see:

- Scientists create more and more data on diseases and the human organisms, producing gene maps that pinpoint the sources of our afflictions. This is promising for the progress of personalized medicine, but it also raises ethical and moral expectations on pharma companies to protect and commercialize this knowledge. Treating a patient is increasingly an economic rather than a medical decision.
- Pharma innovation does not end with the conclusion of clinical trials. To be successful, pharma companies must be able to maneuver public opinion, regulatory decisions, and financial markets alike.
- Emerging countries are catching up: China, a relative backwater for pharma until just a few years ago, now makes an impact on the global life science scene. Global pharma firms set up research centers in Shanghai, Beijing, and other Chinese cities. Chinese research institutes make key contributions to pharmaceutical research, even winning Nobel prizes. No other country has ever attempted a healthcare reform affecting more than a billion people, but China is doing so as you are reading this book. In China, the numbers are always staggering: three hundred thousand hospitals and healthcare facilities offer their services to patients, and 6800 pharmaceutical companies fight for market share.
- Digital health will reshape the pharmaceutical sector dramatically within the next years. Mobile technologies and smart devices developed in the consumer electronic industry enter the healthcare markets. Most pharma companies neglect the disruption from the low end. But as quality of those new entrants is improving, a growing share of the healthcare budget will be reallocated. Digitalization will

change the roles of patients, consumers, and financing partners. Data becomes the new currency, and new business models are arising already. The regulator is challenged in many regions already.

- New technologies such as nanotechnologies, blockchain, deep learning, and artificial intelligence will become central for innovation in the healthcare sector, but most pharmaceutical firms today are not familiar with them.
- Being more open in innovation has been on the agenda of most of the big pharma companies for some years now. Cost pressures, growth expectations, globalization, the growing complexity of R&D, as well as the increasing power of technology providers force pharma executives to redesign their R&D departments into more trim, more flexible, and more open organizations. Technological fields raise the bar for everyone, and even the large pharma companies cannot finance and discover them alone. Collaboration is the new imperative in the industry.

Many challenges remain: the most important one is the widening innovation productivity gap in the pharma industry. We have spared no effort to analyze how industry leaders face these challenges, what tools they deploy, and what new solutions they are testing.

Specifically, we have updated this third edition to include the latest technology and industry information, and we have paid particular attention to new management models such as open innovation, systematic partnering, outlicensing, and international diversification of R&D. This leads not just to new forms of collaboration in the pharmaceutical industry but also to new business models. We introduce a more balanced global perspective by reducing the focus on Switzerland as a lead country and adding more industry cases from the USA and Asia. All in all, this third edition is quite a different book from the earlier two versions some ten years ago.

In this third edition, we revised the book completely and expanded it as follows:

- Chapter 1 comprises up-to-date information on the pharma innovation arena, ranging from the importance of innovation in the pharmaceutical sector and the relevance of pharma companies as key investors in R&D worldwide to the role of blockbusters and mergers and acquisitions as key growth factors for the industry.
- Chapter 2 offers more insight on the complexity of the industry by describing the industry's classification, its product groups, and the six driving forces affecting any company in the pharmaceutical industry: the bargaining power of suppliers and buyers, the risk of entry of new competitors, the uncertainty related with emergence of substitution products (e.g., generics, medical devices, or alternative therapies), the rivalry among established companies, and the power of regulators.
- Chapter 3 gives an update on biologics and the increased role of biotech companies as technology providers for the whole sector. New sciences and technologies are pushing the industry as the underlying drivers for innovation. In this context, we provide the latest information on how drug discovery is performed today—from target identification and validation to the roles of HTS, bioinformatics and 'omics technologies, big data, pharmacogenetics and pharmacogenomics, personalized medicine, and computer-based drug discovery.

- We revised Chap. 4 completely to highlight the relevance of pipeline management, given the changes in the regulatory environment, the huge investments needed in pharmaceutical R&D, and the low overall success rates of drug R&D. We also provide a detailed description of the standard R&D process with a case in point on the importance of preclinical safety studies. Best-in-class project and portfolio management is a must for successful R&D today—including an understanding of why to evaluate a drug project financially, how to analyze a project portfolio, and what needs to be done to manage a project pipeline.
- The changes we made in Chap. 5 reflect the trend that pharma firms increasingly concentrate on their core advantages and try to involve outside innovators. Outsourcing, in- and outlicensing, research collaborations, partnerships, and pharma–pharma co-developments are becoming must-have tools in pharmaceutical R&D. Outsourcing plays a key role in innovation management today and is a core element to access external technologies or to reduce costs of R&D. Here, we highlight the general conditions for outsourcing in pharma and biotech scenarios, exemplified by two strong cases. CROs have also assumed a more prominent role in the pharma R&D value chain, although perhaps not yet as important as the subcontractors in the automobile sector, but with an increasing relevance for all kinds of healthcare firms. Pfizer and its CRO partners provide one example of the strategic role of contract research organizations for big pharma to manage the R&D pipeline flexibly. Takeda’s collaboration with the Center for iPS Cell Research Application (CiRA) at Kyoto University shows how pharma companies need to collaborate with world leading competence centers to access world-class science. Next, the R&D pipeline can also be enhanced by licensing drug candidates along the entire value chain—and not only in the late phases of drug development. Co-development agreements between pharma partners such as Morphosys/Novartis, Pfizer/Merck, and Astra Zeneca/Innate Pharma complement the complex models of accessing and managing innovation.
- The new Chap. 6 on open innovation covers one of the most exciting trends of the last decade. We provide an overview on different open innovation models—virtual R&D, crowdsourcing, open source, private–public partnerships, innovation centers, and venture funds—alongside with several pharma cases. Crowdsourcing is illustrated with examples from YourEncore, Innocentive, the European Lead Factory, and Grants4Targets. Venture funds as a tool to mitigate risk while accessing high-risk early pipeline project and disruptive technologies are illustrated by the Novartis Venture Fund and the Boehringer Ingelheim Venture Fund.
- Chapter 7 addresses the internationalization of R&D, a change from large domestic R&D sites to a network of international, multilocation R&D. Today, pharma companies run a mixed model of in-house R&D with a global footprint combined with open innovation partnerships to access innovation globally. The reasons for this trend are obvious, such as reduced R&D costs, talent acquisition, and technology-friendly legal conditions. In the last years, the emerging markets in China and India have become the fourth global center of gravity for pharmaceutical R&D, supplementing the traditional pharma centers in the USA, Europe, and Japan. Especially China has made quite some impact in this context, both as a

market and as a center for drug development, on the back of an impressive overall economic resurgence.

- Finally, we outline our views on future trends and directions by reviewing them at three levels: R&D efficiency and effectiveness, new business models, and leading people and change. This condensed set of future directions is our final chapter of the book and hopefully stimulates new ideas and new leads for management innovation.

We hope that this book contributes to a better understanding of one of the most fascinating industries and that it helps its leaders to increase competitiveness of their companies.

Whether you are a pharma executive, an innovation researcher, a medical professional, or a member of the general public genuinely interested in the pharmaceutical industry, we hope that you will join us in our appreciation for the tremendous work that is being done by the millions of people engaged in this industry with the respectable goal to provide mankind with better drugs and therapies to live and survive.

St. Gallen, Switzerland
Reutlingen, Germany
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Testimonials

“Health care innovation is possibly the greatest opportunity and challenge of our generation. This important book shows how pharmaceutical companies will continue to play an instrumental role in making our lives better.”

Stefan Thomke, William Barclay Harding Professor of Business Administration, Harvard Business School

“Very comprehensive review and analysis of current challenges for the biopharmaceutical industry. To stay competitive in this new technology driven environment, the industry started to develop new partnership models to close the innovation gap and provide patients with the relevant healthcare toolkits at the convergence of pharmaceuticals, diagnostics and IT technologies. Very exciting times ahead well depicted in this book!”

Karima Boubekeur, VP Emerging Portfolio and Search & Evaluation, AstraZeneca

“Great. The 3rd edition is not only an update. It’s an outstandingly featured summary on the challenges of pharma innovation.”

Eckard von Keutz, SVP and Head of Early Development, Bayer Healthcare

“...a profoundly researched and comprehensively illustrated creation of the value-drivers of pharmaceutical innovation.”

Florian Gantner, VP Translational Medicine & Clinical Pharmacology, Boehringer Ingelheim

“‘*Leading Pharmaceutical Innovation*’ is the benchmark on pharmaceutical innovation management.”

Alexander Musil, CFO Takeda Mexico

“Globalization, internationalization and open innovation are three major trends in the industry. Gassmann, Schuhmacher, von Zedtwitz and Reepmeyer provide most valuable insights in these topics. I highly recommend reading this book.”

Mathias Schmidt, CEO Armagen

“I recommend this new book to pharma managers and researchers in this industry.”

Maximilian von Wuelfing, General Manager Mylan BeLux

“This text is an excellent information source for innovation concepts in the modern era when pharma productivity is getting ever challenging in this global environment”

Praveen Tyle, Executive Vice President R&D, Lexicon Pharmaceuticals

“The book remains the key important publication of pharmaceutical innovation for business executives, scientists and students. The 3rd edition was updated especially regarding innovation alliances and addresses the key challenges that pharmaceutical R&D is facing nowadays.”

Katharina Caspary, Director Pharmacovigilance, Horizon Pharma

“Excellent book for strategies on the management of pharma innovation. Highly recommendable for creating the bigger picture and new perspectives for action.”

Ingo Gaida, Head of IT Operations R&D, Bayer Business Services

“Analytical & critical - a “spot on” review of the constantly changing pharma environment.”

Guenther Forster, former SVP Medical Development & Strategies, MerckSerono

“This great book helps to understand the complexity of the challenges the pharmaceutical industry is facing.”

Ingo Henes, SVP Human Relations at Rentschler Biotechnologie

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