



**Introduction to Biological and Small Molecule  
Drug Research and Development: Chapter 7. The  
structure and business of biopharmaceutical  
companies including the management of risks and  
resources**

*James Samanen*

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# Introduction to Biological and Small Molecule Drug Research and Development: Chapter 7. The structure and business of biopharmaceutical companies including the management of risks and resources

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## **Introduction to Biological and Small Molecule Drug Research and Development: Chapter 7. The structure and business of biopharmaceutical companies including the management of risks and resources** James Samanen

Successful drugs have a good return on investment by bringing in considerably more revenue than the expenses of discovery, development, and manufacturing. Successful drugs pay for all drug projects, those that fail and those that have yet to fail or succeed. Most research and development (R&D) projects fail. Since R&D is the future of the company, a lot is at stake in the business of R&D. This chapter considers the organization of biopharmaceutical R&D, as well as various organizational experiments, that are already under way, that deal with the enormous risk and cost of biopharmaceutical R&D. There is a fairly uniform sequence of events involved in the discovery and development of biopharmaceuticals. The Stage-Gate Organization of the project pipeline is described along with stage-related goals. The high attrition in the industry is examined as well as reasons for project failure, particularly in the clinic. The fact that most projects fail in the biopharmaceutical industry means that risk, the probability that a project will fail, influences a number of key behaviours in biopharmaceutical R&D. The manner in which risk influences probability of success, cost, value and corporate commitment is considered. Not all discoveries occur within a company – many are in-licensed. Reduced revenues challenge a company's ability to develop all its assets, increasing the demands on project and portfolio management, and for out-licencing or partnering. In large biopharmaceutical companies, resource tends to be organized into business units, therapy areas, line departments, and platform technology groups. In the new era of reduced profits many companies are moving away from vertical integration towards decentralization, performing many to most functions in other companies, and in the extreme, towards virtual drug discovery and development. The risks and benefits with the external allocation of resource via outsourcing and partnering are discussed. Experiments with the organizational model of biopharmaceutical R&D are explored which aim to reduce risk, increase success and efficiency, including attempts to be big and small at the same time, planning for failure, and open innovation. There are also external revenue challenges, including generics competition and third-party payer constraints. On the upside are a number of opportunities to increase revenue, including new biologics and new areas of exploration – epigenetics and gene therapy – and by expanding markets into rapidly developing countries. Managers face complex challenges to the business of biopharmaceutical R&D. But, regardless of the type of company or set of partnered companies, academic institutions and service organizations that perform biopharmaceutical R&D, to a large extent the sequence of events in which a drug is discovered and developed will always be the same. And as long as the industry can continue to find new therapies that positively impact the lives of patients, it will continue to be an exciting and challenging industry.

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