New Product Introduction in the Pharmaceutical Industry

Due to the limited time of the monopoly provided by patent protection that is used for recouping the R&D investment, pharmaceutical companies focus on keeping time-to-market for new products as short as possible. This process is however getting more uncertain, as the outcome of clinical trials is unknown and negotiations with authorities have become harder, making market introduction more difficult. This dissertation treats the new product introduction process in the pharmaceutical industry from an operations perspective. The overarching aim of this dissertation is to improve the planning methodology in this critical process. In an empirical study, the process is first analyzed in detail, leading to the identification of several gaps in the industry’s current planning approaches. To support a set of key operational decisions towards market launch, a model is subsequently developed, considering uncertainty and several important industry characteristics. The model is used to gain several insights on the use of risk packaging and on keeping time-to-market short. As capacity in secondary pharmaceutical production is critical for product availability, a capacity planning model for a new drug delivery system is also developed. It captures the ramp-up phase in a better way, while considering inventory build up, plant validation and limited shelf life. The performance of several ramp-up functions is tested and insights into ramp-up management are presented. The dissertation is concluded with showing the new proposed planning structure, concluding in the preceding chapters and outlining future research possibilities.