

## **The Management of Risk in Pharmaceutical R&D**

For about 15 years the pharmaceutical industry has been suffering from decreasing R&D productivity. While there is an exponential increase in R&D investment, the number of approved new drugs per year has remained fairly constant. The presentation will address the statistics and the reasons of development failures. Furthermore, it will outline how a project's risk structure affects its financial value, and how risk can be managed and balanced across R&D portfolios in order to increase the probability of achieving productivity goals.

Risk and uncertainty is not only linked to the molecule, to the unclear relevance of the target for the disease, or to the market and healthpolitical environment. In the pharmaceutical and biotechnology industry, risk is also related to the chosen R&D process, e.g., selected study endpoints and the sequence of activities that may result in a front- or back-loaded project risk structure. It will be demonstrated that the proper management of the R&D process has a tremendous impact on the risk and value of projects.

A structured risk management process will be presented that differentiates between strategic and operational risks. Strategic risks would affect stop/go decisions, while operational risks may impact the effective conduct of R&D, registration, and marketing. Differentiating between strategic and operational risks has proven to be successful in the pharmaceutical and biotechnology context. It will be explored under which conditions the presented process may be applied to other fields of R&D.

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