



## **Systems biology in drug research and development**

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Systems Biology has entered the Big Pharma stage with the big promise to overcome the ever-increasing development costs and the falling number of newly developed drugs. This promise was built on the notion that complexity is one of the main hindrances and that Systems Biology was the ideal way to overcome it. Most of the Systems Biology initiatives in the pharmaceutical industry failed in their original form. However, with this failure scientists learned the drug development trade and observed how population PK/PD modeling was getting firmly established in drug development. At the same time it became clear that descriptive PK/PD models were lacking predictive power and often were too simplistic to provide additional understanding. Taking PK/PD modeling as successful basis, a limited level of biological and physiological elements were added to create Systems Pharmacology as a novel branch in the family of computational methods in drug development. Systems Biology can be seen in this context as a continuation, adding greater mechanistic detail to increase predictability and thus the value of mathematical models. Going forward, the original challenges associated with Systems Biology for drug development must be resolved. Some of the challenges include a clear alignment with the drug development process with addressing the relevant questions, a way to handle the complexity of models and developing models, processes, software tools and methodologies that meet the industry quality standards.