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Just right: Process from drug discovery to development

The discovery and development of new drugs is a very complex machine. Despite increasing investments and process improvements in research and development, the survival rates of drugs in late phases of development has languished during the past decade. Recent analysis of such decline in late phase drug development was attributed to non-drug like compounds synthesized by Medicinal Chemists which exhibit low aqueous solubility with highly potent ligands which will bind to a target. With the current challenges facing "big Pharma", small biotech start-up (BSU's) with limited internal research and development resources in addition to true virtual pharmaceutical companies (VPC's) with only an experienced team of managers without any R&D capabilities are quickly emerging which adds another layer of complexity in arriving to a "just right" approach from drug discovery to development. To recover from such failed approaches, a gate-keeper approach is now the norm, where preclinical and discovery collaborations result in a structure and property-based design. This design now used in lead optimization combines biological activity/potency focus with optimizing structural features of the candidate to optimize absorption and pharmacokinetics. This approach is then effectively progressed to the understanding and defining of solid state phase and formulation of the drug candidate when more material is available. Early engagement of the pharmaceutical development scientists on the identification of an optimal phase and formulation during drug discovery can add significant benefits in drug discovery efforts and downstream development. These benefits include the demonstration of dose limiting toxicity to establish acceptable and reproducible safety margins. Another benefit is the early identification of an optimal phase that minimize multiple changes in phase that can contribute to irreproducible plasma levels in various PK studies as candidate are being considered in toxicity studies. Furthermore, formulation development in preclinical studies will also provide some risk mitigation in the development of clinical trial materials. The current presentation will focus on the "must do" list to successfully help progress drug discovery candidates from any pharma organization to development with low risk that provide a balance of speed and quality.

Speaker Biography

Elizabeth Kwong retired from Merck after 23 years of service. She currently established her own company (Kwong Eureka Solutions) as a consultant for small start-up companies and specialty drug products. Before she retired she was Senior Scientific Director at Merck & Co. Basic Pharmaceutical Sciences. She was also adjunct professor in the Dept of Pharmaceutics at the University of Montreal and Dept of Chemistry at Concordia University. She received her B.S. Pharmacy (1980) and PhD degree (Pharmaceutical Chemistry -1984) from University of British Columbia, Canada. She completed a postdoctoral fellowship in Pharmaceutics at the School of Pharmacy, University of Washington in Seattle (1984-1986).

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