Drug development course – October 5th

Program

Time	Subject	Speaker
9.00 – 9.30 hrs	Drug Development Overview incl. global R&D Trends	Kees Groen
9.30 – 10.15 hrs	Pharmaceutical Development (CMC)	Albert Mekking
10.15 – 11.00 hrs	Non-clinical Development incl. bridging to clinic	Ilonka van Hoof
11.00 -11.15 hrs	Coffee Break	
11.15 – 11.45 hrs	Early clinical Development (up to clinical Proof of Concept)	Ilonka van Hoof
11.45 – 12.15 hrs	Entrepreneurship in development	Wietse Mulder, CEO GenDx
12.15 – 13.00 hrs	Lunch	Albert Mekking & Ilonka van Hoof
13.00 – 13.30 hrs	MERUS bispecific antibody development	To be confirmed, Merus
13:30 – 14:00 hrs	NBE vs NCE	Ilonka van Hoof
14.00 – 17.00 hrs	Round-up and 1-2-1 Free Q&A Opportunity	CBG and Kinesis

1-2-1 Q&A Opportunity

After this course, there will be a 1-2-1 Q&A Opportunity to ask questions about topics discussed in different modules and/or related to your company's current drug development program(s) more specifically. This session will be hosted by the experts of Medicine Evaluation Board (CBG-MEB) and Kinesis Pharma BV.

About the Medicine Evaluation Board: The Medicines Evaluation Board (MEB) assesses and monitors the efficacy, risks and quality of medicines. It is an independent administrative body residing under the Government of the Netherlands. This entails that the MEB independently decides about the authorisation and monitoring of efficacy and safety of human medicinal products. The MEB not only decides about approval of new medicinal products before they can enter the market but has several statutory tasks which are defined in the Dutch Medicines Law. One of the additional tasks is providing scientific advice during drug development. By providing scientific advice, the MEB contributes to the responsible and sound development of medicines from regulatory perspective, early patient access and innovation.

About Kinesis Pharma BV: Kinesis Pharma is a leading partner in drug development which seamlessly integrates chemistry, manufacturing and control, non-clinical development, clinical development, regulatory, quality and project management. Headquarter is located in Breda (1997), the Netherlands and a regional office in Singapore (2010). Kinesis leverages the expertise and experience of its highly-skilled, multi-disciplinary workforce to accelerate development of medicinal products, either small molecules or biologics, herbal medicines or nutraceuticals. This unique concentration of multidisciplinary experts - combined with a direct and pragmatic approach - presents sponsors with flexible service options to cope with fluctuations in business requirements.

More details on the program:

Drug Development Overview. In this part of the course an overview is given of the entire drug development process. The participant will obtain general insight of the different stages of drug development, the different disciplines involves, the type of studies, the timelines, cost and risks of a typical drug development program.

Discovery and Candidate Selection. In this part of the course, an overview of the drug discovery and candidate selection phase will be presented. This part of the drug development cycle starts with the choice of a disease area and defining the therapeutic need that is to be met. The next step is the identification of the lead structure, followed by the design, testing and fine-tuning of the drug molecule to the point where it is deemed suitable for development ("lead optimization"). This all is quite a challenge as in one molecule we prefer to have good potency, efficacy, selectivity, absorption, distribution, metabolism, excretion, safety, synthetic feasibility, stability, solubility and a good patent position as well.

Pharmaceutical Development. Pharmaceutical development comprises everything that is necessary to be able to administer a drug to patients in such a way that quality of the drug product is sound. This to be sure that true results can be expected regarding safety and efficacy. Subsequently, development of the drug product takes place; formulation development to come to the best pharmaceutical form for the goal, supported by process development and analytical development to control the manufacturing process and the final drug product. Stability studies are performed to be sure that the quality of the drug products remains adequate throughout the clinical trials and the shelf life.

Non-clinical Development incl. bridging to the clinic. In this part of the course, an overview of the non-clinical development phase will be presented. The goal of the non-clinical safety assessment includes a characterization of toxic effects with respect to targets organs, dose dependency and relationship to exposure. Before a "new" drug will be approved for human use, its safety needs to be established. Studies to be performed during the development trajectory include studies on (safety)pharmacology, general toxicity, genotoxicity, reproduction toxicity, toxicokinetics and non-clinical pharmacokinetics and the carcinogenic potential of the compound.

It will also be discussed on how non-clinical information can be evaluated to prepare clinical studies with regard to estimating a safe starting dose for the first-in-man trial and to provide estimates of the pharmacological active concentration range.

Early Clinical Development (up to PoC). This part of the course will give an overview of the type of studies that are typically performed in early clinical development such as first-in-man (FIM, single and multiple dosing), bioavailability, food-effect, and drug-drug interactions. Where classical designs of FIM studies focus on tolerability and safety (MTD approach), current emphasis is more on understanding the relationships between plasma concentrations, pharmacological target (biomarker) and desired and undesired effects. Predictions on the pharmacological active concentration range are used to optimize the design of the subsequent Proof-of-Concept study.

Biopharmaceuticals: Key Differences with Small Molecules. This part of the course will provide an introduction to the development of biopharmaceuticals.

When compared to synthetic, chemical "small molecule" drugs, products derived from a biological source or a biological process (such as monocloncal antibodies, therapeutic proteins, vaccines, blood products) are structurally complex and involve manufacturing processes that require stringent control to ensure their safety, quality and efficacy. Biological products, because of their sheer size, are significantly more complex than small molecule drugs. There are large differences in development needs when comparing NCEs (New Chemical Entities) to NBEs (New Biological Entities).