DRUG DEVELOPMENT SIMULATION

ON-LINE VERSION

LBS

LEARNING BY SIMULATION

ABOUT LBS ON-LINE SIMULATIONS

The virtual courses consists of 7-8 interactive blocks of 4 hours over a period of 4 weeks with intermittant homework assignments.

The on-line courses are designed to maintain the high standard known of LBS and provide a similar intensity and interaction as the in-life versions.

LEARNING OBJECTIVES

The overall objective of the simulation is for participants to gain understanding of what is needed in the complex drug development process. More specifically:

- To understand the drug development process and the role of disciplines within the process.
- To experience the interfaces and interactions between the different disciplines.
- To learn about results of actions and decisions to be taken at crucial points in the development process.
- To learn to react on deviations and risks in the drug development environment.

COURSE DESCRIPTION

The simulation starts with detailed pharmacological and chemical information on several preclinical candidates. The teams select one of these to start the development process.

The simulation runs through the preclinical and clinical phases of development until dossier submission to the authorities.

In the on-line version, the participants will use an on-line platform to communicate with each other as well as with the the experts. The team process will be monitored and evaluated together with the facilitator.

A BRIEF TENTATIVE SCHEDULE

Pre-Work

- Access to the communication platform
- Background on the Therapeutic Area
- Explanation on the simulation

Block 1

ON-LINE SESSION

Target Product Profile

- Selection and deselection of clinical candidates
- Target Product Profile
- Introduction to Clinical Phase I

Block 2

ON-LINE SESSION

(Pre-)clinical study planning

- Toxicology and CMC
- Clinical Development Plan
- CMC Development Plan
- Tox Development Plan

Block 3

ON-LINE SESSION

Preclinical data

- CMC activities GMP batch
- FIH dose setting
- Clinical Phase I protocol
- Market analysis

Block 4

ON-LINE SESSION

First in human (FIH) study

- FIH board meeting
- FIH clinical data
- Marketing strategy
- POC criteria

Block 5

ON-LINE SESSION

Proof of Concept

- Clinical Phase IIA/B protocol
- Risk Management Plan
- Proof of Concept meeting

Block 6

ON-LINE SESSION

Regulatory affairs

- End of Phase II meeting
- Introduction Regulatory Affairs
- Mechanism of Action

Block 7

ON-LINE SESSION

Pivotal clinical studies

- Results pivotal trials
- Marketing report
- Environmental Risk Assessment

Block 8

ON-LINE SESSION

Meet the FDA

- FDA advisory board
- Wrap up

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