DRUG DEVELOPMENT SIMULATION

LBS

LEARNING BY SIMULATION

ABOUT LBS-DRIVEN SIMULATIONS

a unique condensed method of training that allows participants to gain insight in the overall working process of their organization.

The participants operate in a team setting to make strategic choices, to make decisions and to improvize. They learn to speak the language of their colleagues and to respect other disciplines.

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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.

A BRIEF TENTATIVE SCHEDULE

Day 1
Preclinical activities

MORNING
- Explanation of the simulation
- Preparation in teams
- Target Product Profile
- Candidate Selection Meeting

AFTERNOON
- Introduction CMC and Drug Safety
- Preclinical Development Plans
- Market analysis

EVENING
- First in Human (FIH) approval meeting
- FIH clinical data
- Evaluation

Day 2
Clinical development

MORNING
- Introduction Clinical Development
- Preparation of clinical Phase IIA studies
- Marketing strategy

AFTERNOON
- Introduction Marketing
- Preparation of clinical Phase IIB and III
- Proof of Concept
- Full Development decision meeting

EVENING
- Evaluation
- Social event

Day 3
Meeting the authorities

MORNING
- Introduction Regulatory Affairs
- Evaluation of clinical Phase IIA data
- End of Phase II meeting

AFTERNOON
- Marketing report
- FDA advisory board
- Final evaluation
- Wrap up

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