BIOLOGICALS 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 development process of biologicals in the oncology indication. More specifically:

- To understand the biologicals discovery and development process and the role of disciplines within this 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 process.
- To learn to react on deviations and risks in the biological discovery and development environment.

COURSE DESCRIPTION

In three days a biological drug candidate will be selected, a production process developed and a clinical trial program executed. In a multidisciplinary approach, an effective and safe novel biological will be developed for patients with an unmet medical need in the area of oncology.

The simulation starts at the stage of target identification and ends with the presentation of clinical Phase I/II results to the managerial board.

A BRIEF TENTATIVE SCHEDULE

Day 1

From target identification to clinical candidate selection

MORNING
- Explanation of the simulation
- Preparation in teams
- Proposal to management for target validation, output, workflow and preliminary oncology indication

AFTERNOON
- Selection of appropriate platform
- Target validation experiments
- Preparation Clinical Candidate meeting

EVENING
- Clinical Candidate meeting
- Evaluation

Day 2

Preclinical development

MORNING
- Introduction on CMC
- Preparation milestone map for development

AFTERNOON
- CMC, bioanalysis and safety studies
- Introduction on clinical development
- Prepare clinical protocol

EVENING
- Internal clinical acceptance meeting
- Evaluation
- Social event

Day 3

Clinical trials

MORNING
- Pre-IND meeting
- Clinical development
- CMC commercial process

AFTERNOON
- End-of Phase II meeting
- Final evaluation
- Wrap up

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