Leveraging Cross-Functional Lessons Learned Case Study

Comprehensive Product Lifecycle Analysis

Insyght Interactive, Inc. 11900 Olympic Blvd. Suite 450 Los Angeles, CA 90064 insyght.com

GOALS

Following the FDA's decision to not approve a new investigational drug, Insyght was commissioned to conduct a cross-functional analysis of our client's processes and procedures in place throughout the product lifecycle in order to establish a clear set of standard operating procedures (SOPs) and to improve the overall effectiveness of the R&D program.

SERVICES

Strategic Direction
- Development of Standard Operating Procedure (SOP) Recommendations

VIP Engagement / Management
- Cross-Functional Participant Identification, Recruitment and Management

Program Content Development
- Engaging Agenda Design
- Design and Organization of Session Presentations

Implementation and Evaluation of ROI
- Facilitation of Multiple Lessons Learned Workshops Across Two Distinct Events
- Executive Report

PROCESS *Our Strategic Intelligence, Your Competitive Advantage™*

Insyght designed and facilitated an intensive Lessons Learned meeting series with more than 50 individuals involved in all aspects of the molecule's lifecycle. Participants included members of the Research and Development, Clinical Development, Medical Sciences, Product Development, Marketing, Emerging Brands, Manufacturing, Medical Affairs, Legal, Regulatory, IT, Finance and Corporate Affairs teams. The meeting series involved group discussions and intensive workshop sessions to explore key accomplishments, perceived challenges, clarity of processes, corporate governance and general communication across clinical development, the Biologics License Application (BLA) process, advisory committee activities, and launch planning stages to identify functional group-specific and global issues.

RESULTS

Insyght's assistance helped distill important issues specific to functional groups, as well as the broader organization, and led to several critical operational changes, including implementation of new cross-functional SOPs, design of more rigorous staff training and evaluation criteria, creation of improved risk assessment tools and integration of a new FDA scenario planning program. These initiatives were each designed to improve operating efficiency and cross-functional effectiveness in order to ultimately improve the development of future biologics.