MasterClass

HOW TO ACCELERATE EARLY DRUG DEVELOPMENT IN ONCOLOGY FOR SMALL MOLECULES AND BIOLOGICS

April 22nd 2020 | 2:00 PM – 3:35 PM

Jointly organized by

Catalent · Leads to Development non-clinical development solutions · CLARA CANCÉROPÔLE LYON AUVERGNE RHÔNE-ALPES

Get an insight into what it takes to move a pre-clinical drug candidate to Phase 1 clinical trial. The lectures will provide guidance on non-clinical and regulatory considerations for early drug development of oncology drugs. In addition, we will also provide expert advice into molecule developability assessment, early formulation strategies and non-clinical activities of both small molecules and biologics from lead candidate selection to Phase 1.

Time	Lesson Plan	Instructors
2:00 pm – 2:05 pm	**Welcome Note**	**Mylène Honorat** Partnership and International relations Mission head, CLARA
SMALL MOLECULE SESSION		
2:05 pm – 2:25 pm	**Formulation Development to Efficiently Complete Preclinical Studies and Transition to First-in-Human Studies** - Molecule developability assessment for oncology drugs - Phase-appropriate formulation: When advanced technologies are required versus simplified approaches - Efficient coordination of manufacturing, packaging, storage and distribution for early-stage clinical development	**Stephen Tindal** Director, Science & Technology, Catalent Pharma Solutions
2:25 pm – 2:35 pm	**Q&A**	
2:35 pm – 2:55 pm	**Navigating Through the Regulatory Challenges of Early -Stage Drug Development (NCE and biologics)** - Overview of non-clinical development strategy (Pharmacology, CMC, ADME, toxicology) - Specificities of oncology products - Anticipate regulatory expectations for your clinical trial application	**Julien Massiot** Project Manager, Leads To Development (L2D)
2:55 – 3:05 pm	**Q&A**	
BIOLOGICS SESSION		
3:05 pm – 3:25 pm	**Challenges and Opportunities in Biopharmaceuticals Development** - Overview of key process, analytical, formulation and manufacturing activities from lead candidate selection to Phase I - Understand why selecting the relevant cell line development technology is critical to the CMC package/IND approval - mAb case studies including presentation of timelines, budget estimates, clinical and commercial COGs	**Christelle Dagoneau** Senior Account Director, Biosimilar Services & Market Specialist, Catalent Biologics
3:25 pm – 3:35 pm	**Q&A and Closing**	