LECTURE SERIES **2017/2018**

BIOMEDICAL RESEARCH

From discovery to patients

LUXEMBOURG INSTITUTE OF **HEALTH**
RESEARCH DEDICATED TO LIFE

22
SEPT. 2017
Friday

LECTURE
House of BIOHEALTH
Conference Room
11.00-12.30pm

MEET & EAT *
Light lunch provided
Conference Room
12.30-1.30pm

*Please register sending a mail to maki.otsuka@lih.lu

9 10 11 12 1 2 3 4 5 6

How to match drug development and regulatory approval?

ABSTRACT

This presentation aims for a practical approach of the regulatory authorities and processes encountered during the development of a drug, from early stages up to the application for marketing authorization. The standard regulatory processes will drive the presentation as its framework, but the goal is actually to go beyond. Indeed, while regulation is grounding the technical aspects and overall documentation of an application dossier, a number of regulators initiatives can make the way much easier and more direct to approval. Where and how researchers can find appropriate regulatory support? Any short-cut on this long way? Any cost-saving approaches? What can be optimized and how? Is there specific assets in my project? What is actually required and what is not?

What are the expectations of the regulators and of the assessors? How can we match the regulatory requirements and the researchers' development goals?
From the sponsor characteristics to the drug candidate specificities and the target conditions to be treated, all aspects may impact the development plan and the route to registration. Knowledge of the numerous regulatory options is a valuable support when building such project plan.

SPEAKER

Dr. Annie-Claude Benichou
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