Bio^{M}-Seminar - May 14, 2019

From Discovery to Clinic: Getting Ready for Phase 1

Time and Place
Tuesday, May 14, 2019, 9:00 am – 1:30 pm
Bio^{M} Biotech Cluster Development GmbH, Am Klopferspitz 19 a (IZB West II, 3. OG), 82152 Martinsried

Content
Today's scientists are under significant time pressure to accelerate their compound from discovery to the clinic. Such pressure can often lead research organizations to adopt short-term thinking and overlook the downstream realities of drug development. Addressing issues early and comprehensively in the development life-cycle can result in fewer problems down the line such as escalating timelines, costs and regulatory issues. It is important to leverage the skills and experience of experts and connect the dots between competencies to optimize the development pathway and enable drug candidates to reach their true potential.

Main Topics
- Developability assessment: Can your molecule become a drug?
- Integrating PK modelling and in vivo studies for improved formulation and dosage form development
- Formulation selection
- Considerations prior to performing a Phase 0 or Phase I clinical trial
- Efficient coordination of clinical supplies

Goal
You will gain insight into key considerations for transitioning a molecule from discovery to phase 1 readiness including active pharmaceutical ingredient and drug product development.

Target Group
This seminar is intended for scientists in either industry or academia who are working in the field of drug discovery and want to bring the candidates successfully into Phase 1.

Speakers
Dr. Daniela Woide, Director Sales and Marketing, ProJect Pharmaceutics GmbH
Dr. William Chin, Technical Specialist, Science & Technology, Catalent
Dr. Guillaume Enderlin, Product Development Supervisor, Catalent
Dr. Jan Neelissen, Scientific Adviser For PK/PD Modeling, Science & Technology, Catalent
Anders Millerhovf, CEO, Clinial Trial Consultants AB
Sascha Sonnenberg, VP Cell&Gene and CTS Services, Marken

Organisation
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The event is free, but a **registration** is necessary: www.bio-m.org/discovery_to_clinic

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Agenda

08:45 am *Registration*

09:00 am *Opening welcome/Introduction*
Gabriele Klingner Bio[M] Biotech Cluster Development
Stefan Willenberg, Account Director, Catalent Pharma Solutions

09:15 am **Developability assessment: Can your molecule become a drug?**
Dr. Daniela Woide, ProJect Pharmaceutics GmbH
- Key to identify & derisking development challenges
- The importance of preformulation characterization to improve small molecule drug developability
- Overcoming solubility issues and maximizing exposure
- Case studies

09:45 am **Integrating PK modelling and in vivo studies for improved formulation and dosage form development**
Dr. Jan Neelissen, Catalent
- The importance of ADME/DMPK considerations in early preclinical studies design
- Model and predict ADME behaviour prior to entering clinical trial
- Understand ADME deficiencies that can be improved through drug design or formulation
- Key decision points in designing your GLP toxicology study
- Case studies

10:30 am *Refreshments & Networking*

11:00 am **Formulation selection**
Dr. Guilllaume Enderlin, Catalent
- Select an appropriate formulation technology and dose form based on the needs of the molecule in development
- Conventional technology such as powder in capsule
- Enabling technologies such as amorphous dispersion, lipid-based formulation, and micronization
- Getting to clinic faster with a suitable Phase 1 enabling formulation and dosage form
- Long term impact to patients of non-proper formulation selection
- Case studies

11:45 am **Considerations Prior to Performing a Phase 0 or Phase I Clinical Trial**
Anders Millerhovf, Clinial Trial Consultants AB

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12:15 pm **Efficient coordination of clinical supplies**
Sascha Sonnenberg, Marken
- Best practices to efficiently coordinate clinical supplies: clinical manufacturing, packaging, sourcing, storage and distribution
- Identifying and contracting the right supply chain partner

12:45 pm **Audience Applied Learning Challenge and Close**
Dr. William Chin, Technical Specialist, Catalent

1:15 pm *Lunch & Networking*