# Smart Drug Development & Design from Candidate to Phase I

**April 4, 2019 | 9:30 AM – 2.15 PM**
**Technologiepark Heidelberg GmbH,**
**Im Neuenheimer Feld 582,**
**69120 Heidelberg, Germany**

This event will focus on key considerations for transitioning a molecule from discovery to phase 1 readiness including API and formulation development, pharmacokinetics, quality and CMC requirements, and incorporation of clinical supply services solutions to meet protocol, clinical site and patient needs.

| | AGENDA | SPEAKERS |
|---|---|---|
| 9:00 am – 9:30 am | REGISTRATION & REFRESHMENTS | |
| 9:30 am – 9:45 am | WELCOME & INTRODUCTION | Dr. Annalisa Zuccotti, BioRN<br>Dr. William Chin<br>Technical Specialist,<br>Catalent Pharma Solutions |
| 9:45 am – 10:30 am | A REFINED DEVELOPABILITY CLASSIFICATION SYSTEM TO ENABLE PRAGMATIC COMPARISON OF DRUG CANDIDATES AND FORMULATION APPROACHES | TBC |
| 10:30 am – 11:15 am | MODELING THE PHARMACOKINETIC CHALLENGES OF ORAL SMALL MOLECULE DRUGS | Dr. Jan Neelissen<br>Scientific Adviser for PBPK Modeling, Catalent Pharma Solutions |
| 11:15 am – 12:00 pm | IMPORTANCE OF API CHARACTERIZATION AND FORMULATION STRATEGIES TO OVERCOME ORAL BIOAVAILABILITY CHALLENGES OF SMALL MOLECULE DRUGS | Dr. Rob Harris<br>Chief Technical Officer, Oral Drug Delivery, Catalent Pharma Solutions |
| 12:00 am – 1:00 pm | NETWORKING LUNCH | |
| 1:00 pm – 1:45 am | INTEGRATING QUALITY AND CMC INTO EARLY DEVELOPMENT | Dr. David Elder, Principal Consultant |
| 1:45 pm – 2:15 pm | STRATEGIC CLINICAL SUPPLY SOLUTIONS FOR EARLY PHASE CLINICAL TRIAL | Dr. Carsten Schmidt,<br>Head Clinical Trial Supply, Grünenthal Innovation |
| 2:15 pm | CONCLUDING REMARKS & MEET THE EXPERTS | Catalent Pharma Solutions |

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