SP Process Development’s Substance & Formulation section applies the entire research and development (R&D) skillset of the institute on pharmaceuticals. Together with our partners, we identify the best administration route, formulation and manufacturing process for the active compound, as well as support to project strategy and risk assessment. The development is guided by scientific principles regarding e.g. intestinal absorption and solid state chemistry. This gives a higher success rate, minimises the risk for expensive delays later in the development and may enable otherwise impossible studies.

Substance & Formulation specialises in pharmaceutical R&D in preclinical project stages, including the first clinical studies. This involves interacting directly with disciplines such as pharmacokinetics, toxicology, and clinical development.

The width of competence as well as instrumentation that SPPD has access to is unique. There is long experience of R&D within synthesis, scale-up and formulation of new chemical entities with high molecular complexity and challenging physicochemical properties. Our scientists have a track record of tight cooperation and interdisciplinary problem solving.

One of the strengths of SPPD is that multidisciplinary groups can be assigned to R&D activities - addressing all aspects illustrated above and more.
**EXPERTISE**

**Preformulation**  
(leak identification through – lead optimisation)  
- Pharmaceutical and chemical R&D to support drug candidate design and selection  
- Formulation strategies for preclinical and clinical studies  
- Preclinical formulation development  
- Physicochemical investigations (e.g. solid state properties, solubility, pKa, logP, polar surface area)  
- Interaction between formulation and human/preclinical absorption (biopharmaceutics)

**CMC**  
(regulatory toxicology through – early clinical studies)  
- Substance: tactical or strategic process development and GMP manufacture (milligrams to kilograms)  
- Formulation: Rational design and development of drug product for preclinical (GLP) and clinical studies  
- GMP manufacture of formulations for oral or parenteral administration (e.g. solutions, suspensions, capsules, semi-solids)  
- Potential Genotoxic Impurity investigations and risk assessments  
- Stability studies (according to GMP for compound and drug product)  
- CMC regulatory documentation for compound, drug product and packaging  
- Long term project risk assessment for substance and formulation  
- Identification of suitable supplier and technology transfer support for later phases

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