CHEMICALS, MANUFACTURING AND CONTROLS (CMC)
Small molecules

SMALL MOLECULE CHEMICALS, MANUFACTURING & CONTROLS

CMC is an essential part for the approval of a drug on the market. Important aspects include effectiveness of the formulation, quality and safety. The CMC team of 3D-PharmXchange can support and integrate complete and smaller parts of your drug development program. We have the ability to work in close collaboration to the non-clinical, clinical and regulatory experts of 3D-PharmXchange.
With our broad network, we obtain reliable and comprehesive results which comply to GMP restrictions and the International Council on Harmonisation (ICH) guidelines. Furthermore, we continuously pay attention to the agreed planning and budget and strive to work as efficiently as possible.

OUR CAPABILITIES

- **Active Pharmaceutical Ingredient** From synthesis route development to large scale manufacturing
- **Formulation development** From early development to market introduction
- **Drug product manufacturing** From (non-) clinical trials to market products
- **CMC project management**
- **Contract (Development and) Manufacturing Organisation (CDMO / CMO) selection**

A COMPLETE SOLUTION

API SYNTHESIS AND LARGE SCALE MANUFACTURING

In the development phase of a new drug entity, a substantial amount of active pharmaceutical ingredient (API) is required. 3D-PharmXchange can support you through the whole process of API sourcing. We can also contribute to other activities that relate to the active substance. The synthesis route or purification process may be designed or changed. Other work includes stability tests, research to control synthesis impurities, API characterization, development and validation of analytical methods.

FORMULATION DEVELOPMENT

At 3D-PharmXchange we can support you at all stages of formulation development. In the early development phase, we can perform a biopharmaceutical evaluation to find the best formulation strategy for optimal exposure of the drug. We can support you at all further stages of formulation development, from early clinical formulations to market formulations. Other aspects in which we can assist are the identification of degradants in the formulation, the development and validation of analytical methods.

DRUG PRODUCT MANUFACTURING AND PACKAGING

We help you to select a manufacturer which produces the drug product according to all requirements. Production of clinical drug product batches need to be produced according to strict GMP procedures. Before production, available analytical methods may be transferred and the manufacturing process is optimized.

CONTACT US

Do you have questions or would you like to discuss the possibilities? Please do not hesitate to contact Janneke Sprangers, Business Development at janneke@3d-pxc.com or +31 1 353 482 72.

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