FACT SHEET

WuXi STA Integrated CMC Platform **Expedited Pathway to IND**

Introduction

The WuXi STA integrated Chemistry, Manufacturing, and Controls (CMC) platform provides innovators with broad resources and deep expertise to accelerate new chemical entity development. Our platform delivers the complete package of drug substance, drug product, analytical services, and global filing support to expedite your candidate from preclinical to IND and beyond.

Fast to IND submission with integrated CMC services



4-6 months saving with integrated

EDEED

- In-parellel activities and close collaboration across different functions
- Efficient material transport, information flow and knowledge retention

ROBUSTNES

- Robust and flexible timeline with easy project
- Avoid challenges of transport and acceptance of materials under different quality systems

Our interdisciplinary CMC teams seamlessly collaborate to support your project through a single point of contact – your program manager oversees all aspects of your CMC program.

Why Trust WuXi STA?

Quality - An Unrivalled Pedigree in Global Regulatory Filings

- We have a track record of meeting all major regulatory agency requirements with products approved in more than 90 countries
- Our platform utilizes a single unified quality system across all sites and functional groups

Scale and Expertise - A Partner with Unsurpassed Excellence in Strategic Planning

- Our platform empowers more than 400 global customers and supports 1,000's of molecules each year
- For 15-years, our expert teams have optimized custom programs using a full spectrum of enabling technologies – we use the right tools for your specific candidate
- Our experienced teams balance a phase-appropriate approach with minimizing the risk of late-stage failure, avoiding costly delays to your development program

Time - Everything We Do is Designed to Help You Deliver Vital Therapies to Patients Faster

- The proximity of our R&D scientists with manufacturing teams enables in-parallel activities with close collaboration between functional groups
- Our centralized GMP facilities delivers super-efficient material transport, information flow, and knowledge retention with robust capacity and flexible timelines.



Enabling Technology

ONE STEP DRUG SUBSTANCE TECHNOLOGY PLATFORM

- Crystallization & Particle
 Engineering
- Biocatalysis
- Chemo Catalysis
- Continuous Processing
 (Flow Chemistry)
- Preparative HPLC and SFC

ONE STEP DRUG PRODUCT TECHNOLOGY PLATFORM

- Spray Dried Dispersion
- Hot Melt Extrusion
- Nano Suspension
- Liquid Filled Hard Capsules