

F2CS : Fast to Clinical Supply Clinical Trial Materials for Phase I



Phase appropriate formulation developed within 8 weeks

CTM for phase I manufactured 4-8 weeks after GMP API receipt



Customized and flexible formulation technology for variety of dose forms for phase I and beyond

Complete bioavailability technology toolbox to ensure optimal exposure



Geographically integrated facilities enable seamless collaboration

Streamlined product shipment from China to the US and Europe

F2CS delivers reliable clinical trial materials (CTM) fast with flexible options custom developed by highly experienced integrated teams equipped with advanced technologies, working in parallel to save time.

Extensive Capacity & Capability

State-of-the-art Facilities

3 sites
Drug Product R&D and Manufacturing
Shanghai and Wuxi city, China
Couvret, Switzerland

Industry leading drug Product R&D team

900+ Scientists
70%+ with Master's degree or Ph.D.

Highly Experienced

2,500+
molecules evaluated in preformulation studies in 2020

1,200+
GMP batches manufactured for clinical supply in 2020

>15
late phase and commercial projects

Bioavailability enhancement technologies

- Spray dried dispersion
- Hot melt extrusion
- Nano suspension
- Softgel & liquid filled hard capsules

Flexible formulation & process options

- API in bottle or capsule
- Powder in capsule
- Tablets
- Injectable
- Lipid formulation
- Roller compaction
- Direct compression
- Wet granulations

Integrated & in parallel CMC

- API R&D and manufacturing
- Formulation development
- CTM manufacturing
- Analytical development & validation
- Packaging and labeling
- Stability testing
- CMC writing



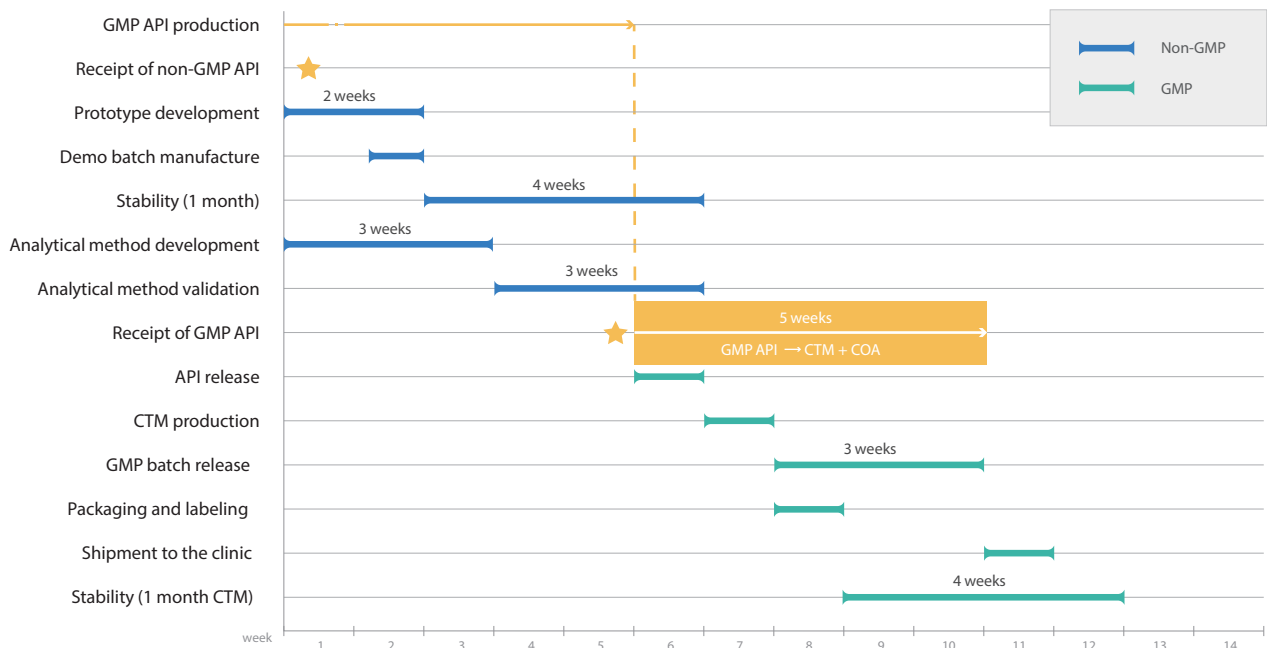
You can trust your innovation with us. Every facility is governed by the same quality and EHS system with a proven track record of approvals from all major regulatory agencies. We have been manufacturing clinical trial materials (CTM) since 2008 supplying to the USA, UK, EU, Australia, Korea, Japan and China.

F2CS - Fast path to custom CTM with your patients in sight

Innovative molecules are as unique as the patients they intend to treat. WuXi STA has been developing and manufacturing CTM materials for over 13 years, delivering more than 1,200 batches in 2020. Our teams work with you to define success. These example roadmaps are a few guideposts to show you how we do it.

Roadmap to FIH within 12 weeks – API in capsule

API in Capsule Standard Development Process



Roadmap to FIH within 14 weeks – blend in capsule

Blend in Capsule Standard Development Process

