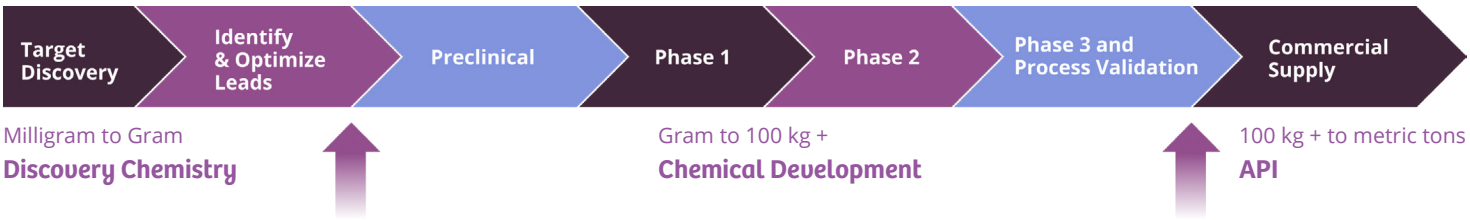
curia
Small Molecule

DEVELOPMENT & MANUFACTURING FACT SHEET

*Curia Small Molecule has over 30 years of experience in process chemistry, process safety, scale up and cGMP API manufacturing for preclinical, clinical and commercial supply. Our chemical development team, comprised of more than **550+ scientists globally**, meets expectations on even the most challenging projects. Working in state-of-the-art laboratories equipped with the latest process and analytical instrumentation, we e iciently conduct route scouting, rapid process development, and optimization of reaction conditions for scale-up of materials for toxicology studies and cGMP clinical and commercial supply.*



Curia Small Molecule can support your program across the entire Drug Development Continuum.

Albany, NY

Quality and Regulatory

cGMP
FDA FEI: 1000220178
Latest FDA Inspection: Q1 2019
Latest EU Inspection Q3 2014
DEA registration for schedule I-V compounds

Capacity

10 cGMP Suites
200 Liter reactors (GMP)
400 Liter reactors (non-GMP)
Gram-scale to 20 Kilograms

Core Technologies

High Potency Process R&D
Controlled Substance Process R&D
Continuous Flow Chemistry
Analytical Method Development
cGMP Manufacturing
Validation Services
Stability Services

Frankfurt, Germany

Quality and Regulatory

ISO 9001:2015
DQS Audit – March 2022

Capacity

48,000 L of total reactor capacity (non-GMP)
SS/GL Reactors from 50 L to 3,000 L
Temperature range - 100 °C to 180 °C
Distillation columns up to 2.5 m³ and 100 theoretical plates

Core Technologies

Cryogenic and organometallic reactions
Enzymatic chemistry
T3P & T3P applications
Organophosphorus compounds
Air oxidations
Hydrogenation
High-performance distillation
Regulatory Starting Material (RSM)
Scale-up/Production

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Leon/San Cristobal, Spain

Quality and Regulatory

cGMP for Phase 1 products

Capacity

Fermentation:

- Lab scale fermenters
- Pilot fermenters up to 15,000 L

Downstream

- Lab scale DSP
- Centrifuges, decanters, filters, dryers
- Tangential flow filtration (including microfiltration, ultrafiltration and nanofiltration)
- Chromatography

Core Technologies

Cell banks and strain improvement programs
Development and scale-up of upstream processing
Bioconversions
Microbiology
Development and scale-up of downstream processing
Chromatography
Microfiltration-ultrafiltration-nanofiltration
Crystallization

High Potency

Our high potency network is SafeBridge® certified. This designation takes into account not only facility infrastructure, but also management and all protocols when it comes to highly potent handling. Curia also has a strong compliance record helping launch multiple new highly potent APIs into the marketplace. Curia also has a long history of handling highly potent compounds with over 50 highly potent projects across our Curia service offerings.

Lipids

Curia is a pioneer in developing and manufacturing lipids, and we were key players in supporting COVID-19 vaccine developers with their lipid supply chains. Our teams operate seamlessly across multiple sites, planning activities in parallel to compress timelines when appropriate for your project. We also select the appropriate site based on the unique process, analytical and chromatographic needs of your project.

Count on Curia's integrated experience across our global network to amplify your innovation:

- Expertise in medicinal chemistry (synthesis) and lipid development
- Testing of multiple lipid structures for the ideal candidates
- Scale-up
- Purification and analytical services
- Preclinical, Clinical and Commercial manufacture
- Regulatory support
- LNP

Comprehensive Integrated CMC Support:

- Analytical
- Formulation
- Fill-Finish
- QA/QC
- Regulatory
- DMPK
- Modeling
- IP filing

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