



cGMP & Custom Synthesis

Providing reliable solutions for over 30 years

Ascensus delivers consistent quality and expertise in cGMP and custom synthesis production. All chemists at the Newburyport site are regularly trained on GMP standards and participate in GMP production to provide customers with reliable products and services.

cGMP Production

Custom synthesis services and process development are conducted under the strictest confidence. A broad range of chemical transformations are possible at our Newburyport facility. For pharmaceutical applications, manufacturing is conducted under current Good Manufacturing Practices (cGMP) in kilo-lab suites. This capability has been available at the Newburyport site since 1988. Complete documentation is provided, including validation and stability studies. Both Active Pharmaceutical Ingredients (APIs) and late stage raw materials for APIs are manufactured. Active Drug Master Files (DMFs) are also maintained in North America and Europe. Quality agreements are in place with major US and International drug companies.

Site Capabilities

GMP Suites & Facilities

- 3 ISO Class 7 rooms
- 2 controlled, non-classified GMP rooms
- Dedicated glassware
- Dedicated production suite
- Verified Line Clearance prior to project change-over

Equipment & Scale

- Kilo-lab production
- Up to 22L dedicated glassware
- Capable of 50-75L
- Expansion capacity (150L)
- 10s to few 100s of kilos of API
- Cryogenic (down to -78°C)
- Max temperature 265°C

Analytical Support

- Method Development
- Methods Transfer
- Methods Verification/Validation
- Data Integrity
- Release and Stability Testing

Cleaning

- Dedicated glassware
- Cleaning SOPs
 - Rinse release
 - Depyrogenated
 - Swab-released
- Cleaning Validation

Current APIs

- Cisplatin
- Carboplatin
- Dexmedetomidine HCl*
- Isoproterenol HCl*
- Selenious Acid**
- Cupric Sulfate Pentahydrate
- Chromic Chloride
- Pamidronic Acid*
- Sodium Sulfide Nonahydrate

* Marketed exclusively through Chemwerth

** Available through Chemwerth if a DMF is required



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