

# CONTRACT DEVELOPMENT & MANUFACTURING CGMP FILL AND FINISH MANUFACTURING

Contract GMP fill and finish services that delivers packaged drug product per specified clinical schedule for Preclinical, Phase I and Phase II trials.

## Protecting your molecules integrity

Symyx provides aseptic filling of liquid and lyophilized drug products, including both manual and automated fills in sterile environments that meet US and EU standards. Our facility provides in-process, release and stability testing services with a range of CGMP analytical techniques.



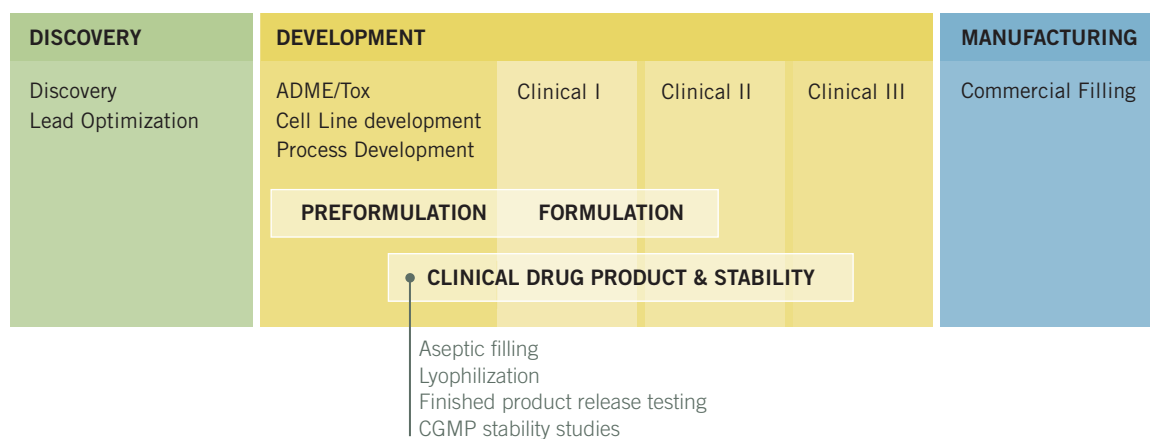
Aseptic Filling



Lyophilization

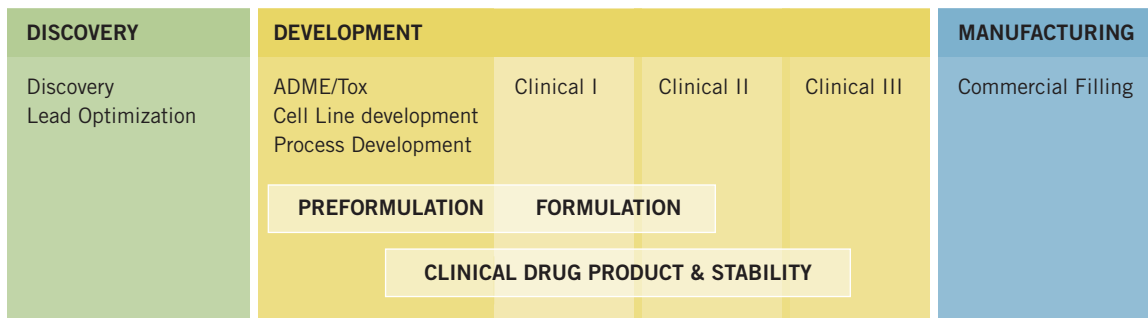


GMP Testing



## Small batch aseptic filling

- Operation and documentation workflows to meet the needs of preclinical and clinical supply quantities
- Operation flexibility – both manual and automated fills
- Manufacturing requirements – meets both US and EU standards
- Release and stability testing – wide range of in-house and contracted analytics



Symyx Contract Development and Manufacturing services for Biopharmaceuticals helps companies to accelerate their time to clinical trials

### Aseptic Filling

New filling facility, combined with our scientific expertise, experienced staff highly trained in GMP operations provides a high-quality platform for supplying your clinical materials

- Manual and automated filling, stopping and capping
- Liquid and lyophilized drug product
- Meets both US/EU environmental standards
- M&O Perry filler and stopper that uses a rolling diaphragm liquid filling pump
- West capper (4000+ vials per hour) soft barrier to meet EU requirements
- Variable vial sizes – range from 2 cc to 20 cc
- Batch size up to 5,000 vial liquid fills
- Batch size up to 3,000 vials lyophilized fills

### Lyophilization

CGMP manufacture of sterile lyophilized formulations

- Direct transfer from our lyophilization cycle development services or clients
- Approximately 9 sq ft BOC Edwards lyophilizer
- Designed for Phase I and II volumes
- CIP/SIP capability
- Opens into Class 100 space

### GMP Testing

Helping our clients bring safe, effective, and FDA-compliant products to the clinic

In-Process, Release and Stability Testing services

- Sterility
- Bioburden
- Endotoxin (Limulus Amebocyte Lysate)
- Protein concentration
- Sub-Visible Particulates
- Moisture analysis
- HPLC (RP,SEC, IEX,CEX)
- Total Organic Carbon
- pH and conductivity
- Osmolality
- SDS Page
- Peptide Mapping

### For more information

Visit [www.symyx.com/CDMO](http://www.symyx.com/CDMO)  
or contact [biopharm.info@symyx.com](mailto:biopharm.info@symyx.com)