

Complex injectable
product or process?



Bring it.



U.S.

BASED INJECTABLES
CDMO

60

YEARS SUPPORTING
PATIENTS

40+

YEAR GLOBAL
REGULATORY TRACK
RECORD

20+

COMMERCIAL
PRODUCTS

50M

UNIT CAPACITY FOR
VIALS, SYRINGES,
CARTRIDGES

► Why Choose Lifecore?

We're creative problem solvers who enjoy helping our customers find solutions to complex processes and products.

We don't have limitations on what we're willing to consider. We're flexible when onboarding customer processes, methods, and equipment at our facilities.

We also have experience working from pre-clinical through commercial with all sizes of organizations. With end-to-end services, Lifecore could be the perfect home for the complete lifecycle of your program.

► What Can We Do?

Proven QMS can support drugs, biologics, medical devices, and combination products:

- Biologics (mAbs, peptides, proteins)
- Small molecules
- Hydrogels, with option to incorporate Lifecore-manufactured hyaluronic acid as an API or excipient
- Microparticles/nanoparticles (lipid/mRNA)
- Biopolymers & synthetic polymers
- Long-acting injectables
- Emulsions/suspensions

Lifecore has a 248,000 ft² campus with ample space to expand.



150,000 ft²



78,000 ft²



20,000 ft²

Minnesota has the highest MedTech workforce concentration in the U.S.*

*Source: Greater MSP MN Medtech 3.0 website



Registered FDA
Device & Drug
Establishment



Certified ISO 13485
Quality System



European GMP
Certified

Capabilities & Experience

- Filtration: PUPSIT, TFF (sterile & non-sterile applications), sterile filtration (150,000 cps requiring up to 850 psi)
- Sterile powder API additions
- Flammable & organic liquid handling
- Low-viscosity (<100 cps) & high-viscosity solutions (>150,000 cps)
- Homogenization including high-shear mixing (>20,000 rpm)
- Bubble-free filling
- Low particulate & residue levels
- Controls for shear, light, temperature & oxygen sensitivity
- Vacuum & vent tube stoppering
- Single-use, glass, & 316L stainless steel components

Formulation & Process Development

- Formulation development & process optimization
- Stability, filtration, & material contact studies
- Technology transfer & feasibility assessment
- Cleaning development
- Fill development & optimization
- Process equipment qualification & sterilization
- SIP qualification
- Aseptic process simulation
- Use Quality by Design (QbD) based on ICH Q8 guidelines to determine critical quality attributes (CQA), Critical Process Parameters (CPP), and design GMP-compliant processes

Filling

- 5 filling suites for range of batch sizes
- Isolator filling capacity
- Range of components and sizes
 - 0.5mL-10mL syringes
 - 2R-100R vials
 - 3, 5, 10mL cartridges

Analytical & Stability

- Analytical method transfer, development, and phase appropriate validation
- In-house testing of in-process, release, and stability product samples.

Physical Testing

- Viscosity, Extrusion Force, Volume in Container, Leak Detection, Rheological Properties, Particulates Analysis

Microbiological Testing

- Sterility, Bacterial Endotoxins, Culture Purity, Microbial Enumeration, Culture Media Growth Promotion
- Full Environmental Monitoring

Analytical Testing

- GC, HPLC/UPLC (including UV/VIS, PDA, RI, ELSD, MS, MALS, CAD, FLR), ICP-OES, Capillary Electrophoresis, SDS-PAGE Gel Electrophoresis, NIR, FT-IR, UV-Vis, Raman, Osmometry, pH, Conductivity, Titration, Karl Fisher, Total Organic Carbon, Custom Dissolution, ELISA, Particle Size Distribution and Polarimetry

Stability

- -20C walk-in, 5C walk-in, 25C/60% RH walk-in, 30C/65% RH walk-in, 40C/75% RH walk-in
- Multiple, configurable reach-in chambers

Packaging

- Automated labeling
- Automated plunger rod insertion & flange extender application
- Trays (blisters), pouches & cartons
- Single unit & bulk packaging
- Serialization

Learn more at lifecore.com or contact us at cdmo@lifecore.com