

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 ft<sup>2</sup> campus with ample space to expand.



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](https://lifecore.com) or contact us at [cdmo@lifecore.com](mailto:cdmo@lifecore.com)

## Premium Sodium Hyaluronate

Whether you need research-grade, hydrogels, custom modifications, or GMP injectable-grade for clinical or commercial use, we offer a broad range of average molecular weights for your application.

### Research & Pharmaceutical Grade

- Research products derived from GMP batches for easy translation from pre-clinical to clinical and commercial.
- Molecular weights from 5KDa-1.8MDa

### Corgel® BioHydrogel

- Based on di-hydroxyphenyl linkages of tyramine substituted sodium hyaluronate, this biocompatible hyaluronan hydrogel meets ISO 10993 safety and toxicity standards.
- Wide range of physical properties depending on the tyramine substitution percentage and the tyramine substituted hyaluronan (TS-NaHy) concentration.
- Our hydrogels are formed from TS-NaHy solutions of 6.25 – 100 mg/mL and display a spectrum of physical properties that include those of a weak gel, a paste, or a fragile solid.

### Custom Modifications

- Cross-linking
- Adding pendant groups, APIs or custom linkers
- Pilot production and scale-up to a cGMP process
- Modifications We've Produced
  - Tyramine-HA
  - Azido-HA (Azide- or Hydrazoic- or Azidyl-)
  - Thiolated HA. Or Thiol-HA
  - Maleimide-HA
  - Alkyl-HA
  - Methacrylate-HA (MeHA)

### Safety and Quality

- US-manufactured with global approvals
- (US DMF, EP-certified, JP-compliant) in an ISO13485-certified facility
- First FDA-approved product with our sodium hyaluronate in 1986

### Proven Applications Worldwide

Our sodium hyaluronate has been used as an active device component, excipient, carrier, and API across a wide range of applications, including:

- Ophthalmology
- Orthopedics
- Drug delivery
- Biomaterials
- Aesthetics
- Oncology
- Pain management

### Reliable Supply for Commercial Manufacturing

- Large-scale, proven process.
- Non-animal-sourced products produced through microbial fermentation since 1982.
- Batches are thoroughly mixed prior to rapid, efficient precipitation. Yields pure, uniform powder that is easy to handle and weigh accurately for precise formulation control.

 Learn more at [lifecore.com](https://lifecore.com) or contact us at [info@lifecore.com](mailto:info@lifecore.com)