



**Hyaluron Contract Manufacturing (HCM)**

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## Vital Statistics

**Year Founded:** 1999

**Number of Employees:** 100

**Annual Revenues:** approximately \$18 million

**Key Personnel:** Dr. Shawn D. Kinney, president; Dr. Andrea Wagner, vice president of business development.

## Who We Are

HCM IS A LEADING CONTRACT MANUFACTURER specializing in sterile formulation, homogenization, aseptic filtration and aseptic filling of syringes, vials and custom containers. HCM works with client who have products in pre-clinical to commercial phase development, including the offering of lyophilization services.

HCM has developed an online vacuum filling and stoppering technology for pre-filled syringes. This **patented bubble-free filling™ technology (zero air gap) inhibits the growth of some micro-organisms** and may offer advantages to oxygen sensitive compounds such as proteins, epinephrine and others where dissolved oxygen may negatively impact solution stability. In addition to benefits in product stability, bubble-free filling™ **eliminates stopper movement** when the syringe is exposed to reduced atmospheric pressure (**during airline shipping and high altitude ground transportation**). HCM is cGMP compliant; ISO 9001 and 13485 certified, and has been inspected by the FDA for drug and medical device.

## Major Markets

HCM WORKS WITH pharmaceutical and biotechnology companies, helping them to bring their liquid drugs and products to market. HCM accommodates clients in pre-clinical and clinical phase development as well as small commercial scale manufacturing.

## Services Offered

### Syringe Filling:

- .5mL to 20mL (up to 150,000/day)
- Vacuum filling and stoppering
- Bubble-free filling™
- Traditional filling

### Vial Filling:

- 1mL to 100mL (up to 75,000/day)
- Liquid filling



- Lyophilization
- Class 100 capping

### Custom Containers:

- Up to 1L
- Screw top bottles

### Hyaluronic Acid:

- Raw material and sterile solutions

### Additional Services and Support Include:

- Stability Optimization Services (SOS)
- Aseptic formulation
- Disposable manufacturing technology
- Homogenization
- GMP analytical lab to support manufacturing
- Redundant systems for product production security assurance
- Product labeling and packaging
- Sterility programs
- Controlled storage

### Our Facility

HCM has a cGMP facility featuring 60,000 sq. feet of manufacturing, laboratory, clean room, and office space.

### Hyaluron has three fill lines

#### *Inova SV-122 Syringe Filler*

- One/Two head filler, accommodating pre-clinical and clinical phase fill needs (50,000 units/day)
- Traditional online stoppering
- Offline vacuum stoppering (Hypac vacuum box)
- Low, 30mL hold-up volume
- +/- .03mL fill precision

#### *Inova H3-5V Syringe Filler*

- Three/Five head filler, accommodating small to medium commercial fill needs (100,000 units/day)
- Online vacuum filling and stoppering
- Bubble-free filling™ - no headspace (optional)

#### *Inova VFVM-3031 Vial Filler*

- Single "Star Wheel" set-up (75,000 units/day)
- Three fill needle format (Pre-gas purge, Product fill, and Post-fill headspace)
- Low, 30mL hold-up volume
- Inline class 100 capping
- Automated online inspection

[www.hyaluron.com](http://www.hyaluron.com)  
[www.bubblefreefilling.com](http://www.bubblefreefilling.com)