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# Pharmaceuticals

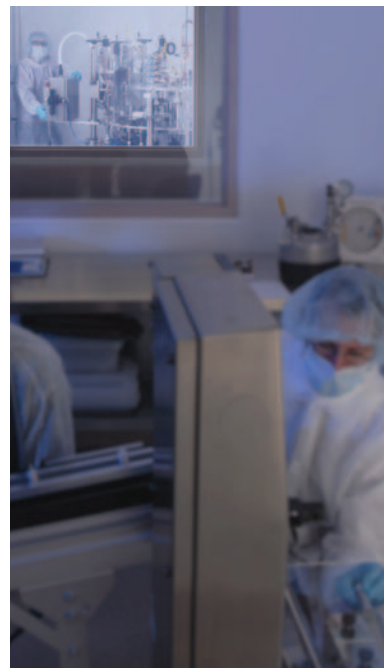
# Contract Product Development and cGMP Manufacturing and Packaging of Pharmaceutical Aerosols

**In January 2008** Exemplar proudly announced the opening of its new 24,000 square foot facility dedicated to the contract cGMP manufacturing of pMDIs, nasal sprays and DPIs for both clinical and commercial product needs. With this expansion, Exemplar's mission is redefined to provide both a full range of integrated product development capabilities specific for aerosol products as well as the ability to produce clinical supplies and finished product. Exemplar Laboratories is structured to provide the GLP development services needed to reach the clinical stages of product development and Exemplar Pharmaceuticals is able to produce the necessary cGMP clinical supplies leading to product approval and finished product manufacturing. For these strategies, Exemplar has put together an outstanding group of highly experienced and successful scientists and production professionals that can assist companies in meeting their expedited time lines.

## The comprehensive and flexible services offered include

- State of the art cGMP/GLP facility and equipment
- Class 100,000 filling suites for pMDIs, DPIs, nasal and buccal sprays
- Process development and scale up
- Pilot scale manufacturing
- Preclinical, toxicology and clinical supplies
- Dedicated space, staff and equipment available
- Process validation
- Supply chain management
- Labeling and packaging services
- Warehousing

*Exemplar's high speed pressure filling line is capable of producing more than 70,000 units per day*





## Analytical Support Services

The highly trained and experienced quality control analytical staff is capable of supporting all activities associated with cGMP manufacturing including

- Cleaning method development and validation
- In process testing
- Release testing
- Product testing
- Incoming inspections (components, excipients, API)
- ICH directed stability testing
- Environmentally controlled stability room
- Product troubleshooting
- Extractables/leachables testing
- Data tracking and trending

# Experienced Technical and Management Team

**Exemplar merges** product development activities with the ability to produce clinical and commercial products in a seamless, cost effective manner. Dedicated filling lines, equipment and space are available and Exemplar will build to suit the client. Capabilities include the filling of:



*Exemplar's 250L pressure vessel*

## **pMDIs**

- Process development & validation
- Automated high speed filling lines
- Pressure filling (single stage and two stage)
- Canister purging
- Vacuum crimping
- 100% checkweighing
- 100% leak testing (non-water bath)
- 100% spray testing
- Unique equipment designed per client needs
- Individual filled canister labeling
- Variable batch scales, 4L to 1000L
- Secondary packaging
- Full release and stability testing
- In vitro BA/BE testing

## **DPIs (developed in conjunction with known device companies)**

- Formulation blending
- Packaging (cold formed blisters)
- Filling (capsules, blisters, dis-kettes)
- Blister sealing/cutting
- In process inspections (optical, analytical, seal integrity)
- Secondary packaging/pouching
- Full release and stability testing
- In vitro BA/BE testing

## **Nasal Sprays**

- Automated high speed filling line (single or multiple spray designs)
- Crimp on, snap on and screw on pump sealing
- 100% check weighing
- Individual in line filled bottle labeling
- In process inspections
- Secondary packaging
- Full release and stability testing
- In vitro BA/BE testing



*ICH stability room*



*Blister forming and sealing*



*USP water system*

# Clinical Supplies



Exemplar's pMDI filling suite

**The ability to move development stage products** into *First in Man* clinical studies is now a key step in accelerating the development process. To better serve these client needs, Exemplar provides state of the art cGMP compliant, Class 100,000 manufacturing suites for pMDIs, DPIs, nasal and buccal sprays in support of Phase I through Phase IV activities. All processes are carried out in controlled environments.

## Filling Capabilities

### pMDI

- Small (30L) to large scale (200L) pressure vessels
- Manual and semi-automatic Pamasol crimping and filling equipment
- Process development and scale up support
- Placebo and toxicology supplies

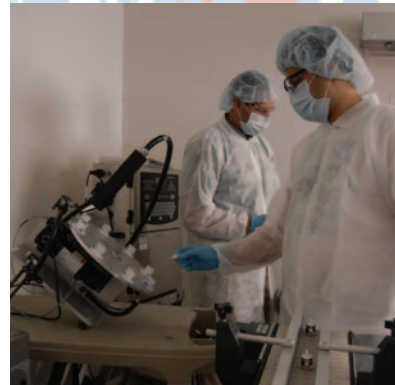
### DPI

The filling approach is based on the inhaler device technology chosen. Exemplar will work with the client to develop product and device specific filling processes

### Aqueous Nasal Sprays

- Semi-automatic filling processes for solution or suspension products
- Manual and semi-automatic filling of single and bi-dose products

## Labeling, Packaging and Assembly Services Provided



Individual unit coding



Unique double blind masking devices for pMDIs and nasal sprays



**Exemplar** is an internationally contracted research and development and now manufacturing business established in 2002 in partnership with pharmaceutical, biotechnology, generic, virtual and medical device companies to meet the CMC aspects of their development and commercial timelines.

Located off Route 24 in Fall River, Mass, Exemplar is 30 miles north of Providence RI and 42 miles south of Boston.

**Exemplar is FDA registered and audited**, DEA licensed and cGMP/GLP compliant. Company audits of our facilities are encouraged and quality plans are welcomed.

#### **Senior Management**

Charles R. Eck, Ph.D, *president*

Abdul Zahir, Ph.D. R.Ph, *vice president, operations*

Edward Shaugnessy, *plant manager*

Richard Kracunas, *assistant plant manager*

John Armstrong, *scientific advisory board (chairman)*

Richard Armstrong, *scientific advisory board (production consultant)*

#### **Contact Exemplar for more information on our services**

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