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**Laboratories**

**Exemplar Laboratories** is a contract services company focusing on the development of nasal and inhalation products targeting the lungs, nasal passages and the buccal cavity. Our expertise and experience is without peer in the CRO industry where this laboratory has successfully met clients needs since 2002.

Exemplar provides the most sophisticated aerosol formulation and delivery technologies and product development support services to meet precise needs. We are among the first commercial facilities in the world to offer inhalation technologies development in conjunction with other key services including production of cGMP clinical and commercial supplies. The broad scientific experience of our staff ensures that we can effectively develop, analyze and produce a wide range of pharmaceutical and biopharmaceutical products.

**Our expertise is focused on three targets**

- Pulmonary
- Nasal
- Buccal

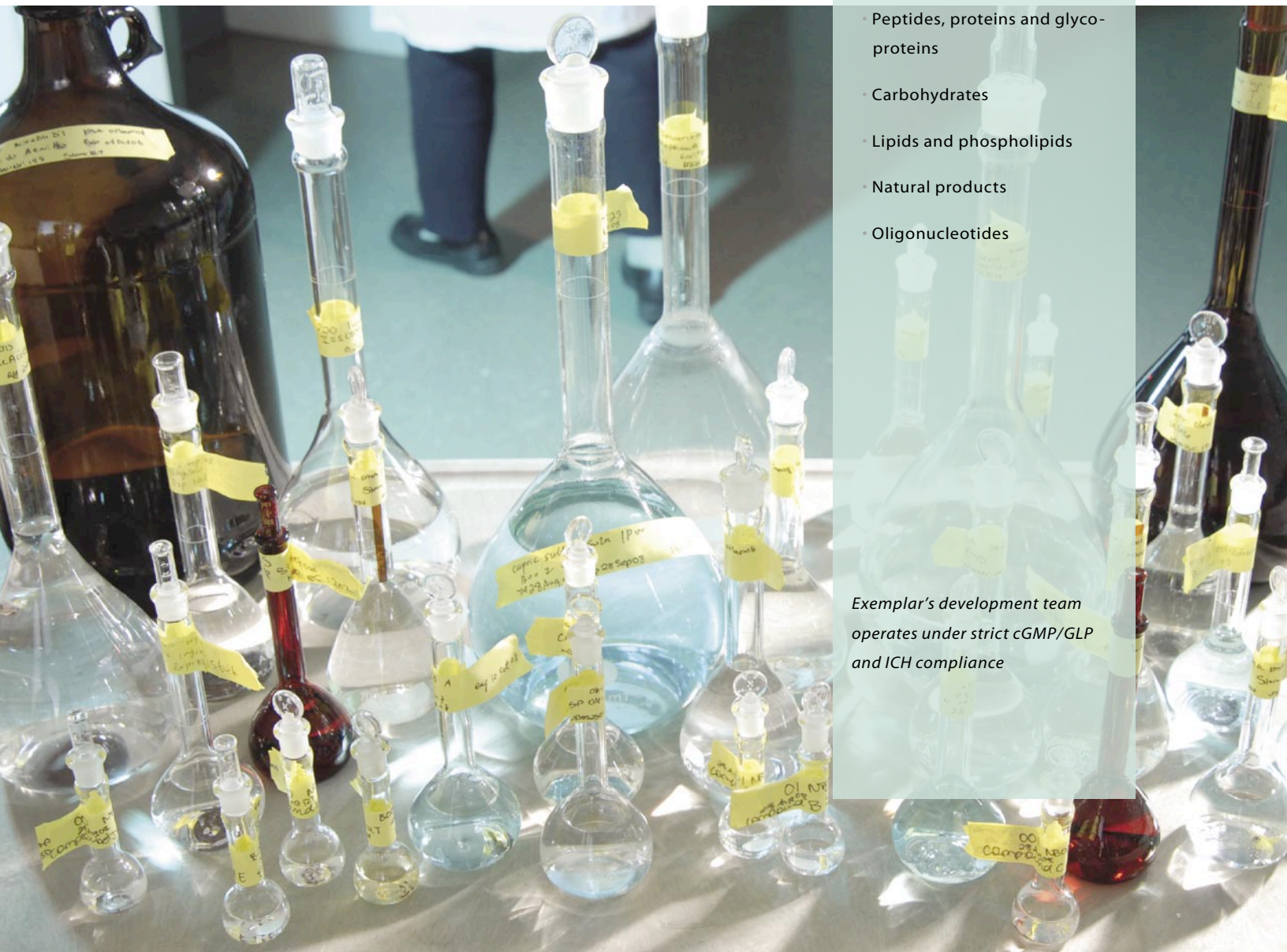
**Dosage forms include**

- Metered dose inhalers (pMDI)
- Dry powder inhalers (DPI)
- Soft mist or liquid inhalers (LI)
- Nebulizers
- Nasal aerosols or sprays
- Buccal aerosols or sprays

**Classes of molecules**

- Small molecules
- Peptides, proteins and glyco-proteins
- Carbohydrates
- Lipids and phospholipids
- Natural products
- Oligonucleotides

*Exemplar's development team operates under strict cGMP/GLP and ICH compliance*



# Development



*Exemplar develops and tests a variety of novel oral and nasal delivery systems*

**Innovative Approaches to Formulation Development** Exemplar's formulation development activities focus on the dynamic application of physicochemical principles that are the cornerstone of creative drug formulation. We apply knowledge gleaned from rigorous drug characterization techniques to develop robust drug formulations and dosage form systems. New technologies including targeted delivery and controlled release systems as well as sophisticated delivery systems designed to overcome biological barriers, are rapidly changing the conventional methods of formulation development. Any successful development program often hinges upon the application of such innovative technologies.



*Exemplar's development activities focus on the dynamic application of physicochemical principles*

**Delivery Technologies** Our inhalation technology team specializes in developing and testing a variety of novel oral and nasal delivery systems, ranging from Metered Dose Inhaler (HFA) and Dry Powder Inhalers to Liquid Inhalers, Nebulizers and Nasal Sprays. Exemplar has formal and well-established relationships with a number of inhalation device companies that allow a seamless development timeline from formulation to final dosage form.

## **Formulation services**

- Preformulation/formulation
- Formulation and device options
- Feasibility studies
- Dosage form options
- Particle engineering options
- Container/closure evaluations
- Excipient compatibility
- Drug compatibility
- Stability evaluations



# Analytical



*Full analytical support for formulation and dosage form development*

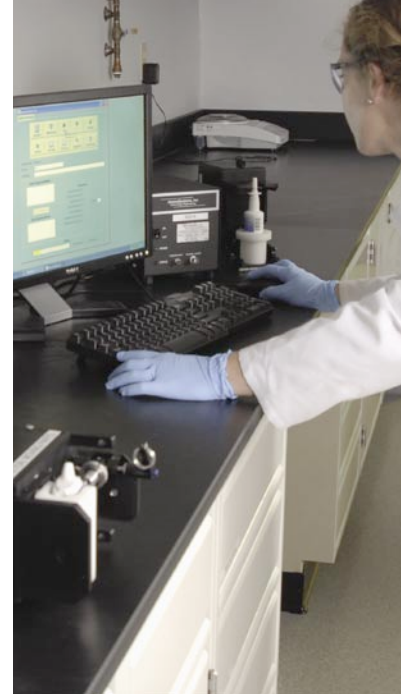
**Analytical Chemistry** Exemplar's analytical chemistry group serves as an extension of our clients' R&D analytical and quality control laboratories. Utilizing our extensive and sophisticated analytical instrumentation, Exemplar's scientists provide method development and validation services from bulk drug to final product including identification and quantitation of related substances, impurities, degradants and excipients for lot release, product performance and stability assessment.

**ICH Stability Programs** Exemplar offers comprehensive stability programs for drug substances, drug product, formulation evaluations, clinical supplies, and commercialized finished products. Our cGMP/GLP facilities are equipped with fully mapped stability chambers, each of which is independently controlled and monitored with redundant alarm systems. Our services include on-time testing and customized report generation.

Exemplar is regularly in touch with FDA regarding the interpretation of FDA guidances that control various aspects of both CMC and BA/BE requirements.

- Protocol development
- NDA required in vitro BA testing
- ANDA required in vitro BE testing
- Report generation in FDA submittable format
- Statistical analysis in FDA submittable format

**Methods Development and Validation** The technical expertise of our cGMP/GLP compliant drug development facilities are equipped to develop and validate all of the test methods required for aerosol products to meet FDA, EMEA and Health Canada requirements.



*Specialized aerosol testing instrumentation*

## **Analytical services**

- Method development and validation
- Cleaning validation
- Drug substance characterization
- Reference standard certification
- Drug substance and product lot release
- QC Testing
- Impurity profile, isolation, characterization
- Excipient analysis
- Method and product troubleshooting

## **Available programs**

- Protocol development
- Shelf life/accelerated or customized storage conditions
- Program design and management
- Freeze/thaw testing
- Statistical analysis, expiration dating and data trending
- In vitro BA/BE Testing

# Clinical

**Clinical Trial Material** 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 clinical supplies manufacturing Class 100,000 suites for pMDIs, DPIs, nasal and buccal sprays in support of Phase I through Phase IV activities. All processes are carried out in environmentally controlled rooms.

**Regulatory Support** Exemplar's expertise can assist in the process of choosing the correct regulatory pathway for your product including specific issues related to the pharmaceutical medical device and biotechnology industries. Our staff is capable of assisting in the preparation of IND, NDA, ANDA and like applications.

*Exemplar's clinical filling operation*



## 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

### DPI

- Based on the specific inhaler technology chosen, Exemplar will work with the client to develop product- and device-specific filling processes

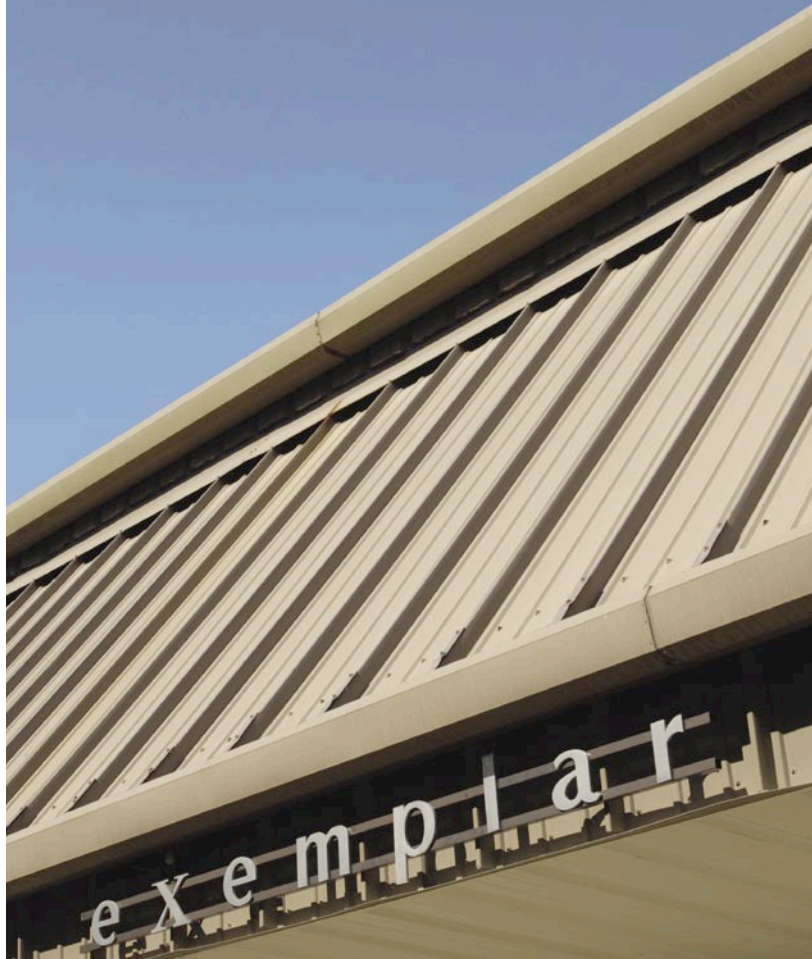
### Aqueous Nasal Sprays

- 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

*Exemplar is the sole representative of Pharmask, Inc. for their unique line of double blind clinical masking devices. These devices will accommodate most commercial pMDI and nasal spray products. Exemplar provides double blind clinical masking and labeling services for these devices.*





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

- Analytical chemistry
- Bioanalytical chemistry
- Formulation development
- Dosage form development
- Preclinical and clinical supplies
- Double blind masking devices
- In vitro BA/BE testing
- Drug product characterization studies
- Stability programs

**A leader in inhalation product development services** Exemplar Laboratories is an internationally used contract research organization (CRO), delivering product development services in partnership with pharmaceutical, biotechnology, chemical, generic, virtual and medical device industries to meet their product development needs. Exemplar can play a critical role in the commercial development of human therapeutics, from preclinical support to clinical supplies manufacturing and release testing of marketed products.

**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*

John Armstrong, *scientific advisory board (chairman)*

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

  
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