# Non-GMP and GMP Services From Lab Scale R&D to Bulk API Production

(grams to tons)



Facilities in Asia, Europe, and North America

- One Stop Manufacturing from Lab to Commercial Scale
- Full Time Equivalents (FTE)
- Products to Support Discovery
- Product Development Services
- Catalytic Screening
- Medicinal Chemistry Services
- Analytical and Compliance Expertise
- Separations Technology





# **Alfa Aesar Offers Manufacturing Services**From the Lab to Bulk API Production

Alfa Aesar, a Johnson Matthey Company, now offers chemical products and services to cover the full scope

meet your high expectations.

of over 33,000 products to cGMP compliant commercial manufacturing and a full suite of services in between, Alfa Aesar and Johnson Matthey Pharmaceutical Services and Materials bring together all the resources needed to

of the drug development life cycle. From the catalog

Our professional team is ready to assist you in the successful development of small molecules, natural products and in the manufacture of highly potent active ingredients, including controlled drug substances. Let Alfa Aesar and Johnson Matthey Pharmaceutical Services and Materials be your partner in development and manufacturing.

With facilities
around the globe,
Alfa Aesar and
Johnson Matthey
Pharmaceutical
Services and
Materials are ready
to assist with your
production needs.



## Feeding the Discovery Pipeline

#### In Stock, Around the Globe

Alfa Aesar offers 33,000 products from its Research Chemicals Catalog. To help keep your discovery activities moving ahead without delay, a unique range of screening compounds, intermediates and other useful compounds are available from stock for immediate dispatch.

#### **Thousands of New Products**

If you are on the look out for new boronic acids, alternative amino pyridine derivatives, or a variety of heterocyclic compounds, just to name a few, keep an eye on Alfa Aesar's new product announcements. Hundreds of interesting new products are added each month.

#### **Broad Based Production Experience**

Being a global research chemicals business for nearly 50 years means we have practical experience with the more complex organic reactions and safe routes to thousands of molecules that have been developed in house.

#### **Lab Scale Production**

Our research scale labs in Heysham, UK utilize 100 fume hoods for a variety of chemical reactions. The Heysham team is set up to handle projects in the 1kg to 100kg scale.

#### Kilo Lab and Small Pilot Plant

The Alfa Aesar Synmax production labs in Yantai, China offer a diverse selection of production capabilities. Alfa Aesar Synmax utilizes up to 2000L reactor vessels for development and pilot scale batches. Additional Johnson Matthey kilo labs in the United States are available to support non-GMP production.

#### **Product Data and Interfaces**

Through print and the advanced web based catalog as well as third party data access systems such as the Available Chemicals Directory (ACD), Ariba and SciQuest, the Alfa Aesar catalog is available in a variety of formats and media. Contact us to set up a direct link to our complete catalog and new product updates.







### **Product** Development Services

As part of the Johnson Matthey Fine Chemicals Division, Alfa Aesar and Johnson Matthey Pharmaceutical Services and Materials offer services that cater to the entire drug development life cycle. Strong cGMP and regulatory compliance are the foundation for our full selection of services, from custom synthesis, process development, scale-up, optimization and validation to manufacturing from milligrams to commercial scale.

#### **Catalytic Screening**

Our goal is to help you accelerate your leads to the clinical stage. The Catalytic Technology Screening Center saves you time and money by incorporating optimized catalytic steps into your process. State of the art facilities, with the core competence and equipment to scale these chemistries, supplement our proprietary Johnson Matthey technologies.

#### **Analytical and Regulatory Compliance**

Specialized quality assurance and compliance techniques developed at Johnson Matthey are at your disposal. A flexible quality system and cGMP, ISO 9000 compliant facilities are the backbone for our analytical and regulatory compliance services. We understand the importance of quality assurance to our valued customers. On request, we will be pleased to provide historical compliance documentation on all Johnson Matthey facilities.



**Chemical Development** 

thousands of new chemical entities. We put this experience at your service, whether it is in the design, development and optimization of synthetic routes, the production and scale up of intermediates and APIs, or process development, process

# Medicinal Chemistry Services

Your goal is a viable pre-clinical candidate. Taking advantage of the latest technology and state of the art facilities, such as our Catalytic Technology Screening Center, our medicinal chemistry services team designs novel synthetic routes with the goal of scaling your process as quickly and efficiently as possible.



#### **Separation Technologies**

We offer an extensive set of separation techniques in developing a process to suit your need.

These include crystallization, drying and evaporation separation techniques, fractional distillation, micro and ultra-filtration, preparative chromatography, as well as Simulated Moving Bed (SMB) chromatography and SFC (Supercritical Fluid Chromatography). We use feasibility/lab bench studies to evaluate your project to determine the viability of various techniques.

#### **Highly Potent APIs**

We have prepared thousands of highly potent active pharmaceutical ingredients (HPAI) over the years. In our potent compound laboratories, we employ robust containment chemistry services for the production of HPAIs up to category IV (Safebridge scale) for both clinical and commercial use.

#### **Full Time Equivalents**

Alfa Aesar Synmax also offers Full Time Equivalent (FTE) services for those customers not requiring GMP certification. A variety of packages are available utilizing our R&D labs, Kilo labs and the pilot plant. Contact an Alfa Aesar sales office for more details.

# A Variety of Manufacturing Options

#### Lab and Kilo Scale

#### **Commercial Grade Production**

Our research scale labs in Heysham, UK employ dozens of PhD production chemists utilizing 100 fume hoods for a variety of chemical reactions. Our team is process oriented, having extensive experience developing routes that are both scaleable and efficient. The Heysham team is set up to handle projects in the 1kg to 100kg scale.

At the brand new Alfa Aesar Synmax production labs in Yantai, China, an experienced team uses proven techniques and state of the art facilities to offer a diverse selection of production capabilities. Alfa Aesar Synmax utilizes up to 2000L reactor vessels for development and pilot scale batches.

#### Full Time Equivalents

Alfa Aesar Synmax also offers Full Time Equivalent (FTE) services for those customers not requiring GMP certification. A variety of packages are available utilizing our R&D labs, Kilo labs and the pilot plant. Contact an Alfa Aesar sales office for more details.

#### APIs and cGMP Production

Our New Jersey and Massachusetts operations all offer cGMP production of kilogram quantities of API and intermediate compounds in one of our 24 cGMP kilo labs.

#### **Small Commercial and Pilot Scale**

Our Devens, Massachusetts plant consists of state of the art, self contained manufacturing suites featuring 375L to 1900L glass lined and hastelloy reactors with cryogenic cooling capabilities.

The North Andover, Massachusetts facility houses three additional reactor trains and a separations technology component. This site enables synthesis of API under cGMP conditions in reactors up to 750L for clinical development and small scale commercial quantities.







#### **Bulk API Production**

Our strictly controlled, self contained reactor trains and DEA registered facilities produce Phase III bulk API specializing in Class I-V controlled substances. All production is under cGMP conditions and is controlled under ISO 9000 standards.

Our bulk cGMP API facility located in West Deptford, New Jersey houses hastelloy and glass-lined reactor trains ranging in capacity 19 to 7,500L. The facility is in strict compliance with DEA manufacturing requirements and utilizes class 100,000 contamination-control rooms with HEPA filtered air handling systems. Our extensive product list includes cisplatin, carboplatin, fentanyl citrate and base, hydrocodone, bitartrate, hydromorphone HCI and oxycodone HCI.

Riverside, our dedicated API manufacturing facility in Conshohocken, Pennsylvania, further expands our large scale operations. With a total reactor capacity of 140,000L and a 5,600m² production area, this facility is a scalable, flexible, multi-purpose production facility with highly automated, DCS recipe driven operations. The facility also features reactors up to 11,000L to fit large scale needs. Riverside is equipped to manufacture parenteral grade APIs (microbial/endotoxin environmental controls) and is licensed to produce DEA controlled substances in Schedules I and II.











A Johnson Matthey Company

#### Alfa Aesar North America

(International Sales Headquarters) 26 Parkridge Road Ward Hill, MA 01835 USA Tel: 1-800-343-0660 or 1-978-521-6300 Fax: 1-978-521-6350 Email: Info@alfa.com

#### **Alfa Aesar United Kingdom**

Shore Road
Port of Heysham Industrial Park
Heysham LA3 2XY
England
Tel: 0800-801812 or +44 (0)1524 850506
Fax: +44 (0)1524 850608
Email: uksales@alfa.com

#### Alfa Aesar Germany Postbox 11 07 65

76057 Karlsruhe Germany Tel: 800 4566 4566 or +49 (0)721 84007 280 Fax: +49 (0)721 84007 300 Email: EuroSales@alfa.com

#### Alfa Aesar France

2 allée d'Oslo 67300 Schiltigheim France Tel: 0800 03 51 47 or +33 (0)3 8862 2690 Fax: 0800 10 20 67 or +33 (0)3 8862 6864 Email: FrVentes@alfa.com

#### Alfa Aesar China

Room 1509 CBD International Building No. 16 Yong'An Dong Li Chao Yang District, Beijing, China 100022 Tel: 800-810-6000 or 86 (010)-8567-8600 or 400 610 6006 Bulk Sales: 800 810 6006 Fax: 86 (010)-8567-8601 Email: saleschina@alfa-asia.com

#### Alfa Aesar Korea

101-3701, Lotte Castle President O-Dong 467, Gongduk-Dong, Mapo-Gu Seoul, 121-805, Korea Tel: +82-2-3140-6000 Fax: +82-2-3140-6002 Email: saleskorea@alfa-asia.com

#### Alfa Aesar India

(Johnson Matthey Chemicals India Pvt. Ltd.)
Kandlakoya Village
Medchal Mandal
R R District
Hyderabad - 501401
Andhra Pradesh, India
Tel: +91 8008 812424 or +91 8008 812525
or +91 8008 812626
Fax: +91 8418 260060
Email: India@alfa.com

#### Distributed By:

#### Hydrus Chemical Inc.

Uchikanda 3-Chome, Chiyoda-Ku Tokyo 101-0047 Japan Tel: 03(3258)50331 Fax: 03(3258)6535 Email: info@hydrus.co.jp

#### **VWR Singapore Pte Ltd**

18 Gul Drive Singapore 629468 Tel: +65 6505 0760 Fax: +65 6264 3780 Email: sales@sg.vwr.com

#### **Uni-Onward**

3F-2 93 Wenhau 1st Rd, Sec 1, Linkou Shiang 244, Taipei County Taiwan Tel: 886-2-2600-0611 Fax: 886-2-2600-0654 Emaili: service@uni-onward.com.tw

#### Echo Chemical Co. Ltd

16, Gongyeh Rd, Lu-Chu Li Toufen, 351, Miaoli Taiwan Tel: 866-37-629988 Email: purchase@echochemical.com