Johnson Matthey

# Pharma Services

**API solutions** from discovery through commercial manufacturing

Johnson Matthey

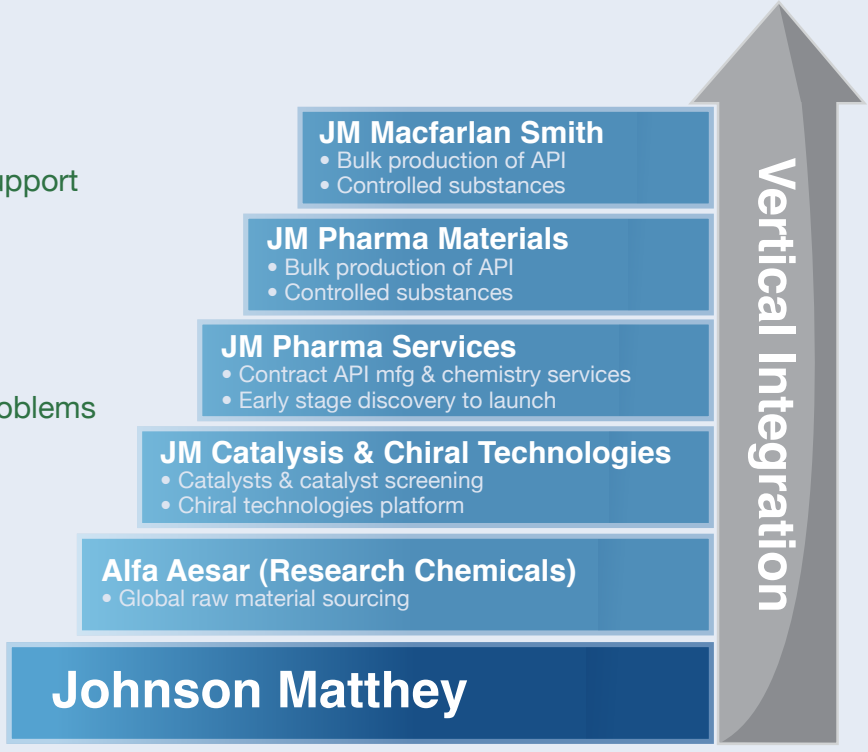
# Pharma Services

## Getting the most from our experience & expertise

- Over 35 years of excellence in highly complex, multi-step chemistry.
- Organic and Analytical Chemistry services to support all phases of API development.
- Expertise with structurally complex, highly potent APIs that are difficult to purify.
- cGMP manufacturing in US and Europe.
- Comprehensive Quality and Regulatory support with an excellent history of compliance.
- Exemplary project management.
- Specialty capabilities to solve complex problems enabling your project's success.
- Scale up proficiency to move safely and effectively from bench to plant.

*Johnson Matthey Pharma Services is a chemistry services company, dedicated to providing high quality and reliable API development and manufacturing solutions from discovery through commercial production.*

*With over 35 years experience and over 125 professionals in the Boston area, our broad range of services encompass all areas of research, development and manufacturing, and allows us to deliver your project on time, on target, and on budget.*




**1817** P. Johnson establishes business as a gold assayer in London

**1851** George Matthey joins company to form Johnson & Matthey

**1909** Johnson Matthey Inc. founded

**1919** Acquired JM & Co. Inc. - USA

**1927** Company acquires majority interest in J Bishop Platinum works

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# Why Choose Pharma Services?

## Along with our vast service offerings and capabilities, we also offer unique technologies and resources:

- ✓ Intelligence-driven chiral solutions
- ✓ Specialty separation technologies
- ✓ Vertical integration with global presence
- ✓ Gateway to catalytic expertise
- ✓ Potent compound capabilities from lab to plant
- ✓ Cryogenic plant capacity
- ✓ Process development for complex chemistry

### Pharmaceutical Materials & Services - US

| | | | |
|---|---|---|---|
| **Geographical Location** | Devens, MA | W. Deptford, NJ | Conshohocken, PA |
| **Total Capacity (gal)** | > 2,000 gal | 28,330 gal | 37,000 gal |
| **# Plant reactor trains** | 3 | 14 | 20 |
| **Reactor size** | 50 - 500 gal (plant)<br>20 -100L (Kilo-lab) | 30 - 2000 gal<br>50L (Kilo-lab) | 200 - 3000 gal |
| **Mat'l of construction** | Glass-lined steel and Hastelloy C | Glass-lined steel and Hastelloy C | Glass-lined steel, Stainless steel, and Hastelloy C |
| **Hydrogenation / Pressure** | < 100 psi | < 100 psi | < 300 psi |
| **Controlled substances** | Research: II - V<br>Mfg: II - V | Research: I - V<br>Mfg: I - V | Research: I - V<br>Mfg: I - V |
| **# Kilo labs** | 28 | 1 | 0 |
| **# Analytical / QC labs** | 4 | 3 | 3 |
| **Drying, Filtration & Milling** | • Portable Pressure Nutsches<br>• Pressure Filter & Tumble Dryers | • Pressure Nutsches<br>• Pressure Filter, Tumble, and Vacuum Tray Dryers<br>• Quadro, Impact, and Jet Mills | • Hastelloy Funda, Nutsche, Sparkler, Bag, & Cartridge filters<br>• Spherical, Double Cone, Tumble, and Tray dryers<br>• Cone & Hammer mills |
| **Additional Capabilities** | • Cryogenics<br>• Lab to Commercial Scale Chromatography<br>• High Potency | • Supercritical Fluid Chromatography (SFC) | • Solvent Recovery System<br>• Only active liquid waste incinerator in the state of PA |

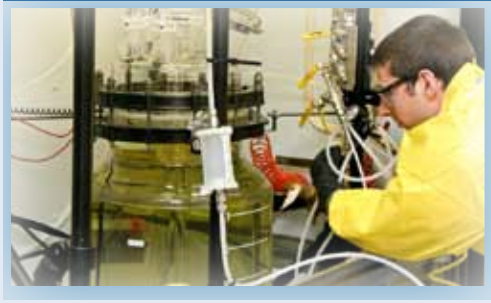
# Service Offerings

## API Outsourcing Solutions

Johnson Matthey Pharma Services supports every aspect of the API development lifecycle. We understand the needs of our clients and provide fit-for-purpose process development, scale-up, and manufacturing through all phases of development from pre-clinical to commercialization.

Our customer-focused team provides superior service to customers and a devout commitment to your project's success.

## Chemical Process & Development



We offer you a rapid scale-up to your first kilogram of API and beyond. Whether you require optimizing synthetic routes, scaling intermediates, or process development, we have the resources to get the job done. Our cross-functional teams provide you a seamless transfer to kilo-lab or plant.

The breadth of our expertise includes high potency handling, controlled substance management, custom separation technologies, and catalytic solutions.

## Analytical

Utilizing state-of-the-art equipment, our highly skilled analysts support the successful development of your drug candidate. Our expertise in the development of chiral and chemical methods ensures your API meets established quality standards.

As your program develops, we manage the qualification and validation of analytical methods to support regulatory filings. Your comprehensive analytical program is complemented by full ICH stability programs.

## cGMP Manufacturing

Our committed manufacturing teams enable you to realize the next series of milestones in the drug development cycle. Manufacturing is facilitated in dedicated kilo-laboratories and self-contained suites, allowing us to handle the most complex chemistry and process conditions.

In all cases, we offer you cost effective and efficient manufacturing while adhering to environmental and process safety best practices.

**1950's**

Rapid deployment of European and worldwide operations

**1954**

Universal Matthey Products formed to produce platinum catalysts

**1974**

The world's first catalysts to control vehicle pollution are produced

**1977**

Production of Cisplatin for Bristol-Myers Squibb begins

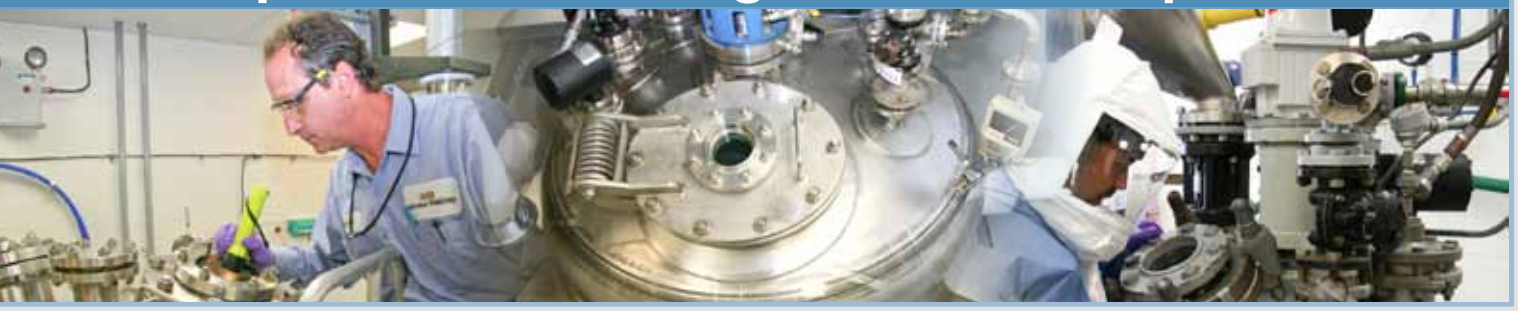
**1983**

Commercialization of JM-developed platinum based anticancer drugs

Opened West Deptford, NJ facility, home to JM Pharma Mat'ls & Services

# & Capabilities

## ...from pre-clinical through commercial production



- ✓ Physical assessment
- ✓ Route scouting
- ✓ Catalyst process screening
- ✓ Process R&D
- ✓ Rapid scale-up
- ✓ Supply chain development
- ✓ Impurity identification
- ✓ Design of experiments
- ✓ Salt selection
- ✓ Reference standard preparation

- ✓ Methods development
- ✓ Method transfer protocols
- ✓ Qualification & validation
- ✓ UPLC method development
- ✓ Chiral method development
- ✓ Structure elucidation
- ✓ Impurity characterization
- ✓ CFR-21 Part 11 compliant
- ✓ Reference standard qualification
- ✓ ICH compliant stability program

- ✓ Kilo lab through commercial scale
- ✓ Milling & micronization
- ✓ Lyophilization
- ✓ Specialty separation technologies
- ✓ High potency
- ✓ Controlled substances
- ✓ Cryogenic capacity
- ✓ Ultrafiltration
- ✓ Tangential Flow Filtration

# Specialty Capabilities

## Polymer Drug Conjugates

Over a decade of experience developing and scaling up processes for linking small molecule payloads to polymers in support of PDCs, ADCs, and other drug delivery applications.

- ✓ Complex molecules, high potency capabilities (up to SafeBridge® Category 4)
- ✓ Diafiltration, tangential flow filtration, reverse osmosis
- ✓ Large scale chromatography, lyophilization
- ✓ GPC/SEC for molecular weight determination, MALs detector

## High Potency Capabilities

Our highly trained staff ensures safety while developing your process by employing robust containment and isolation techniques.

- ✓ Rigorous but measured safety standards
- ✓ Operate on the SafeBridge® Categorization System
- ✓ Capable of operating under cGMP or non-GMP conditions
- ✓ Kilo lab-scale through Category 4
- ✓ Plant-scale through Category 3

## Solid Form Screening

Accomplished scientists, proficient in solid state technologies and molecular polymorphism, will effectively plan and perform comprehensive characterization and screening experiments on your API.

- ✓ Selection of the most viable and stable polymorph
- ✓ Salt screening and selection
- ✓ Development of an optimal crystallization and isolation process
- ✓ Resolution of oiling out issues

## Additional Differentiators

As your long-term partner, we can leverage our unique, integrated technologies and specialty capabilities to ensure your success.

- ✓ Catalytic process screening
- ✓ Controlled substances (Schedules I-V)
- ✓ Production scale chromatography (medium pressure and SFC)
- ✓ Cryogenic reactors (-80° C) up to 2000 L scale

**1991**

Queen's Award for work on platinum based anticancer drugs

cGMP operations opened in MA

**1995**

The company acquires Alfa Aesar

**2000**

Devens, MA facility opens

**2002**

Acquisition of Pharm-Eco Laboratories and Meconic plc.

MA facilities begin Separations work

**2003**

JM Catalysts Division created

# Quality

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Pharma Services

We are committed to providing you with the highest standard of quality. Our exemplary quality practices provide seamless, worry-free control throughout the duration of your project and beyond.

## Quality Assurance

Every step of the way, your project will be held to the same quality standards that have enabled us to achieve three decades of successful FDA audits.

- ✓ Strict control of raw material, intermediate and final API quality
- ✓ Systems to ensure compliance and continuous improvement
- ✓ Internal quality review board
- ✓ Validated software systems

## Compliance

Our commitment to quality is the foundation of long-lasting relationships that are built on trust and dependability.

- ✓ Routine FDA audits and DEA inspections
- ✓ Successful PAI audits at all US manufacturing sites
- ✓ Numerous client audits annually
- ✓ Uncompromising adherence to OSHA and EPA guidelines

## Regulatory Affairs

At Johnson Matthey Pharma Services, we offer regulatory support for any size client.

- ✓ Active commercial product lines
- ✓ Full support for regulatory filings
- ✓ Experience in supporting US, EU and world markets
- ✓ Nearly 200 DMFs filed and managed globally

Johnson Matthey Inc. celebrates its 100th year of incorporation.

**2004**

Lancaster Synthesis acquired

JM celebrates 30 years in the development of autocatalysts

**2005**

MA facilities begin High Potency operations

**2007**

JM launches "Sustainability 2017"

**2009**

Alfa Aesar China plant opens

**Gaining a competitive advantage for your API outsourcing is key. Developing the most efficient synthetic route is essential. Reliability is not negotiable. Simultaneously accessing the technologies to accomplish all three is the power behind Johnson Matthey Pharmaceutical Materials & Services.**


# Together, making a world of difference

**Sustainability 2017** is Johnson Matthey's long term vision for sustainability. It sets the direction and our aspirations for what we want to achieve in the future. Throughout the company we are committed to the principles of sustainable development and strive for outstanding resource efficiency and carbon neutrality.

Going forward, we aim to further develop and enhance sustainability as a core competence and key driver of competitiveness for our business. We aim to encourage our suppliers and customers to adopt the values of sustainability which we uphold and, for the benefit of our customers, we aim to apply our expertise to the development of a new generation of sustainable products and services.

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Johnson Matthey
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