

COMPANY PROFILE

Dishman is a global outsourcing partner for the pharmaceutical industry offering a portfolio of development, scale-up and manufacturing services. Dishman improves its customers businesses by providing a range of development and manufacturing solutions at locations in Europe, China and India. Our commitment is to deliver cost-competitive technical excellence and to be a reliable partner to our customers, protecting their interests as if they were our own.

DISHMAN GROUP

Business Unit

Dishman Contract Research and Manufacturing Services (CRAMS)

Manufacturing Locations

India, China

Business Focus

High-value, cost-competitive contract services. Process development, process optimisation, manufacture for late stage clinical and commercial supply.

CARBOGEN AMCIS

Switzerland, United Kingdom, India

High quality process research and development. API supply to support clinical trial requirements. Niche scale commercial manufacture. Highly Potent API supply.

Dishman Specialty Chemicals

India, China, Saudi Arabia

World leading manufacture of Phase Transfer Catalysts. High quality supply of intermediates, fine chemicals, and products for the pharmaceutical, cosmetic and related industries.

Dishman Vitamins and Chemicals

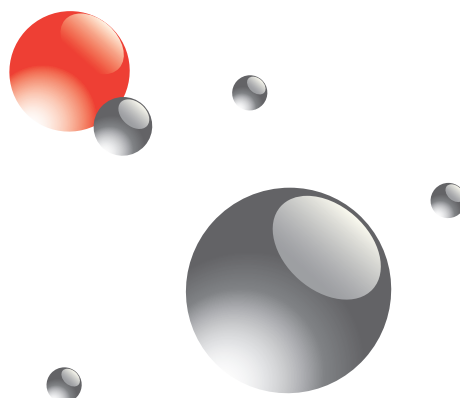
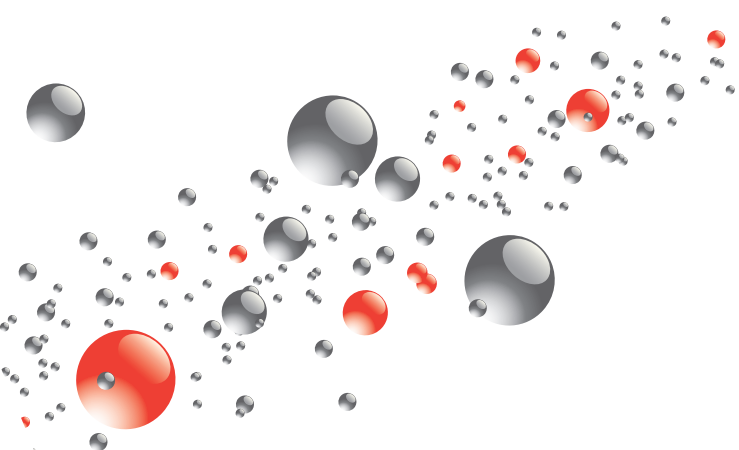
Netherlands, India

Vitamin D2, Vitamin D3, Vitamin D analogues, cholesterol and lanolin related products for pharmaceutical, cosmetic and related markets.

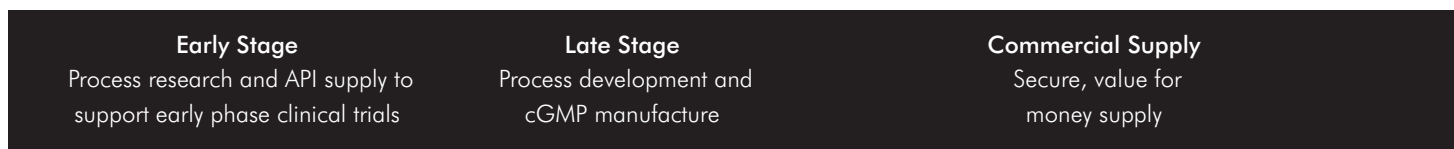
Dishman Disinfectants

India, Australasia, Saudi Arabia

Next generation innovative antiseptic and disinfectant formulations.



CONTRACT RESEARCH AND MANUFACTURING SERVICES



CARBOGEN AMCIS

DISHMAN



PROCESS OPTIMISATION AND CGMP MANUFACTURING

- Development services, kilo supply, pilot production, full scale manufacture
- Large dedicated R&D centre (with multiple shift R&D operations), cGMP pilot plants
- 12 multi-purpose and dedicated production facilities for APIs, intermediates
- 1125m³ dedicated API manufacturing capacity
- Broad range of technical skills and capabilities encompassing all routine chemistries and a wide variety of sophisticated modern technologies.

Dishman offers innovation, security of supply and value for money

QUALITY

- USFDA inspected facilities
- All sites operate to the highest international standard of quality, safety and environmental control
- Complete API regulatory support including substantial experience in generating DMFs and ECOS.

CUSTOMER SERVICE

- Dishman do business in local culture. Dishman have local representation, local support in all major markets
- Rigorous project management procedures delivered by dedicated project management personnel
- Openness throughout the customer relationship
- Communication and reporting tailored to match customer specific requirements.

RISK MANAGEMENT

- Strong, tenured leadership at corporate and local levels
- Multiple site, multiple country locations
- Strong IP protection policies
- Global supply chain and logistics support.

PARTNERSHIP

- Single partner for R&D, process development and commercial production
- Offering the best of the New World as a centre for commerce
- Offering flexible, innovative terms for partnership
- An ongoing commitment to add services and expertise valued by our pharmaceutical customers.

Dishman – Global Partnership Solutions



CONTRACT RESEARCH & MANUFACTURING SERVICES

Dishman's contract research and manufacturing services are the very core of our business. We offer a portfolio of services from process R&D, through kilo and pilot supply to full scale & commercial manufacture from purpose built and dedicated facilities.

By offering technical and manufacturing excellence in multiple locations around the globe, Dishman is **THE** global outsourcing partner for the pharmaceutical industry, providing innovative development to value-for-money, long-term commercial supply.

PROCESS R&D

Dishman offers Process R&D with a specialisation in developing processes that are truly scalable through to commercialisation, be this through Process Research, Process Development or Optimisation. We have 200 staff operating in continuous three shifts, 6 day R&D operations in state of the art dedicated R&D centres. Our promise is safe, efficient scale-up and problem solving delivering robust, economic processes.

Dishman enforces strict IP protection policies. **We protect our customers' interests as if they were our own.**

ANALYTICAL SERVICES

Analytical services support both process control and material characterisation for R&D and manufacturing operations, from initial raw material release through to the release of the final APIs. The range of our equipment is necessarily extensive, mirroring that which one would find within an integrated pharmaceutical company.



Top image: R&D centre at Bavla, India

Bottom image: Kilo plant at Bavla, India

PILOT, FULL SCALE AND COMMERCIAL SUPPLY

Dishman offers an extensive range of segregated, purpose built, kilo and pilot scale facilities for cGMP production of API. These facilities are an integral part of our R&D centres to facilitate maximum interaction and ensure seamless process transfer from laboratory to plant.

At commercial scale, Dishman offers a vast range of dedicated and multipurpose facilities for the cGMP production of APIs and intermediates.

- 12 multi-purpose and dedicated production facilities
- USFDA inspected facilities
- >1125m³ of reactor capacity
- Comprehensive range of skills and capabilities encompassing all routine chemistries and a wide range of sophisticated, modern technologies
- Multiple site, multiple country locations, all operating to the highest international standards of quality, safety and environmental control
- An ongoing commitment to add services and expertise valued by our customers.



Why is **DISHMAN** the **PARTNER** for **YOU**?

CUSTOMER SERVICE

- A relationship driven business model that invests in pharmaceutical companies rather than competes with them
- Transparency through open, responsive customer service and project management
- A continuum of services offered under flexible and innovative terms.

SECURITY OF SUPPLY

- Technical and manufacturing excellence in multiple-site, multiple country locations lever the best in cost optimisation and provide security of supply
- We protect our customers interests as if they were our own
- Strong, tenured leadership at corporate and local levels.

ADDING VALUE

- Commitment to deliver cost competitive, technical excellence
- Offering the best of the New World as a centre for commerce
- Innovative development to competitive, long term commercial supply

HIGHLY POTENT API SUPPLY

The Dishman group offer unparalleled capability in scale-up development and commercial manufacture for Highly Potent compounds. These highly potent services are offered under the CARBOGEN AMCIS business.

The Dishman group provide state-of-the-art containment services. All facilities operate to current Good Manufacturing Practice (cGMP) and can produce material for preclinical testing, clinical trials and commercial use.

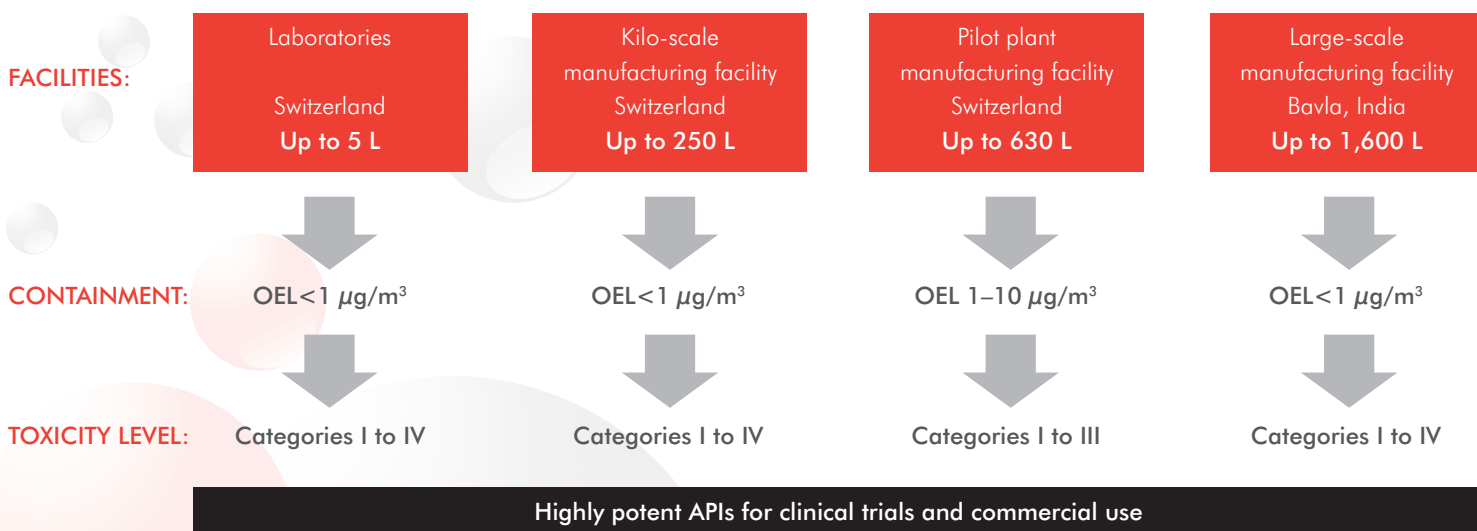
In 2008 the US Food and Drug Administration (FDA) performed a successful PAI audit of the Swiss containment facilities, concluding without any FDA-483 observations.

All of the containment facilities are designed based on a containment concept utilizing the "split-butterfly valve" and barrier isolation technology, which thus allows the safe handling of highly potent compounds of all categories, including cytostatics/cytotoxics.

The Dishman group offer services starting from laboratory scale for process research and development purposes, up to large-scale manufacturing on 630 L in Switzerland, as well as 1,600 L scale in Bavla, India, including category IV compounds ($OEL < 1 \mu g/m^3$).

To support the Active Pharmaceutical Ingredient (API) development process through all stages, a variety of high-containment analytical and purification capabilities complement the chemistry service portfolio.

HIGHLY POTENT API SUPPLY



SAFETY AND PRODUCT QUALITY

The Dishman group is fully committed to managing the risks associated with handling and producing highly potent and/or toxic materials. Safety and quality considerations encompass our personnel, our customers and patients using the materials we produce, as well as the environment and our neighbours. We are dedicated to maintaining and improving safety, environmental and health standards above and beyond the standard legal requirements. This remains the responsibility of both our management and individual employees. All processes follow our “protection cascade” of four increasing levels of containment technology systems and procedures, ensuring that worker safety and product quality are never compromised.

In addition, a rigorous system of Standard Operating Procedures (SOPs) and Unit Operation Procedures (UOPs), supplemented by extensive worker training, enhance safe working processes and awareness of potent compound safety.

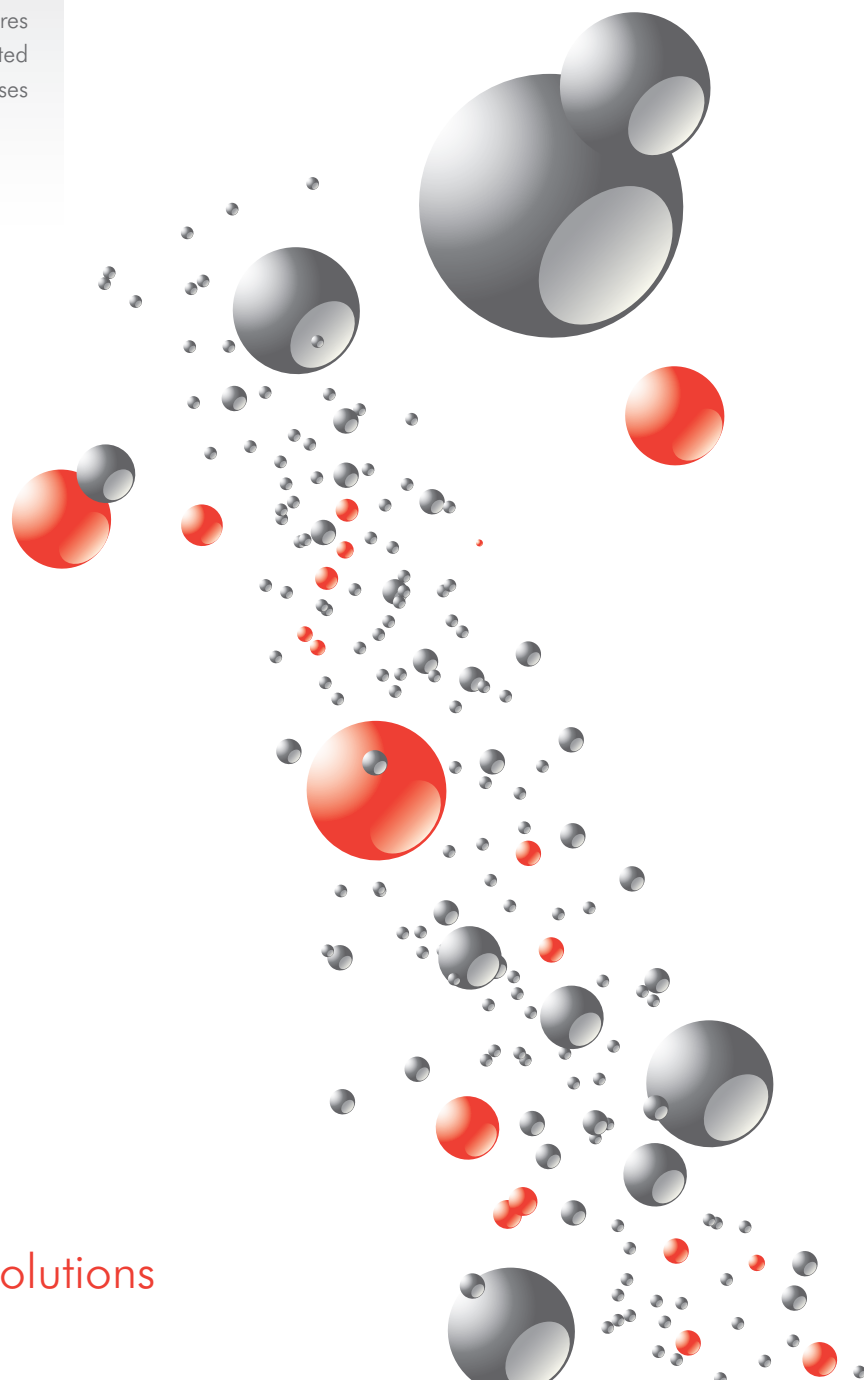
SOPs, UOPs, DOCUMENT SYSTEMS, TRAINING

LEVEL 4: Occupational health monitoring and back-up Personal Protective Equipment

LEVEL 3: Room and associated environment

LEVEL 2: Containment

LEVEL 1: Process system



TECHNOLOGY TRANSFER – CASE STUDIES

The Dishman group is a global, multi-site, multi-location organisation, offering our customers the opportunity to obtain a comprehensive range of chemical and manufacturing solutions from one single supplier. This extends from rapid Active Pharmaceutical Ingredients (APIs) supply for preclinical and clinical use (through CARBOGEN AMCIS) to large-scale manufacture of intermediates and APIs. An efficient technology transfer process is the key for a successful transfer either from the customer to Dishman or among the Dishman group sites.

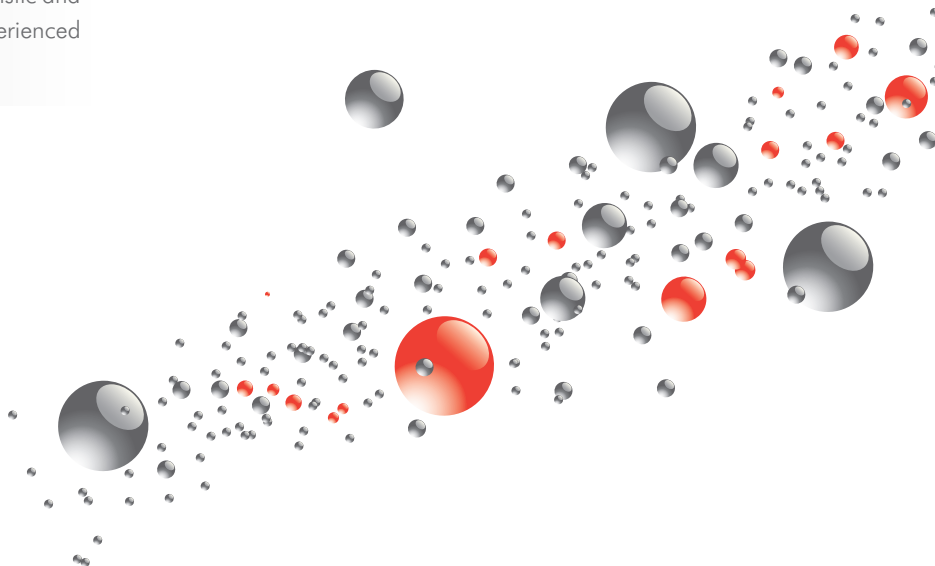
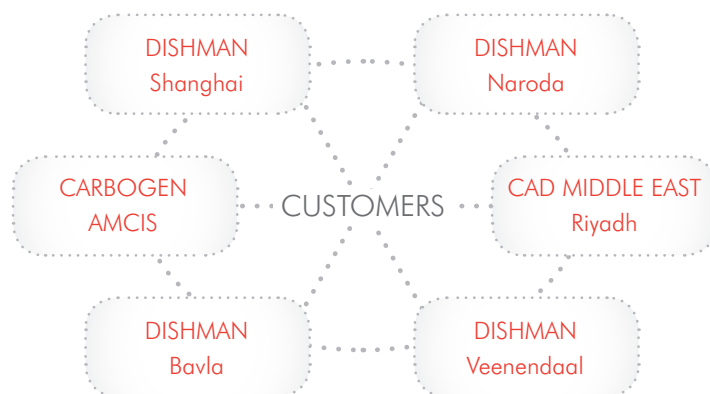
TECHNOLOGY TRANSFER PROCESS

Complex, multi-step processes under both Good Manufacturing Practice (GMP) and non-GMP have been successfully transferred. A specialist team follows an established three-stage procedure:

- 1. Initiation:** the scope and goals are agreed upon by all parties – preparation of technology transfer master plan, definition of responsibilities, as well as preparation and transfer of technical information package;
- 2. Piloting:** the process is trialed in the lab and in small production runs and extensively reviewed – compliance with regulatory and quality standards; and
- 3. Sign-off:** the mutually agreed process is accepted by all parties – production against established batch instructions. A crucial element in successfully transferring technology processes across linguistic and cultural barriers is frequent communication involving our experienced personnel.

Clear definitions of the responsibilities of the technology transfer team members during the transfer process minimize the time and effort needed for this critical step in the successful scale-up of intermediates or APIs.

Dishman can also offer technology transfer for our own processes which will enable our customers to produce their APIs with our technologies.



CASE STUDY 1:

Cost Advantages and Continuous Local Management

The first three steps from a registered process, previously run in Switzerland on 1,600 L scale, were successfully transferred to operations in India within a timeframe of five months. The intermediate of an API which goes generic in a few years required us to provide larger quantities of intermediates at lower costs. The process is now being performed on a scale up to 4,000 L with the intermediate being sent to Switzerland for further conversion to the final API. This approach offers the maximum flexibility in handling the cost and quantity demands of the product in development and commercialisation life cycles. The customer benefits from cost advantage and continuous local project management.

CASE STUDY 2:

Customer dedicated facilities

A large, multinational pharmaceutical company required significant cost of goods reduction to deliver a market leading drug product.

Dishman optimised the process and built a dedicated facility for the API production. Dishman further reduced costs by developing its own more cost-effective routes for the three key starting materials. An overall cost reduction of more than 50% was achieved. Routine commercial manufacture is now ongoing at the Bavla site, offering the customer significant cost advantages and a simplified and secure supply chain.

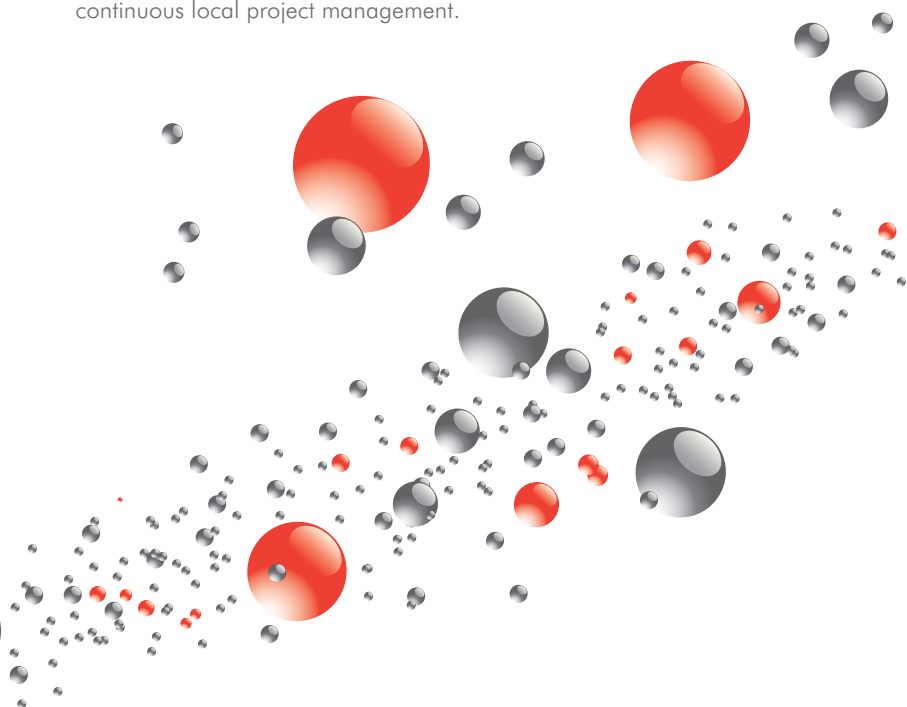
CASE STUDY 3:

Commercialisation from a Laboratory Process within 12 months

A European Speciality Pharmaceutical company approached Dishman for the contract manufacture of a late life cycle API. The Client had a non-infringing laboratory scale process for the API which needed optimisation and scale up to commercial production.

The process was transferred & then optimised at an R&D level. This was followed by pilot scale validation batches and then 10mT commercial production within 9 months of initiating technology transfer.

During the commercial production, alternative, more cost effective supply solutions were found for key starting materials & these were incorporated into production post validation. An agreed regulatory programme was completed and Dishman provided the Client with a full technical dossier to enable regulatory filings. As a consequence of the success of this program, the Client has transferred a further 3 projects into the Dishman group.



Dishman (Headquarters)

Bhadr-Raj Chambers, Swastik Cross Road
Navrangpura, Ahmedabad - 380 009
Gujarat, INDIA

Tel: 91 (79) 26443053

Fax: 91 (79) 26420198

www.dishmangroup.com

