CARBOGEN AMCIS

A Dishman Group Company

BRINGING YOUR SCIENCE TO LIFE

Company Profile

Welcome to CARBOGEN AMCIS

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CARBOGEN AMCIS HQ, Bubendorf, Switzerland

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About Us

CARBOGEN AMCIS is a leading service provider CDMO, offering a portfolio of drug development and commercialization services to the pharmaceutical and bio-pharmaceutical industries at all stages of drug development.

Our integrated services for Drug Substances (DS) and Drug Products (DP) provide innovative solutions to support timely and safe drug development.

Besides being a service provider, we also offer high quality Cholesterol and Vitamin D analog products produced at our facility in The Netherlands. These products are used in a variety of markets around the globe.

Curious to know what a customer journey at CARBOGEN AMCIS could look like? Watch our video.

Drug Substance

Gain from our strong experience in API development and manufacturing.

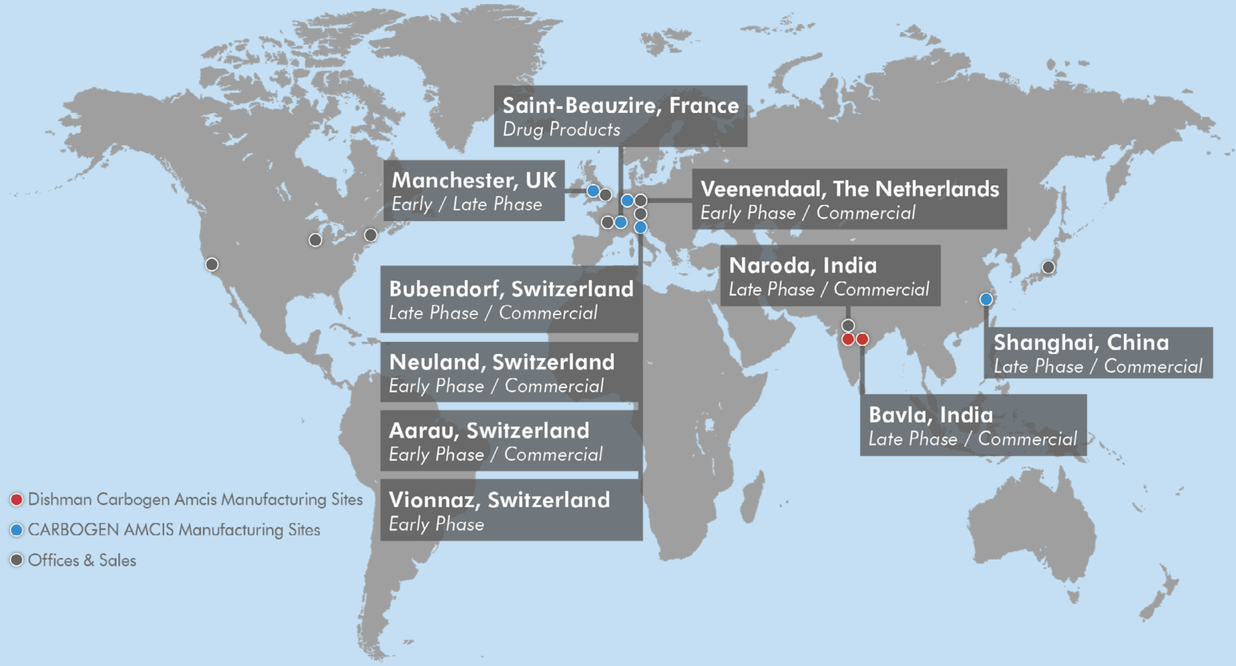
Sterile Drug Product

Benefit from our state-of-the-art facility for development and manufacturing of your injectable Drug Product.

Specialities

Discover our Specialties from GMP cosmetics to high quality Cholesterol and Vitamin D analog products.

All Around the World



Company Profile

Our flexible approach enables customers to benefit from tailored packages of work which balance their needs in terms of speed, cost and quality. We also adapt our communication and reporting to match customer-specific requirements and documentation.

"CARBOGEN AMCIS is full of people passionate about process chemistry, inter-project collaboration is actively encouraged and the availability of highly skilled people to help problem solve is very reassuring. There is continued investment in facilities and resources to offer the best service to customers."

John – Project Chemist

Process Research & Rapid Supply of APIs

Early phase Active Pharmaceutical Ingredient (API) manufacture centers on the rapid synthesis of supplies necessary to perform both toxicology and early phase clinical trials. Typical batch sizes here range from 1 gram to 50 kg scale and are prepared in the highest standard of cGMP.

We also have an extensive toolbox including micro-reactor technology, spray drying, lyophilization, milling and wet-milling and a range of chromatography techniques (SMB, HPLC, MPLC, TFF, Biotage). The combination of tools and experienced personnel allows CARBOGEN AMCIS to solve complex chemistry issues and to provide rapid supply of initial quantities of APIs.

Process Optimization & cGMP Manufacturing

Process optimization skills are critical in ensuring a safe and efficient scale-up from development scale to routine cGMP and eventual commercial API manufacture.

We offer experience with a broad range of organic chemistry reactions. This consists of a diverse selection of routine chemistries as well as a wide variety of sophisticated modern technologies, including low temperature and high pressure reactions, metallo-organic reactions, peptide synthesis, and chiral synthesis etc.

Pharmaceutical Intermediates Supply

The CARBOGEN AMCIS Manchester and Shanghai facilities focus on process research and the synthesis of pharmaceutical intermediates. The large-scale production capacities (up to 8,000 L) allow the efficient production of non-GMP intermediates that can be further processed at the CARBOGEN AMCIS Swiss facilities.

Manufacturing of Drug Products

Our site in Saint-Beauzire, France, offers custom development and automated aseptic production of liquid and lyophilized drug products, with a specialization in developing sterile and pyrogen-free parenteral formulations for preclinical and clinical trials (phases I, II and III) and small scale commercial. With this end-to-end service, CARBOGEN AMCIS is your partner of choice for complex and demanding products that require the highest level of quality in our industry.

Analytical Services

Analytics provides the foundation for process research and manufacturing activities. A thorough understanding of reactions is critical in process development and validation work. Analytical chemistry services support both process control and material characterization for laboratory and production chemistry, from initial raw material release to the release of the final APIs and the Drug Products.

Moving Toward Full-Scale API Manufacturing

The Shanghai facility can offer large scale production for API Manufacturing. As part of the Dishman Carbogen Amcis Group, CARBOGEN AMCIS can also provide solutions for internal technology transfer to FDA-approved large-scale production facilities in India.

Products Sales Cholesterol & Vitamin D Analogs

CARBOGEN AMCIS is active in the manufacturing, marketing/sales and distribution of Vitamin D analogs, Vitamin D2, Cholesterol and Lanolin derivatives, used in pharmaceuticals, cosmetics, feed, food, shrimp farming and industrial applications.

We have more than 70 years of experience in the development, production, and worldwide sales of these ingredients. Our production site in Veenendaal is operated under cGMP regime, is certified as EU GMP, and classified as acceptable by US FDA for API manufacturing.

Highly Potent API Supply

CARBOGEN AMCIS provides services for the development and manufacture of highly potent drug substances (APIs) and drug products applying state-of-the-art containment technologies. All facilities operate to current Good Manufacturing Practices (cGMP) and can produce material for preclinical testing, clinical trials and commercial use. Our manufacturing sites are regularly inspected by the US Food and Drug Administration (FDA) and local regulatory authorities.

Our containment facilities are designed based on a containment concept utilizing barrier isolation technology and Rapid Transfer Ports (RTPs) as well as a strict zone concept with pressure cascades, airlocks and access controls. This allows the safe handling of highly potent compounds including cytotoxics. We offer services starting from laboratory scale for process research and development purposes up to large scale manufacturing in 1'600 L vessels.

> ***"My work has a daily impact on many people, as we continually strive to increase the company level of health and safety whilst minimising our environmental impact."***
>
> **Gavin** – Head of ESH

Highly Potent API Supply

The highest category in CARBOGEN AMCIS' categorization system is category 4 with an Occupational Exposure Limit (OEL) range of 1 - 0.05 $\mu g/m^3$. However, recent containment testing performed according to *ISPE's *SMEPAC-guideline, has shown that CARBOGEN AMCIS can safely handle ultra-potent toxins with an OEL as low as 0.01 $\mu g/m^3$ (10 ng/m^3) 8hr-TWA. Very highly potent toxins with an OEL of 10 ng/m^3 are often used as warheads for new generation targeted cancer treatments such as ADCs.

*ISPE = International Society for Pharmaceutical Engineering
*SMEPAC = Standardized Measurement of Equipment Particulate Airborne Concentration

In addition to our process research and manufacturing services for the fast supply of highly potent APIs, we offer conjugation services for Antibody Drug Conjugates (ADCs) as well as fill-and-finish and freeze-drying services for drug products.

Highly Potent API for (Pre)Clinical Trials & Commercial Use

Switzerland	Up to Category 4 OEL down to 0.05 $\mu g/m^3$	Laboratories Up to 30 L
	Up to Category 4 OEL down to 0.05 $\mu g/m^3$	Conjugation Laboratories Up to 20 L
	Up to Category 4 OEL down to 0.05 $\mu g/m^3$	Large-Scale Manufacturing Facility up to 850 L
	Up to Category 3 OEL down to 1 $\mu g/m^3$	Pilot Plant Manufacturing Facility up to 1,600 L
Bavla India	Up to Category 4 OEL down to 0.05 $\mu g/m^3$	Large-Scale Manufacturing Facility up to 1,600 L
Shanghai China	Up to Category 3 OEL down to 1 $\mu g/m^3$	Large-Scale Manufacturing Facility up to 6,300 L
Saint-Beauzire France	Up to Category 4+ OEL down to 0.05 $\mu g/m^3$	Sterile Drug Products up to 50,000 units

NB: Containment is ensured through rigid barrier isolation systems and flexible segregation of key equipment. Results are validated by containment testing performed according to ISPE's SMEPAC-guideline.
* Result of surrogate containment testing: 0.01 $\mu g/m^3$

Safety & Product Quality

We are 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 neighbors. 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.

Scientific Specialities

CARBOGEN AMCIS exists to provide innovative solutions for drug development and supply to the pharmaceutical and bio-pharmaceutical industries that enable customers to bring new generation medicines to market.

We have built up a portfolio of specialist services to give our customers the highest degree of flexibility possible.

"We advise our customers on the best conjugation strategy to successfully manage projects from drug-linker synthesis to final drug product manufacturer."

Luca – Manager ADC

Bioconjugation & Antibody Drug Conjugates

We have successfully managed numerous drug-linker projects. Many customers, ranging from small biotech to large pharmaceutical companies, expressed a growing interest in our ADC and bioconjugation abilities. We have handled projects from payload/warhead manufacture to drug-linker, then to conjugation and final drug product all in house.

Our clean room suites are fully qualified for cGMP manufacturing dedicated to bioconjugation. In conjunction with our state of the art purification technologies, exceptional analytical/fill-and-finish capabilities, our customers are also provided with regulatory and CMC support.

Chromatography

Chromatography often forms part of a fast route to producing initial quantities of material. We offer customized chromatography solutions for the separation and purification of APIs and intermediates, including highly active APIs and impurity isolation. Our dedicated group of chemists have great experience in method development and scale-up in a variety of different chromatographic techniques, all in accordance with current Good Manufacturing Practice (cGMP) environment.

CARBOGEN AMCIS offers Flash Chromatography (Biotage), SMB and HPLC to effectively produce clinical trial quantities of APIs and commercial products.

Ultrafiltration & Nanofiltration

This technique allows concentration of large chromatographic fractions under very mild conditions. In combination with lyophilization, this technique gives access to isolation of highly instable compounds.

Micro-reactors & Flow Chemistry

Micro-reactors and flow chemistry technology are currently used on a number of projects in parallel with conventional chemistry. Micro-reactors offer solutions where classical methods reach their limits. Examples are highly energetic reactions or unstable intermediates. Whilst the size of the vessels is small, the continuous processing allows this technique to produce material also at an intermediate scale.

Small scale flow chemistry may help to overcome technical limitations on conventional large scale production and makes syntheses more controllable with regards to temperature, pressure or concentration. It will help to optimize the production process by widening the possible range of parameters (process intensification) and opens the doors for new chemical prospects.

Crystallization Services

Defining the best crystalline form of an Active Pharmaceutical Ingredient (API) is crucial in drug development, since it has a significant impact on its bioavailability and formulation properties. CARBOGEN AMCIS has established a service supporting our customers with crystallization investigations including solubility tests, salt screening, and optimization of the crystallization process and the solid/liquid separation in the API isolation process. Polymorphism screening complements the service portfolio. We offer online monitoring of critical parameters such as particle size, turbidity, temperature, and pH value, as well as analytical services dedicated to solid phase characterization including hot stage microscopy, differential scanning calorimetry, Dynamic Vapor Sorption (DVS) and x-ray powder diffraction.

Technology Transfer – Case Studies

As part of a multi-site, transcontinental organization, we offer our customers the opportunity to obtain a comprehensive range of chemical and manufacturing solutions from a single supplier. This extends from rapid supply of intermediates and Active Pharmaceutical Ingredients (APIs) for preclinical use, to large-scale commercial manufacturing. An efficient and effective technology transfer process is the key to the successful transfer of processes either from the customer to CARBOGEN AMCIS or between two CARBOGEN AMCIS sites.

Our technology transfer expertise is a key element in our ability to take advantage of the economies of scale and lower cost base associated with the CARBOGEN AMCIS high potency plants in India and China.

Technology Transfer Process

Complex, multi-step processes under both current Good Manufacturing Practice (cGMP) and non-GMP have been successfully transferred. For transfer outside of Switzerland, 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 trialled in the lab, analytical method transfer is completed, along with the key change review and pre-manufacturing review processes to ensure compliance with regulatory and quality standards. Finally trial batches are produced;

3 **Sign-off:** the trial campaign is reviewed in detail, any further learning implemented, and the transfer signed off. Routine production follows against established batch instructions.

A crucial element in successfully transferring technology across linguistic and cultural barriers is the quality of the communication between our experienced personnel, alongside clear definition of roles and responsibilities.

Where it provides benefits, team members from the transferring site are present at the receiving site, for example for project kick-off, and during production start-up.

Case Study 1:

Reduced lead time and cost with continuous local project management

The first 4 steps of an eight stage registered process, previously run in Switzerland on 1,600 L scale, were successfully transferred to operations in India within a timeframe of 5 months. The transfer was mainly driven by growth in product volume coupled to the need to reduce overall lead times. The process is now executed in India at 4 times the previous scale, allowing us to make significant reductions in both cost and lead time. The intermediate is sent to Switzerland for conversion to the final API with no measurable difference in quality. This approach offers the customer flexibility in managing cost and quality demands without draining their own resources.

Case Study 2:

Product lifecycle management

A 3-stage process to manufacture a launched API for a US customer had been successfully running in Switzerland for over 10 years. To support the customer in the generic market with lower costs, the exact process was transferred to India. Following regulatory approval of the change of site, the customer will benefit from a more economic source of the API with identical quality, while the supply chain is maintained with ongoing manufacture in Switzerland.

Case Study 3:

Cost and feasibility aspects

A multistage production process for a non-GMP intermediate was performed at CARBOGEN AMCIS' Manchester site for a Japanese customer. Subsequent transfer to India was successfully accomplished, and the process was subsequently scaled up to 300 kg batches in a multi-ton campaign within 6 months. A chemist from Manchester supported the transfer on-site. In this case the transfer was driven mainly by the scale of production, but the customer also obtained a cost advantage from the increased scale at the new site.

Production Equipment

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CARBOGEN AMCIS delivers leading process research services that support the drug development process. Early Active Pharmaceutical Ingredient (API) manufacture centers on the rapid synthesis of supplies necessary to perform both toxicology and early phase clinical trials. Typical batch sizes here range from 1 gram to 50 kg scale and are prepared in the highest standard of current Good Manufacturing Practices (cGMP).

We have over 20 years' of experience in the supply of APIs for clinical trials and commercial production and are specialized in the multi-step cGMP manufacture of APIs (20 kg to 2000 kg). The goal is to supply our clients with market-ready quantities of APIs including drug master files and regulatory documentation. Our services are tailored to the individual needs of each client from initial route finding through to cGMP production.

Process Research & Development

We currently have more than 100 hoods available for PR&D and production support activities. The state-of-the-art infrastructure including double jacket reactors, lab automation and micro-reactor capabilities ensures an efficient and comfortable working atmosphere.

Our chromatography and crystallization services provide an invaluable resource in producing and isolating material without recourse to excessive development time or costs.

Production & cGMP Manufacturing

We are highly experienced and equipped for handling a broad range of organic reactions embracing sophisticated modern technologies including low temperature reactions, organometallic reactions, chiral synthesis and hydrogenation at elevated temperatures.

Our purification capabilities applying chromatography or distillation allow an efficient synthesis of your compounds.

Our equipment includes:

- More than 80 multi-purpose reactors from 6 L to 8'000 L, glass-lined, Hastelloy, and stainless steel in a temperature range from -100°C to +160°C
- More than 10 filter dryers (0.15 m^2 to 1 m^2 Hastelloy)
- 400 L temperature-controlled pressure filter dryer (Hastelloy)
- High temperature reactor (200 L) in a temperature range from -120°C to +350°C
- High-Pressure autoclaves, pressure range up to 20 bar
- High vacuum distillation, 200 L to 900 L, 40 theoretical plates
- 6 cryogenic reactors 10 L to 3'000 L (< -70°C)
- Horizontal Pharma-Peeler Centrifuge, Diameter 630mm
- Lab automation system
- Milling and wet-milling
- Micronization
- Freeze dryers up to 30 kg ice per run


Bubendorf


Vionnaz


Shanghai


Neuland


Aarau


Manchester

Analytical Equipment

We internally optimize each site with all the equipment necessary to help your project to become a success. We provide un-paralleled analytical support for research, development and commercial production of late-stage intermediates and APIs, including pre-formulation studies to support drug product development.

"We support our customers during and beyond the project by advising them on how to improve the process and the quality of the drug."

Darja – Chemist QC&A

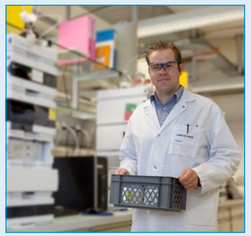
Analytical Services

Analytics provides the foundation for process research and manufacturing activities. A thorough understanding of reactions is critical in process development and validation work.

CARBOGEN AMCIS has always strived to provide a comprehensive range of tools and techniques to facilitate this work. Analytical chemistry services support both process control and material characterization for laboratory and production chemistry from initial raw material release to the release of the final APIs.

ICH Stability studies:

- 25°C / 60% r. H.
- 30°C / 65% r. H.
- 40°C / 75% r. H.
- 5°C
- - 20°C
- - 80°C



Our equipment includes:

- 3 NMR (400 MHz; H, C, P, F, N)
- 79 HPLC (DAD, ECD, ELSD, RI, MALLS, VWD, CAD
- 14 UHPLC
- 6 HPLC-MS (single Quad)
- 1 HPLC-MS/MS (Ion trap) AAPI, APCI, ESI
- 26 GC (ECD, FID, NPD, TCD, Head Space)
- 1 GC-MS (single Quad)
- 1 GC-MS (triple Quad)
- 6 DSC
- 2 RC1
- 5 FTIR (ATR, KBR, DRIFT)
- 6 UV-Spectrophotometers
- 3 TGA
- 4 Polarimeters
- 2 Particle Sizer
- 6 Ion Chromatographs (conductivity) - 3 anionic and 3 cationic
- 7 Automated Titrators
- 2 Densitymeter
- 3 Refractometers
- 2 XRPD
- 1 Capillary Electrophoresis
- 1 ICP/OES for metal analyses
- 1 Small scale jet mill
- 1 Water activity and moisture analyzing instrument
- 1 Dynamic vapour sorption analyzer
- 2 Microscopes

Highly Potent API Supply Equipment

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•• Our state-of-the-art infrastructure includes process research and development (PR&D) laboratories and, one laboratory dedicated to conjugation of small and large molecules and manufacturing capabilities.

The specialized laboratories and kilo-scale manufacturing equipment for small batch sizes of up to 15 kg are designed to operate safely at 0.05 µg/m³ OEL*. This performance allows safe handling of highly potent compounds, including cytotoxic warheads applied in antibody drug conjugates (ADC). Our intermediate and large scale manufacturing equipment currently operates down to 1 µg/m³ OEL (Switzerland) or down to 0.05 µg/m³ OEL (India) on a scale up to 1'600 L producing batches in the 200 kg range.

Our facilities & equipment include:

Bubendorf, Switzerland

•• 4 PR&D laboratories proven to operate below below 0.05 µg/m³ OEL; (grade D) * The facilities enable process development for up to 8 projects in parallel and/or up to 3 lab scale cGMP projects in parallel.

•• Conjugation laboratory with Grade C and D areas designed to operate below 0.05 µg/m³ OEL

•• Kilo-scale manufacturing facility designed to operate below 0.05 µg/m³ OEL Air Cleanliness Class ISO 7 (Class 10'000) *

- 4 Reactors from 100 L to 250 L (hastelloy and glass-lined), temperature range from -100°C to +160°C, pressure up to 12 bar
- Hastelloy Filter Dryer with glove box (0.125 m²)
- Hastelloy Filter Dryer with glove box (0.22 m²)

•• Intermediate-scale production facility designed to operate down to 1 µg/m³ OEL by utilizing Rapid Transfer Ports (RTPs), barrier isolation technology and flexible containment of technology

Key equipment:

- Reactors from 250 L to 1'000 L, temperature range from -100°C to +160°C, pressure up to 20 bar
- Hastelloy Filter Dryers (0.25 and 0.4 m²)

Vionnaz, Switzerland

•• PR&D labs designed to operate down to 0.05 µg/m³ OEL. The facilities enable process development for up to 3 PR&D projects in parallel

•• Pilot plant unit (10, 15 and 30 L) designed to operate down to 0.05 µg/m³ OEL (up to about 1 kg). The facilities enable process development for up to 2 cGMP projects in parallel.

•• Chromatography suite equipped with Asahi/Kasei System to enable running MPLC and HPLC up to 15 cm

•• Lyophilization capability with up to 30 kg ice designed to operate down to 0.05 µg/m³ OEL

Hunzenschwil (Neuland), Switzerland

•• PR&D laboratory designed to operate down to 1 µg/m³ OEL

•• Intermediate-scale production facility designed to operate down to 1 µg/m³ OEL

- 4 Glass-lined reactors of 630 L (2x) and to 160 L (2x), pressure up to 6 bar
- 2 Filters (0.28 m² and 0.16 m²)

* Performance of the equipment and trained operators was demonstrated down to levels of 0.01 µg/m³

Analytics of Highly Potent APIs

•• NMR •• HPLC (SEC-UV, GPC-MALLS, HPLC-MS) •• GC (FID, Headspace) •• pH meter •• UV/VIS •• IR (KBr pellet) •• KF-determination •• DSC (closed pan only) •• Heavy metals •• Residue on ignition •• Optical rotation •• RC1 ••

•• Access to crystallization development and screening for metastable zones in closed vials

•• Access to powder X-ray diffraction and particle size determination

•• Malvern particle size distribution (PSD)

Purification of Highly Potent APIs (Bubendorf)

•• Chromatography suite dedicated to highly potent APIs

- 3 Multipurpose Walk-in-Barrier Hoods
- Preparative Chromatography (up and prep. HPLC up to 15cm)

•• Tangential Flow Filtration for macromolecules from 10's to 100's of kilo Dalton

•• Gel Permeation Chromatography for the removal of aggregates and higher molecular impurities

Drug Products

CARBOGEN AMCIS
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Welcome to CARBOGEN AMCIS, where innovation meets excellence in drug product development and manufacturing. Our commitment to advancing pharmaceutical solutions extends beyond Drug Substance services, as we are dedicated to fostering continuous growth in our Drug Product capabilities.

In Saint-Beauzire, France, our cutting-edge facility boasts two state-of-the-art sterile production lines, meticulously designed and validated in accordance with the latest Annex 1 standards. Furthermore, our site houses a newly established 350m² development laboratory, meticulously segmented into two specialized areas - one dedicated to analytical functions and the other focused on formulation and process development. In 2025 the site was GMP certified by the French regulatory authority ANSM.

At CARBOGEN AMCIS, we embark on the comprehensive journey of your new injectable Drug Product, offering a full spectrum of formulation development services for both liquid and lyophilized products with full commitment to excellence.

Our capabilities encompass the entire spectrum of parenteral formulations, spanning small molecules, cytotoxics, proteins, peptides, enzyme inhibitors, antibiotics (non-beta-lactam), vaccines (non-live), mAbs, and antibody-drug conjugates (ADC).

Drug Products Services Offer

- Formulation
- Process
- Lyo cycle optimisation

- Regulatory strategy
- Filing Writing

- From Phase 1 to commercial
- Scale up & commercial transfer
- Validation & life cycle management

- Liquid
- Injectable lyo
- Conventionnal & complex compounds

- Quality control
- Stability ICH

Why choose us?

Highly Potent
Handling molecules up to category 4+, including biologics, peptides and ADCs

Dedicated Team
A multi-disciplinary and extensively experienced team

Challenging Formulations
Experience in handling poorly soluble APIs

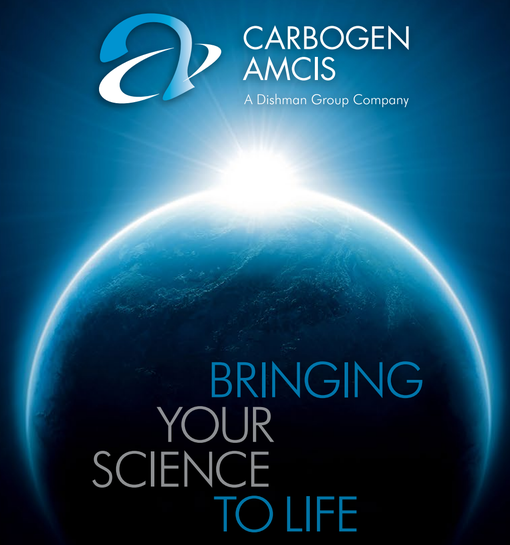
Formulation Development
Lyophilized and liquid forms

Aseptic Manufacturing
Technical and clinical batches

Complex Processes
Viscous Formulation or particle generation

Drug Delivery System
Nano/Micro particles and spheres

Analytics & Microbiological Testing
State-of-the-art analytical platform



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