CARBOGEN AMCIS

A Dishman Group Company

BRINGING YOUR SCIENCE TO LIFE

Development and Aseptic Production of Drug Products

About Us

CARBOGEN AMCIS
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At CARBOGEN AMCIS SAS we have developed a comprehensive range of services for the formulation and aseptic production of parenteral drugs for non-GMP manufacture, GMP clinical (phases I, II and III) and commercial supply.

We have gained experience in developing formulations and processes for highly potent APIs including Cytotoxics, Cytostatics, Peptides, Biologics both for liquid and lyophilized Drug Products.

Much of our experience is in the area of highly potent drug products and antibody drug conjugates (ADC), both addressing the rapidly growing oncology sector.

"In our state-of-the-art facility, as a production technician, I thrive on teamwork and the diverse challenges that come my way. Every day brings new opportunities to make a difference to the patient who will receive the final treatment."

Coralie – Production Technician

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 of molecules up to category 4+ such as Biologics, Peptides & 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 Manufacture
Technical and clinical batches

Complex Process
Viscous Formulation or particle generation

Drug Delivery System
Nano/Micro particles and spheres

Analytics & Microbiological Testing
State of the art analytical platform

From Drug Product Development to Manufacturing

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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.

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

CARBOGEN AMCIS specializes in ADC strategies, providing expertise in every aspect.
Watch our video.

Formulation and Process Development

The program of development is specifically designed for each API to meet customer's objectives whether for preclinical or clinical use.

- Formulation development/re-formulation
- Stress study (heat, light, air...), excursion time and freeze-thaw studies
- Selection of packaging components
- Selection and validation of sterilizing filter membrane
- Process development (incl. compatibility with process components)
- Freeze drying cycle development
- Liquid formulation development
- Stability in-use and short/long term stability studies

Analytical Development

We have a dedicated analytical team experienced with the development and validation of analytical methods.

- Technology platform available on-site:
  - UV-Vis, HPLC including RP, SEC, RI
  - pH, O2, osmolality
  - Particle size and viscosity
  - Endotoxin, bioburden, incubators and safety cabinets
  - CCIT
- ICH stability studies

Manufacture of Technical and Clinical Batches Non-GMP Manufacture:

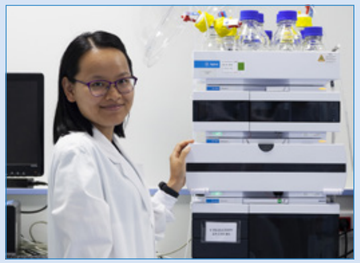
Following successful completion of the development, the process will be scaled-up and validated prior to its transfer to the GMP suite. Technical batches are manufactured to demonstrate the process is fit for purpose and to provide our customers with representative material.

- Process scale-up and demonstration batches
- Validation of aseptic process (media fill testing)
- Technical batches with low-bioburden for use in stability or toxicology studies

Clinical Manufacture:

The availability of flexible isolator technology in our GMP Suite allows the manufacture of a variety of cGMP material for clinical use.

- Liquid or Lyophilised
- Vials (from 2R to 100R) or Prefilled syringes
- Clinical batches (phases I, II and III and commercial))
- Filling line: up to 3,600 units per hour




Development Capacity


Production Capacity

State-of-the-Art Facility

CARBOGEN AMCIS expanded services and capacities for the manufacture of Drug Products with a new state-of-the-art facility. This new site is able to supply both clinical batches up to phase III and small-scale for commercial with the ability to handle complex formulations, including a large range of APIs from biologics to highly potent compounds.

The site is equipped with two automated lines: the first one for both liquid filling plus lyophilization and the second one dedicated to liquid forms. In addition, state-of-the-art development and analytical laboratories are incorporated to support customer projects.

New site in Saint-Beauzire, France

Manufacturing Capacities

Building 9500 m² – All inclusive – Clinical and niche commercial supply

- Two production lines
  - Line 1: Liquid and lyophilized forms – Vials only
  - Line 2: Liquid only – Vials, Prefilled Syringes and Cartridges
- Technology: Skan (isolators), Bausch + Ströbel (filling lines), HOF (lyophiliser)
- Capacities
  - Filling line: up to 3,600 units per hour
  - Lyophilizer: starting with 30,000 units – Max batch size up to 45,000 units over 2 shifts
- Packaging format: Vials from 2R to 100R & Prefilled syringes from 1 to 10ml
- Special features:
  - Hipo API (incl. Toxins)
  - Viscous products
  - Inert atmosphere
  - Aseptic formulation
  - Low temperature

Annex 1 Compliance

- Concept CCS: Contamination Control Strategy (Annex1)
  - Filling in grade A under isolators (grade C surrounding) : no RABS
  - Fully automated loading-unloading of the Lyo under Grade A isolator
  - Stoppers & caps as RTU (pre-sterilized) with aseptic connection RTP port
  - Single use pre-sterilized assemblies for product flow
- Concept CCCS: Cross Contamination Control Strategy (multiproducts facility)
  - Operations under full containment
  - «Single use » for all items that are in direct contact with product (formulation/filling)
  - One HVAC / room + specific cascade pressure design (negative pressure rooms)
  - External cleaning- automated in-line- of the vials after lyo unloading.
  - Individual 100% in-line datamatrix vials encoding (invisible UV ink)
- MFT strategy
  - Global Lead Time validated in MFT is 6 Days → 4 days (96h) max lyo cycle duration
  - Format validated : based on risk analysis, worse case format is challenged – covering 2R/4R/6R/10R/20R

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Bubendorf (Headquarters)
CARBOGEN AMCIS
Hauptstrasse 171
CH-4416 Bubendorf Switzerland
drugproduct@carbogen-amcis.com
www.carbogen-amcis.com