CARBOGEN AMCIS

A Dishman Group Company

BRINGING YOUR SCIENCE TO LIFE

Development & Aseptic Production of Drug Products

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At CARBOGEN AMCIS SAS we have developed a comprehensive range of services for the formulation of New Molecular Entities (NMEs) and aseptic production of parenteral drugs for preclinical and clinical trials (phases I, II and III).

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

"It's rewarding to be able to help manage projects and to watch them develop into the production stage successfully. Each project is unique so you're faced with new challenges to overcome each day which breaks up the daily routine."

Emmanuelle – Pharmaceutical Development Project Leader

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 50R) or Prefilled syringes
- Clinical batches (phases I, II and III)
- Up to 4,500 vials and even more in the future

Flexible Business Model

We support our customers through all stages of injectable drug product development, including the supply of technical and clinical batches. Our flexible approach allows us to also work on specific parts of a project to help our customers to meet their objectives, e.g:

- Process development done at CARBOGEN AMCIS with subsequent transfer to a third party for manufacture
- Implementation of developed processes in our GMP facility
- Trouble shooting
- And many more...

The program of work is designed to meet our specific customer's needs.

Our Service Offerings:

Preclinical and Clinical Studies

- Complex products
- Highly potents
- Biological products including ADC

Track Records Since 2000:

- > 500 Batches produced under cGMP environment
- > 193 Clinical batches
- > 142 Media fill tests

Why choose us?

Highly Potent
Handling of category 3 and 4 molecules such as Biologics, Peptides & ADCs

Challenging Formulations
Experience in handling poorly soluble APIs

Aseptic Manufacture
Technical and clinical batches

Drug Delivery System
Nano/Micro particles and spheres

Formulation Development
Lyophilized and liquid forms

Dedicated Team
A multi-disciplinary and extensively experienced team

Complex Process
Viscous Formulation or particle generation

Analytics
State of the art analytical platform

Expansion for Small-Scale Commercial Drug Products

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CARBOGEN AMCIS has announced an investment to expand our services and capacities for the manufacture of Drug Products. This new French site will be 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.

There will be 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 will be incorporated to support customer projects. This new facility will be situated a few kilometres away from the original Riom site, in the city of Saint Beauzire - North of Clermont-Ferrand in Auvergne, France. Operations will commence during Q1 of 2023.

Future 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)
  - Aseptic formulation
  - Viscous products
  - Low temperature
  - Inert atmosphere

Looking for New Talent!

We are recruiting new collaborators to work with us in this new facility, which is one of the most important industrial pharmaceutical project in the region. The facility in Riom currently employs about 50 people. With our second site, between 40 and 50 new positions will be created.

The profiles sought are varied and, for many of them, highly qualified. If you are looking for a new career opportunity in a growing company and are motivated by the idea of investing yourself in a long-term commitment to an ambitious project, then you are the person we are looking for!

For any question or information: do not hesitate to contact our recruitment team at: HR_Riom@carbogen-amcis.com

You can also regularly check the job offers available for our Riom site on our website www.carbogen-amcis.com (location: Riom, France)

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CARBOGEN AMCIS is a leading service provider, offering a portfolio of drug-development and commercialization services to the pharmaceutical and biopharmaceutical industry at all stages of drug development. The integrated services provide innovative chemistry solutions to support timely and safe drug development allowing customers to make the best use of available resources. CARBOGEN AMCIS is also active in the marketing/sales and manufacture of Vitamin D analogues, Vitamin D, Cholesterol and lanolin related products for key markets as pharmaceutical, cosmetic, food, feed as well as industry applications.