Development and Aseptic Production of Drug Products
CARBOGEN AMCIS offers a comprehensive range of development and manufacturing services for the formulation of New Molecular Entities (NMEs) and the reformulation of existing drugs. We are specialized in developing sterile and pyrogen-free parenteral formulations for preclinical and clinical trials (phases I, II and III). With over 15 years of experience, we have gained the necessary expertise to safely develop injectables and liquid pharmaceutical forms for a wide range of drugs including drug delivery, highly potent and antibody drug conjugates (ADC). Our trained and experienced personnel operate in state-of-the-art containment facilities and can handle materials of the highest occupational exposure band, including cytotoxics.

Our service offerings for drug products span from pre-formulation and formulation services to aseptic production of clinical batches for parenteral drugs. Formulation services are fully integrated with CARBOGEN AMCIS' API process research and manufacturing services for the fast supply of the product for clinical trials.

### Pre-Formulation Services
Pre-formulation services in Switzerland encompass several activities, such as the physicochemical characterization of the API, the selection of the best crystalline forms and the stability profile of the material. We offer comprehensive pre-formulation services and integrated analytical and solid state services designed to provide key information for the formulation of drug substances in both solution and solid states.

**Key Services:**
- Feasibility and pilot studies for dispersing microaerosols and particle size distribution
- Bioavailability studies: dissolution, disintegration, testing and solubility testing (simulation in physiological conditions)
- Designed for: solutions and solids, including drug in capsule (DIC) and drug in bottle (DIB)

### Formulation & Process Development Services
CARBOGEN AMCIS offers a complete range of formulation and process development services for parenteral forms. We have extensive experience with a broad range of substrates, such as small molecules, cytotoxics, proteins, peptides, enzyme inhibitors, antibiotics (non-beta-lactam), vaccines (non-live), mAbs and antibody drug conjugates (ADC).

**Key Services:**
- Formulation of new products and optimization of existing formulations
- Development and optimization of lyophilization cycles
- Process development and Scale-up
- Designed for: liquid or freeze-dried injectables

### Aseptic Production
We offer current Good Manufacturing Practices (cGMP) services for the fast supply of preclinical and clinical batches of liquid or lyophilized parenterals. We provide aseptic filling in a wide range of volumes in vials, syringes and cartridges, from one milliliter to several hundred milliliters.

**Key Services:**
- Preclinical batches and clinical batches (phases I, II and III)
- Validation of aseptic process (media fill testing)
- Process development and scale-up
- Class A (ISO 4.8) sterility
- Maximum batch size: up to 4000 vials
- Designed for: liquid or freeze-dried injectables

### Our Service Offerings:

**Preclinical and Clinical Studies**
- Complex products
- Highly potent
- Biological products

**Drug Products**
- **Pre-Formulation**
  - Particle size distribution
  - Feasibility / pilot studies
  - Dispensing / microaerosol
- **Formulation**
  - New formulation
  - Reformulations
  - Lyophilization cycles
  - Parenteral drugs
- **Sterile Production**
  - Clinical batches (I, II & III)
  - Preclinical batches
  - Media Fill Testing
  - Parenteral drugs

**Drug Substances**
- **High Potency**
  - FDA-approved
  - Reconstructed safety
- **State-of-the-art facility**
  - In-house categorization
- **Chromatography**
  - Fast purification of APIs
  - Feasibility studies
  - Dedicated experts
  - Wide range of solutions
- **Custom Manufacturing**
  - Supply of intermediates
  - Process development
  - Process research
  - Supply of APIs

**Our Benefits:**
- Chemistry and manufacturing controls (CMC) support from development to market
- State-of-the-art infrastructure
- Highly skilled, cross-functional teams of scientists with decades of experience

**Track Records Since 2000:**
- > 320 Batches produced under cGMP environment
- > 160 Clinical batches
- > 129 Media Fill tests

**Drug Products & Substances**

**Analytical**
- Method validation
- Physical-chemical
- Moisture analysis
- Microbiological controls
- ICH Stabilty Studies
- ICH studies
- Forced / stress tests
- Stability indicating method
- Customized studies

**Solid State & Crystallization**
- Polymorphism screening
- Stereochemical stability
- Structure elucidation
- Salt screening

**Our Benefits:**
- Dedicated project and product managers
- Breadth of equipment and personnel ensuring flexibility and capability to tailor projects to specific needs
- Flawless track record
- Recognized leader in high-potency manufacturing
Immune Targeting Systems (ITS) Limited is a London-based Biotech Company developing synthetic vaccines for mutating viruses. Their proprietary vaccine technology relies on highly selected long peptides containing protective T cell epitopes modified with a fluorocarbon vector. Designed as a stable freeze-dried formulation, the vaccine delivers the antigens into the body to promote robust T-cell immunity without requiring potentially toxic adjuvants. ITS’ lead candidate is a universal influenza-A vaccine containing multiple fluoropeptides.

Needs:
ITS was looking for a CMO that could meet challenging timelines and provide a high level of technical expertise to convert a lab process into a scalable cGMP manufacturing process. The overall project encompassed the transfer of the formulation process and analytical methods, the optimization of manufacturing steps including formulation and freeze-drying and the successful manufacturing of technical and cGMP batches.

Realization
In close partnership with ITS, CARBOGEN AMCIS SAS was able to successfully manufacture several batches to specification, including two engineering batches, one cGMP toxology batch and a cGMP clinical batch in less than 6 months. Technical challenges were successfully overcome such as:
1. Ensuring the physico-chemical integrity of the product during formulation: Based on a formulation process designed by ITS, CARBOGEN AMCIS SAS successfully scaled-up the process. Technical solutions were implemented to achieve a perfect solubilization of all APIs and prevent aggregation while ensuring good filtration recovery. All specifications were met through an efficient control of all formulation parameters such as process time and temperature around a dedicated and specialized organization in the cGMP suite.
2. Optimization of freeze-dried cycle: CARBOGEN AMCIS SAS reactivity and flexibility permitted the production of an additional engineering batch at full scale to optimize the lyophilization cycle in order to improve the quality of the cake. CARBOGEN AMCIS SAS provided ITS with a strategy that engaged a limited amount of their valuable APIs while ensuring the pertinence and robustness of results generated.
3. Technical and Regulatory support: CARBOGEN AMCIS SAS guided ITS through the product development phase in order to compile a regulatory data package regarding key aspects of the process including filter and microbiology method validation.

Outcomes
CARBOGEN AMCIS SAS successfully met all the project timelines and released a product that met specification for first-in-man studies. This will allow ITS to progress this innovative product through clinical development and keep momentum for their fund raising.

Customer Testimonial
“CARBOGEN AMCIS SAS has not only successfully provided a service, but our project has benefited a great deal from their technical expertise. It has been a pleasure to work with a highly professional and proactive team responsive to customer needs.”
Bertrand Georges, PhD.
Head of Vaccine Technology and Innovation.
Immune Targeting Systems, Ltd. London.