



- ● **Client:**
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 fluoro-peptides.

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 toxicology 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 key 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.

Equipment for Drug Product

In addition to pre-formulation services, solid state and crystallization services, and analytical support for physico-chemical characterization and method validation, CARBOGEN AMCIS offers a complete range of formulation services for parenteral and highly-potent products. Our formulation and aseptic drug products services are performed at Riom, France site, which is exclusively dedicated to the development of parenteral products and to the fast supply of batches for clinical trials.

Our cGMP equipment includes:

- 2 aseptic filling isolators (running under class A)
- 5 isolators (running under class C)
- 3 laminar flow hoods
- Terruzzi freeze dryer (1.2 square meters) with CIP and SIP for cGMP production
- Nitrogen loop system
- Autoclave
- Dry heat oven
- Water activity and moisture analyzing instrument
- HPLC chains
- Biological safety cabinet
- Incubators

Development devices:

- Semi-automated dosing Xcelolab
- Powder, closed-loop weight dispenser
- Glovebox (2.4 square meters) for the formulation of new highly-potent compounds
- Segregated (0.6 square meters) Telstar lyophilizer
- Cytotoxic safety cabinet

