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CARBOGEN AMCIS
A Dishman Group Company

PRESS RELEASE

CARBOGEN AMCIS Passes Successful Inspection by Swissmedic

CARBOGEN AMCIS' Vionnaz facility, recognized as cGMP compliant by Swissmedic, will allow the company to expand its capabilities for bio conjugation projects.

BUBENDORF, Switzerland (September 10, 2015) - CARBOGEN AMCIS, the Swiss-based pharmaceutical process development and Active Pharmaceutical Ingredient (API) manufacturing company, has announced a successful inspection by Swissmedic of its recently acquired site in Vionnaz, Switzerland.

The site has been inspected by Swissmedic and by the U.S. Food and Drug Administration (FDA) in the past and the re-audit is due to the change of ownership. The two-and-a-half-day audit covered the Quality System related to development and manufacture of highly potent APIs at the Vionnaz facility, including Analytical and Quality Control. This is the first stage in the facility's cGMP certification process, which will be completed in the next two months.

The high potency facility in Vionnaz is designed to operate at an occupational exposure limit (OEL) level down to 0.05µg/m^3. CARBOGEN AMCIS acquired the facility in August 2014 to significantly increase the development and manufacturing capacity of highly potent APIs. This site is a real opportunity for CARBOGEN AMCIS to expand its abilities for bio conjugation projects. Indeed, the facility has already demonstrated the capability to produce highly potent warheads and linkers, which can be transferred to bio conjugation facility of the company to create Antibody Drug conjugates (ADC).

This bio conjugation facility, located in Bubendorf Switzerland, features a 328 ft^2 ADC cleanroom suite dedicated to the development and production of ADC clinical material under current good manufacturing practices. Consisting of grade D and grade C areas, the facility was constructed to allow aseptic and safe handling of highly potent compounds also down to an OEL of 0.05µg/m^3.

The grade D area of the lab is dedicated to operations such as the preparation of reagents and buffers as well as the sterilization of production equipment by dry oven or autoclave. The segregated grade C area is exclusively used for the conjugation, the purification, and the packaging of ADC material under cGMP and features an isolator for the preparation of toxin solutions, a barrier system for aseptic filtration, a walk-in fume hood for handling of organic solvents, and a bio-safety cabinet (classified grade C) for antibodies and ADCs.
Since construction in 2014, the bio conjugation facility has been fully qualified and has been audited by customers and Swissmedic.

"I am proud of what our team has achieved in such a short length of time. The Vionnaz cGMP certification is the next step for the expansion of our Antibody Drug Conjugate Services. It will allow CARBOGEN AMCIS to provide full cGMP manufacturing services from small scale to commercial phase" commented Mark Griffiths, CEO, CARBOGEN AMCIS and the Dishman Group.

CARBOGEN AMCIS AG (www.carbogen-amcis.com) 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 AG is owned by Dishman Pharmaceuticals and Chemicals Ltd., Ahmedabad, India.

Dishman Group (www.dishmangroup.com) is a global outsourcing partner for the pharmaceutical industry, offering a portfolio of development, scale-up and manufacturing services. Dishman Group improves its customers' businesses by providing a range of development and manufacturing solutions at locations in Europe, China and India.