

Swissmedic Inspection Success Highlights Excellence at CARBOGEN AMCIS Vionnaz Site

CARBOGEN AMCIS, a leader in API manufacturing, announces the successful Swissmedic inspection of its Vionnaz facility, reaffirming regulatory compliance.

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"This successful inspection underscores our track record of delivering high-quality development and manufacturing services."

Hélène Mazuel, Quality Director - Drug Substance

[CARBOGEN AMCIS](#), a leading pharmaceutical process development and Active Pharmaceutical Ingredient (API) manufacturing company, is pleased to announce the successful completion of a Swissmedic inspection of its [Vionnaz facility](#), reaffirming the site's compliance with high regulatory standards.

Swissmedic, the Swiss Agency for Therapeutic Products, conducted a routine two-day inspection at the company's Vionnaz site in Switzerland from 13 to 14 November 2024.

Led by an inspector from the Regional Medicines Inspectorate of Western Switzerland (ISOPTh), the inspection focused on the Quality Management System compliance for the development and manufacture of [highly potent APIs](#), including analytical and quality control processes. The site's GMP Certification has been successfully renewed.

Hélène Mazuel, Quality Director - Drug Substance CARBOGEN AMCIS, Switzerland, said: "This successful inspection underscores our track record of delivering high-quality development and manufacturing services. It reflects the unwavering commitment of our team to consistently meet the highest quality standards required for the site.

I am immensely proud of the Vionnaz team for this achievement, supported by our expert groups across Switzerland. Demonstrating our ability to meet all aspects of quality to Swissmedic is a significant milestone that further strengthens our reputation."

This continues a series of successful inspections in Vionnaz, starting with the first in 2015 and followed by subsequent inspections in 2016, 2017, 2020, and 2022. It reinforces CARBOGEN AMCIS's strong history of compliance with Swissmedic requirements.

Acquired by CARBOGEN AMCIS in 2014, the Vionnaz facility specializes in the development and small-scale production of Highly Potent APIs (up to category 5), including the capability to

produce highly potent warheads and linkers for antibody-drug conjugates (ADC). The site features three process development laboratories, a dedicated QC laboratory, three production units with reactors up to 30 L, preparative chromatography systems and freeze dryers up to pilot scale.

For further information about CARBOGEN AMCIS and its capabilities, please visit (www.carbogen-amcis.com) or contact Lucie Framinet at lucie.framinet@carbogen-amcis.com or call +33 7 84 23 10 69

CARBOGEN AMCIS (www.carbogen-amcis.com) is a leading service provider offering a portfolio of drug development and commercialization services to the pharmaceutical and biopharmaceutical industries across all stages of clinical development and product life cycle. Our integrated services and innovative chemistry solutions support timely and safe drug development, allowing customers to better optimize available resources. CARBOGEN AMCIS is a wholly owned subsidiary of Dishman Carbogen Amcis Limited, Ahmedabad, India.

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

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