

## CARBOGEN AMCIS Announces Two Successful FDA Inspections at Its Manufacturing Sites in Neuland and Aarau, Switzerland

CARBOGEN AMCIS, is pleased to announce the successful completion of U.S. Food and Drug Administration (FDA) inspections at its Neuland and Aarau sites.

BUBENDORF, SWITZERLAND, July 23, 2024 /EINPresswire.com/ -- Switzerland-based CARBOGEN

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This accomplishment reflects years of dedication and hard work by our team, maintaining the highest standards of quality and building on our record of successful regulatory audits and inspections."

Mr Arpit Vyas, Global Managing Director of the Dishman Group. AMCIS, a leading pharmaceutical process development and Active Pharmaceutical Ingredient (API) manufacturing company, is pleased to announce the successful completion of U.S. Food and Drug Administration (FDA) inspections at its Neuland and Aarau sites.

The FDA conducted routine inspections over five days in Neuland from June 17-21, 2024, and three days in Aarau from June 24-26, 2024. The inspections concluded with no Form 483 observations or significant critical findings, affirming that No Actions Indicated (NAIs) were identified.

"The successful inspections at our Aarau and Neuland sites

highlight CARBOGEN AMCIS's consistent track record of high-quality development and manufacturing. This achievement reinforces our commitment to delivering the superior quality our customers expect," said Pascal Villemagne, CEO of CARBOGEN AMCIS. "Our Quality Team collaborates closely with every CARBOGEN AMCIS facility to uphold a robust and reliable quality policy across the company."

"I am delighted about these positive reports from the FDA," said Mr Arpit Vyas, Global Managing Director of the Dishman Group. "This accomplishment reflects years of dedication and hard work by our team, maintaining the highest standards of quality and building on our extensive record of successful regulatory audits and inspections."

About the Neuland Facility

Opened in 2000, the Neuland facility, located in Hunzenschwil, specializes in drug development

and small to medium-scale cGMP manufacturing. It is CARBOGEN AMCIS's second site dedicated to laboratories for developing highly potent compounds. The facility is equipped to handle analytical services, API and intermediate stability studies, API process research and development, and small-scale commercial API supply.

About the Aarau Facility
Established in 1994, the Aarau facility
focuses on drug substance
development and small to mediumscale cGMP manufacturing. Centrally
located in Switzerland, it offers a wide
array of technology tools, including
solid-state analysis, chromatography
separation, isolation, and analytical
capabilities. The primary activities



CARBOGEN AMCIS' Neuland Facility

include API process research and development, small-scale commercial API supply, and chromatography services.

<u>The Neuland and Aarau facilities</u> are designed to be flexible, accommodating various projects, whether API or analytical. Situated just 10km apart, they employ over 300 professionals and are fully cGMP-compliant and Swiss Medic-approved. Together, they operate 30 vessels ranging from 10L to 640L.

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

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CARBOGEN AMCIS (<u>www.carbogen-amcis.com</u>) is a leading service provider offering drug development and commercialization services to the pharmaceutical and biopharmaceutical industries across all clinical development and product life cycle stages.

Our integrated services and innovative chemistry solutions support timely and safe drug development, allowing customers to optimize available resources better. CARBOGEN AMCIS is a wholly owned subsidiary of Dishman Carbogen Amcis Limited, Ahmedabad, India.

Dishman Carbogen Amcis Limited (<a href="www.imdcal.com">www.imdcal.com</a>) 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 in Europe and India.

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