



CordenPharma Colorado Increases US Peptide Manufacturing Capacity through Innovation & Investment – First Phase

In order to accommodate the continuous growth and evolution of the peptide therapeutic market, CordenPharma Colorado completed earlier this year an expansion of its Solid-Phase Peptide Synthesis manufacturing capacity with the addition of an extra-large 3'000 L SPPS vessel. Our strategy is to anticipate expanding US market needs by investing in new manufacturing techniques to constantly improve the productivity of our peptide assets – in particular *via* the deployment of innovative Process Analytical Technology (PAT).

Now with even greater demand to rapidly respond to our partners' accelerated programs, a long-term expansion initiative was approved to further increase our flexibility, efficiency and ultimately, cost-effective production. For the first phase of this commitment, customized automated synthesizer production lines will be installed supporting fast and efficient GMP manufacturing. This infrastructure will further strengthen the existing manufacturing of Peptides in the low to mid-kg scale range by complementing the current state-of-the art large-scale manufacturing capabilities at CordenPharma Colorado.

In addition, special emphasis on design will further harmonize our network and enable a seamless Tech Transfer process from our Peptide Development Centre of Excellence in Frankfurt, Germany, due to an exact mirroring of its new non-GMP production lines that are currently being installed.

The new expansion initiative will be augmented by our integrated supply of peptide APIs to Injectable Drug Products from CordenPharma Caponago, our facility in Italy dedicated to the Formulation Development and Drug Product manufacturing of sterile injectables. By leveraging our global facility network, this vertical supply model spans the complete cGMP supply chain from regulated raw materials, intermediates, and APIs, to commercial-scale Drug Product manufacturing, finished dosage formulation, clinical trial services, & pharma logistics. This fully integrated peptide solution uniquely positions CordenPharma as the only CDMO to truly offer integrated peptides services in the industry.

Organized under the <u>Peptides, Lipids & Carbohydrates platform</u>, CordenPharma is a recognized leader in Peptide supply with over 110 years of cumulative Peptide experience across our global facility network in Europe and the US. Our experience gained in both solid-phase and liquid-phase manufacturing allows for a high level of response to growing local demand at the country and community level, particularly during the recent COVID-19 pandemic.

With approximately 350 employees, CordenPharma Colorado has grown a strong focus in the development & manufacturing of APIs from laboratory-scale to commercialization at ton-scale, due to their unique large-scale SPPS capabilities. The purification of the final peptide is performed at any scale using column chromatography, with columns ranging from 5 cm to 100 cm. To avoid the tedious and poor productivity of the final isolation step by lyophilization, their development team has gained an unmatched expertise in the isolation of peptides by precipitation that has been successfully transferred to production in a number of commercial products. The site has a long record of accomplishment in the large-scale manufacturing of Peptides, where all potencies, including picogram levels, are managed.



GMP Peptide Manufacturing at CordenPharma Colorado (US)

About CordenPharma

CordenPharma, the global pharmaceutical service & manufacturing platform of International Chemical Investors Group (ICIG), is a full-service partner in the Contract Development & Manufacturing (CDMO) of APIs, Drug Products, and associated Packaging Services. Through a growing network of cGMP facilities across Europe and the US organized under four Technology Platforms – Peptides, Lipids & Carbohydrates, Injectables, Highly Potent & Oncology, and Small Molecules – CordenPharma experts translate complex processes and projects at any stage of development into high-value products.

For more information about CordenPharma, contact us or visit cordenpharma.com.

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