



Experts taking care.

Frankfurt, Germany  
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## CordenPharma Latina US-FDA Warning Letter Closed

CordenPharma is pleased to announce that CordenPharma Latina, located near Sermoneta, Italy, has received news that the US-FDA warning letter previously received has been closed, with a closeout date of August 15, 2017. This success is the result of a holistic and systematic approach to remediate the observations throughout the facility.

Since inception, CordenPharma's Corporate Compliance Team has developed a company-wide strategic approach to enhancing all quality and compliance systems by systematically reviewing and assessing each CordenPharma facility and establishing harmonization programs, knowledge management and sharing of best practices. In order to ensure effectiveness, CordenPharma has planned a long-term high investment program in regards to corporate and quality systems, organizational structure and infrastructure, including a process to involve customers in improving transparency.

CordenPharma's Leadership Team is committed to enabling all facilities to operate according to the highest level of quality, compliance structures and systems, with a consistent focus on patient safety, guidelines, legislations, and strict adherence to current industry standards.

CordenPharma is currently achieving and sustaining these quality and compliance objectives proactively through continuous improvement strategies and collaboration with regulatory agencies, with the aim to serve patients and customers worldwide as a reliable and benchmark CDMO partner in the pharmaceutical, biotech and healthcare industry.

### **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 five Technology Platforms – Peptides, Oligonucleotides, Lipids & Carbohydrates; Injectables; Highly Potent & Oncology; Small Molecules; and Antibiotics – CordenPharma experts translate complex processes, ideas and projects at any stage of development into high-value products. For more information visit [www.cordenpharma.com](http://www.cordenpharma.com). Inquiries: [www.cordenpharma.com/contact-us/](http://www.cordenpharma.com/contact-us/)

## **About CordenPharma Latina**

CordenPharma Latina is a fully integrated manufacturer of oral and sterile anti-infective penicillins and cephalosporins, with a special focus on oral and sterile oncological formulation and oral API molecule synthesis. Core capabilities include expertise in process development, process improvement, complex technology transfer as well as new product launches, industrial engineering and scale-up. For more information visit [www.cordenpharma.com/facilities/latina/](http://www.cordenpharma.com/facilities/latina/)

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