Diapharm implements European GMP guidelines in China

Münster (DE), London (UK), Ningbo (CN), 20 December 2013 –

Pharmaceutical service provider Diapharm (www.diapharm.com) is increasing its business activities in China: Diapharm has now implemented a “European” quality management system for Neptune Pharma Ltd (www.neptunepharma.com) in their Joint Venture Partner’s factory in Ningbo, Zhejiang Province. And it has done so successfully: The veterinary medicinal product Trident 500mg/g Powder for Suspension for Fish Treatment (www.trident-50.com), is manufactured onsite under EU GMP standards. Trident has Marketing Authorisations in the UK & Norway to combat fish lice. It is set to hit the market in December 2013.

Pharmaceutical companies that are planning to launch medicinal products in the European Union which are manufactured abroad have to prove, amongst other things, that production complies with Europe’s Good Manufacturing Practice (EU GMP) guidelines. Therefore, contract manufacturers from other countries have to adapt their quality management to conform to EU standards. “While GMP rules are similar worldwide, a number of differences are found in the details,” stated Senior Manager GMP Services Dr. Alwin Sobe from Diapharm. He added, “Implementing EU GMP guidelines is therefore always a challenge.”

As a result, Neptune Pharma decided to bring experts from Europe on board when transitioning from Chinese SFDA GMP to EU GMP regulations. Over a period of several months, Diapharm helped to restructure the quality management system and to train employees in Ningbo.

Contact:
Diapharm
Press Office
Hafenweg 18-20
48155 Münster, Germany

Contact person:
Nicole Sibbing

Tel.: +49 (0)251 - 60935-517
nicole.sibbing@diapharm.de
www.diapharm.de

Agency contact:
co-operate Wegener & Rieke GmbH
Zumsandestrasse 32
48155 Münster, Germany

Contact person:
Christian Rieke

Tel.: +49 (0)251 - 3222611
wort@co-operate.net
www.co-operate.net

Press releases from Diapharm and photo material in print quality may be downloaded from:
www.diapharm.com/pr.html

“Thanks to the team’s efforts, we were able to secure the necessary manufacturing permit quickly,” commended CEO Adrian Endacott from Neptune Pharma. The Veterinary Medicines Directorate, a British supervisory authority, inspected the Chinese factory and officially confirmed the EU conformity of its production as part of the Trident authorisation procedure. Everything is now in place for the market launch in December.

(approx. 1,950 characters)

Caption (Sobe_Dr_Alwin_DIAPHARM.jpg)

Diapharm’s Dr. Alwin Sobe oversaw the restructuring of quality management from SFDA GMP to EU GMP guidelines at the Ningbo factory.

Background information: Diapharm

Diapharm is an international full-service provider to the healthcare industry. Founded in 1988, Diapharm supports pharmaceutical companies in all questions concerning regulatory affairs, medical & clinical development, quality management and business development. Its activities focus on the sectors of medicinal products, food supplements and dietetic food, medical devices and cosmetics. With over 100 employees in Germany, Austria and the United Kingdom, Diapharm is at the service of multinational companies as well as of new start-up companies and small to mid-sized businesses.