

blue inspection body audits active pharmaceutical ingredient manufacturers in China and India

Muenster (Germany), 13 February 2009. The audit service provider blue inspection body GmbH (www.blue-inspection.com) will be conducting third-party audits of excipient and active pharmaceutical ingredient (API) manufacturers in Asia at the beginning of March. The company, accredited for this purpose, offers manufacturing authorisation holders in Europe to take part in this audit travel in order to qualify their suppliers from the regions of Hyderabad (India) and Shandong (China).

API audits are regarded as important means to enhance drug safety. The audits have to be conducted at the premises of the API manufacturer either by the pharmaceutical manufacturer himself or by a specifically qualified third-party auditor. They are a prerequisite for importing APIs into the European Union and processing them into medicinal products.

Currently, blue represents the only ISO 17020 accredited third-party API auditor for that purpose within the European Union. The recently published 'pharma package' by the EU-Commission aims to extend the European pharmaceutical directive 2001/83/EC; an accreditation may therefore become mandatory for all third-party audits by next year.

Contact for audit enquiries: phone +49 (0)251 625620-40, mail info@blue-inspection.com

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Contact:

blue inspection body GmbH
Hafenweg 18-20
D-48155 Münster

Personal contact:
Dr. Stefan Kettelhoit

phone: +49 (0)251 - 625620-40
stefan.kettelhoit@blue-inspection.com
www.blue-inspection.com

Agency contact:

Advertising & Public relations
co-operate Wegener & Rieke GmbH
Zumsandstraße 32
D-48145 Münster

Personal contact:
Christian Rieke

phone: +49 (0)251 - 3222611
dialog@co-operate.net
www.co-operate.net

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Background information: blue inspection body GmbH

The blue inspection body GmbH examines the Good Manufacturing Practice (GMP) of pharmaceutical companies around the globe. Third-party audits by blue efficiently relieve manufacturing authorisation holders, API suppliers and API manufacturers. The blue inspection body GmbH is the first independent and accredited service provider for GMP audits within the European Union.
