

Diapharm starts GMP audit service for active pharmaceutical ingredients

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Press release from: [Diapharm](#)

Agency: **co-operate Wegener & Rieke GmbH**

Münster (Germany), 11 September 2008. Pharma service provider Diapharm (diapharm.com) is now offering accredited shared third-party audits for active pharmaceutical ingredients (APIs). In a shared audit several medicinal product manufacturers jointly commission the check of production conditions for a starting material or API such as ibuprofen or naproxen. The resulting audit report serves to prove whether the rules of good manufacturing practice (GMP) are followed in the manufacture of the ingredient. This proof of GMP compliance is mandatory for European manufacturers of medicinal products. "Accredited third-party audits offer additional security, since they are also recognized internationally by the authorities", explains Dorothee Klöpf of Diapharm, responsible for the GMP audit service. For these checks Diapharm collaborates with the independent, accredited blue inspection body GmbH. Upon request, blue also undertakes the management of deficiencies.

About 80 percent of the starting materials and APIs used in the production process of medicinal products in Europe come from third countries such as India or China. With the shared audit concept, Diapharm spreads the cost of auditing the APIs among several parties, interested medicinal product manufacturers in Europe who jointly commission an audit of an API manufacturer.

For the 4th quarter of 2008 Diapharm is coordinating shared-audit trips to China and India. Audits are to be made of, among others, manufacturers of acetylsalicylic acid, atorvastatin, ciprofloxacin, caffeine, donepezil, hydrocortisone, ibuprofen, levofloxacin, lovastatin, metamizole, naproxen, naratriptan, paracetamol, pravastatin, propyphenazone, rizatriptan, rosiglitazone, rosuvastatin, simvastatin, sotalol, sumatriptan, theophylline, trimethoprim and zolmitriptan. Diapharm also supplies ready-made GMP audit reports for a steadily increasing number of starting materials and APIs. For further details and information, please contact Karin Müller at Diapharm International GmbH, telephone: +49 (0)251 60935-11.

(approx. 2260 characters)

Background information: Diapharm

Diapharm supports companies in the pharmaceutical and health care product industry in all regulatory, medicinal and pharmaceutical questions associated with medicinal products, medical devices, food supplements, biocides and cosmetics. A team of more than 80 employees in Lübeck, Münster and Oldenburg provides, inter alia, strategic advice, management and responsible care for trademarks and product portfolios. Diapharm is present throughout Europe with partners in France, Great Britain, Poland, Portugal, Slovenia, Spain, the Czech Republic and Hungary.

Contact:

Diapharm

Press office

Hafenweg 18-20

D-48155 Münster

Contact person:

Nicole Sibbing

Tel.: +49 (0)251 - 60935-17

nicole.sibbing@diapharm.de

www.diapharm.com

Agency contact:

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

Contact person:
Christian Rieke

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

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