

Wörwag treads unconventional paths in quality assurance

Böblingen, Münster (Germany), 30. April 2009. Wörwag R&D, specialised in the development of medicinal products, has for the first time sought certification of good manufacturing practices (GMP) for two new generics by an external accredited auditor. The blue inspection body GmbH (www.blue-inspection.com) served as an independent third-party auditor for the GMP compliant manufacturing of Clopidogrel and Losartan. The company is the first accredited, commercially organized inspection body for active pharmaceutical ingredients (APIs) in Europe. "With the external quality assessment of blue inspection body we obtain an additional competitive advantage for our new medicinal products for prophylaxis of thrombosis and the treatment of hypertension", Dr. Alexander Bachmann, Managing Director of Wörwag R&D GmbH (www.woerwagpharma.de) explains: "These accredited API audits underline our pioneering role in quality assurance."

The contracting of accredited, i.e. demonstrably independent, external GMP auditors is not yet common practice. This situation shall, however, soon change. The currently discussed revision of the European medicinal product directive 2001/83/EG stipulates that external API audits have to be exclusively conducted by accredited auditors in the future. So far, blue inspection body GmbH is the only third party auditor accredited according to ISO 17020 for GMP of APIs in the European Union.

For the generic medicinal products developed by Wörwag R&D containing Clopidogrel or Losartan, respectively, licences are still available for acquisition.

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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.

Background information: Wörwag R&D GmbH

Wörwag R&D GmbH globally develops pharmaceutical products for OTC- and generic companies. The custom-tailored granting of licences ensures a highly competitive market entrance especially for small and medium sized pharmaceutical companies.
