

Evonik Birmingham Laboratories earns cGMP Certification

March 26, 2013

In March 2013, the Evonik Birmingham Laboratories site received Current Good Manufacturing Practices (cGMP) certification from the Medicines and Healthcare Products Regulatory Agency (MHRA). The MHRA, a competent UK authority, conducted the audit on behalf of the European Medicines Agency (EMA) in the course of registering a new product called SCENESSE® for the Evonik client Clinuvel. This is a proprietary, first-in-class photoprotective drug delivered via a subcutaneous, dissolving implant. Upon approval, the drug product will be manufactured at the Evonik Birmingham, Alabama (USA) site.

Dr. Jean-Luc Herbeaux, head of the Health Care Business Line of Evonik commented: "The certification provides our clients with additional assurance regarding the readiness of this facility to meet the highest quality and regulatory standards. We look forward to further growth in the area of manufacturing of complex dosage forms."

Evonik acquired the Birmingham Laboratories facility in November of 2011. Prior to that, since its commissioning in 2010, it had been used for manufacturing clinical lots for many clients. Today it serves as the Evonik hub for parenteral drug delivery and commercial drug product manufacture for non-proprietary or customer-proprietary formulations. Birmingham Laboratories focuses primarily on the production of aseptic and terminally sterilized complex dosage forms including microspheres, drug loaded implants, and liposomes. Currently, it is equipped with four suites capable of producing multiple products.

Birmingham Laboratories is also one of two Evonik sites worldwide that manufacture cGMP biodegradable polymers based on poly (lactic-co-glycolic acid) (PLGA), a critical raw material for

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advanced drug delivery products and bioresorbable medical devices.

Company information

Evonik, the creative industrial group from Germany, is one of the world leaders in specialty chemicals. Profitable growth and a sustained increase in the value of the company form the heart of Evonik's corporate strategy. Its activities focus on the key megatrends health, nutrition, resource efficiency and globalization. Evonik benefits specifically from its innovative prowess and integrated technology platforms.

Evonik is active in over 100 countries around the world. In fiscal 2012 more than 33,000 employees generated sales of around €13.6 billion and an operating profit (adjusted EBITDA) of about €2.6 billion.

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