

Evonik Birmingham Laboratories receives renewal of GMP certification

Essen. In May 2016, Evonik Birmingham Laboratories in Alabama (USA) hosted a Good Manufacturing Practices (GMP) inspection conducted by the British health authority, the MHRA. The audit concluded successfully, with the renewal of the EU GMP certification for the site. The facility first received its EU GMP certificate in 2013 after a successful pre-approval inspection for a new commercial product.

The certification covers the manufacturing of sterile human medicinal products for terminally-sterilized solids and implants. It acknowledges that the site complies with the principles and guidelines of Good Manufacturing Practice for finished dosage forms as required by the Commission Directive 2003/94/EC.

“This successful audit serves as confirmation to our pharma clients that the Birmingham manufacturing site continues to achieve a high standard of quality resulting from full regulatory compliance”, says Dr. Jean-Luc Herbeaux, Head of the Health Care Business Line at Evonik.

The Birmingham Laboratories facility was acquired by Evonik in November 2011. The site serves as the Evonik hub for parenteral drug delivery and commercial drug product manufacturing. It focuses primarily on the production of aseptic and terminally-sterilized complex dosage forms including drug loaded microspheres, implants and liposomes.

Company information

Evonik, the creative industrial group from Germany, is one of the world leaders in specialty chemicals, operating in the Nutrition & Care, Resource Efficiency and Performance Materials segments. The company benefits from its innovative prowess and integrated technology platforms. In 2015 more than 33,500 employees generated sales of around €13.5 billion and an operating profit (adjusted EBITDA) of about €2.47 billion.

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About Nutrition & Care

The Nutrition & Care segment is led by Evonik Nutrition & Care GmbH and contributes to fulfilling basic human needs. That includes applications for everyday consumer goods as well as animal nutrition and health care. This segment employed about 7,000 employees, and generated sales of around €4.9 billion in 2015.

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