



NextPharma Technologies Receives Successful FDA Inspection at its Waltrop site in Germany

Surrey, UK, 2nd December, 2008 - NextPharma, the leading European provider of product development, contract manufacturing and cold chain and logistics outsourcing services to the pharmaceutical and biotech industry, is pleased to announce that it has received a successful FDA Inspection at its Waltrop site in Germany.

The inspection covered activities associated with Product Development Services (including technology transfer, analytical method validation and stability testing) and Contract Manufacturing Services (including facility qualification and process validation). Key to the successful outcome of the FDA investigation was the “state of readiness” of personnel, documents and data.

The investigation was undertaken in two parts 1) pre-approval assessment of data/records against the regulatory submission and 2) compliance of the Quality Management System with the FDA six GMP systems. The outcome of the assessment highlighted confidence in the site team and the supporting quality system. The inspection additionally confirmed that the approach to facility qualification and risk management was in line with FDA thinking.

Bill Wedlake, CEO, NextPharma Technologies, commented: ‘We are delighted to have received such a positive result at Waltrop and I’d like to commend the site team and the quality specialists who have contributed to this excellent achievement. This positive endorsement of our Waltrop site is another major step for NextPharma in its objective to be the leading provider of World Class, quality pharmaceutical product development and contract manufacturing services to the global pharmaceutical and biotechnology market’.

NextPharma Waltrop has extensive know how in contract manufacturing, packaging, quality control of conventional dosage forms and has specific expertise and a separate packaging area for oral contraceptives. Waltrop is a centre of excellence for hormones

and steroids, solid and semi-solid formulations and provides product development services including hormones, steroidal products and oral and topical liquid/semi-solids, analytical and stability studies for products and clinical materials preparation and packaging for liquids and semi-solids.

NextPharma develops, manufactures, packages, and distributes a broad range of products and formulations for its customers from tablets and capsules to antibiotics, hormones and controlled release medicines. It has an established leadership position in the high technology area of injectables manufacturing, with particular expertise in product development and manufacture of oncology medicines.

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Notes to Editors:

About NextPharma

NextPharma Technologies, headquartered in the UK and founded in 2000, is a world class outsourcing partner to the pharmaceutical and biotechnology industry.

We offer a full range of services from early phase product development, through clinical trial packaging to high volume commercial manufacturing. We are a world leader in lyophilization, sterile fill finish and pellet technologies and in specialist product manufacturing including cytotoxics, hormones, penicillins, cephalosporins and narcotics. Our sterile development and production offers a full range of drug delivery technologies including pre-filled syringes, vials and ampoules.

We operate globally with seven product development centres, seven manufacturing plants and six temperature controlled storage and distribution sites across Europe and North America, supplying customers in North America, Europe and Japan.

We have 1,200 employees dedicated to serving over 200 customers world wide and a customer base, which includes many of the world's leading pharmaceutical, specialty pharma and biotech companies

We have a proven track record in almost all pharmaceutical technologies and product forms and in addition to the specialist areas above have capabilities in solids, semi-solids, liquids, sprays and dry dosage form technologies.

All of our sites are either FDA inspected, in the process of upgrade for inspection or targeted for upgrade for inspection.