

CO.DON AG: CO.DON receives manufacturing licence for own and contract production at Leipzig site

Berlin / Leipzig / Teltow, 21.01.2020 – Following the first approval inspection by the national authority PEI (Paul-Ehrlich-Institut) and the local authority in Saxony, CO.DON AG was awarded a manufacturing licence for its newly built production plant in Leipzig. The licence covers both the company's own product, Spherox, and cell production on a contract manufacturing basis. This means that the Leipzig site is certified as GMP-compliant at the same time. GMP stands for Good Manufacturing Practice, a binding international standard to ensure the highest safety and quality in pharmaceutical production processes.

Before granting the licence the authorities carried out an intensive, three-day inspection of the new operating site, combined with a compliance audit relating to regulatory and statutory requirements in connection with the manufacture, approval and distribution of biological medical products. The team of five inspectors was very impressed by the technical execution of the new incubators, isolators and loading system. In the course of their inspection they also looked closely at the qualifying documentation and the quality management system.

In the final meeting the Chief Inspector for the GMP audit specifically mentioned the excellent preparation, the smooth organisation of the visit and the great dedication of all the staff at CO.DON AG.

Dr. Andreas Eberle, Vice President and Head of Technical Operations: "Building a new production site in compliance with all the regulatory requirements and legal standards for the pharma industry is always a time-consuming and cost-intensive process. CO.DON AG has been totally successful in mastering this challenge, from the start of the project to the award of the manufacturing licence, within the original budget, in just over two years. This success was made possible above all because we succeeded in filling important key positions during the course of the project with suitably experienced specialist personnel and in forming a highly motivated team of competent employees. In addition, we worked together with strong external partners for the technical implementation. I would like to thank all those involved at the CO.DON locations Leipzig, Teltow and Berlin, as well as our external contractors for this extraordinary team effort!"

Timann Bur, Executive Board of CO.DON AG: „Our modern production facility in Leipzig enables us to manufacture human cell products on an industrial scale using state-of-the-art technology. CO.DON AG is thus in a position to ensure the market supply of novel, cell-based pharmaceuticals in the future under continuously increasing quality requirements for the benefit of our patients and customers".

CO.DON AG develops, produces and distributes autologous cell therapies for the minimally invasive repair of cartilage defects. The product being marketed is a cell therapy product for the minimally invasive treatment of cartilage damage in the knee joint that uses only the patient's own cartilage cells ("autologous chondrocytes"). CO.DON's method is currently used in over 200 clinics in Germany and more than 14,500 patients have already been treated. In July 2017 CO.DON AG received central EU marketing authorisation for this product from the European Medicines Agency (EMA). At the Leipzig site, CO.DON has built one of the world's largest and most modern facilities for the production of human cells on an industrial scale for in-house and contract manufacturing. The shares in CO.DON AG are listed on the Frankfurt Stock Exchange (ISIN: DE000A1K0227). Executive Board: Tilmann Bur.

Further information is available from www.codon.de.

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