

Press Release

Activoris obtains Manufacturing License for Clinical Trial Material

Gemünden (Wohra), Germany, February 27, 2018 – Activoris Medizintechnik GmbH expands its packaging services towards drugs for clinical trials.

Activoris received the manufacturing and import license for secondary packaging of clinical samples after the successful inspection by the competent authority, district council Darmstadt. The Gemünden-based medtech and pharma specialist herewith completes a further important step in its corporate development. Packaging and labeling services, which are currently conducted for medtech and diagnostic clients, can now also be offered for the research pharmaceutical industry.

The comprehensive inspection by the local district authority in December 2017 confirmed the GMP compliance (GMP: Good Manufacturing Practice) of the facilities and the relevant manufacturing processes. Activoris obtained the license according to Art. 13 of the Directive 2001/20/EC (Sect 13 para 1 and Sec 72, German Drug Law) and can now import, re-pack, release and ship drugs to be used in human clinical trials. The authorization includes non-sterile drugs, biologicals, human or animal extracted products, hormones, prostaglandins, cytokines as well as immune-suppressives for phase I, II, and III clinical trials.

Axel Fischer, CEO at Activoris Medizintechnik GmbH, commented: „We are very happy about the successful inspection and the subsequent manufacturing and import license. During the last year, we have made thorough preparations to comply with all requirements related to our organization, staff, processes and facility. Clinical research aims to establish new therapies for human beings. It is a specialized business which requires dedicated expertise in the field of manufacturing and logistics of clinical trial materials. Based on our competences, we can now further strengthen our positioning for being a reliable partner for the researching community.“

About Activoris

Activoris is a German outsourcing specialist for pharma, medtech and diagnostics companies. Activoris supports its clients with contract manufacturing, device developments, regulatory and business consulting as well as administration support. Activoris' clients are among both well-established corporations and life science startups. With Activoris, they achieve more flexible, cost-efficiency and a faster time-to-market.

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