Information

EUROAPI R&D supports CDMO strategy through landmark white paper on enzyme production

- Thorough "recombinant transaminase" case study developed by EUROAPI Brindisi to support scaling up from miniaturized level to pilot plant (10m^3) -

January 11, 2024

Increased market demand for enzymes and EUROAPI's vision have been driving services, products and R&D capabilities at the Group's Brindisi site over the past years. New technologies have been implemented in Brindisi to turn historical experience in fermentation for antibiotic production and new fermentation processes into precision fermentation capabilities. The aim is to obtain new classes of products of industrial and pharmaceutical interest, including Active Pharmaceutical Ingredients, intermediates, recombinant products and other molecules, opening the door to a new generation of biotechnology products and supporting EUROAPI's strategy in CDMO.

In line with this strategy, EUROAPI has just published a white paper describing the case study of the recombinant transaminase production process development, from enzyme screening through miniaturized system to final scale-up in pilot plant (10m^3), which was performed by the R&D department of EUROAPI Brindisi.

The results described in this white paper support the end-to-end development approach applied by the EUROAPI R&D team to recombinant enzyme production. These results enable a complete process development train, from lab to pilot scale with non-GMP batch manufacturing up to 10m^3 scale.

In more detail, the whole transaminase case study developed by the R&D Brindisi department starts with a miniaturized screening of *E. coli* strains expressing different recombinant transaminases. This step, aimed at selecting the enzyme with the highest bioconversion activities of native and industrial substrates, was performed in microtiter plates (working volume of 0.5-1 mL), supported by an automated screening system.

The enzyme production process was then developed at 1L scale, using a parallel bioreactor system, testing different process parameters to define optimal enzyme expression conditions, and then transferred to 20L lab fermenter scale. The process was successfully scaled up, and the transaminase was produced in a 10m^3 scale pilot plant. The downstream process for active enzyme recovery was performed with lab-scale equipment from 10m^3 fermentation broth.