

Significantly strengthens its business for medium-molecular pharmaceutical raw materials, including oligonucleotides and peptides

Otsuka Chemical to expand its business for medium-molecular pharmaceuticals, including oligonucleotides and peptides:

- New base for CDMO in Naruto, Tokushima Prefecture to start full-scale operations in 2023 -

Otsuka Chemical Co., Ltd. (Head office: Osaka, Japan; President: Kohei Tosa; hereinafter referred to as “Otsuka Chemical”) is expanding its CDMO (Contract Development and Manufacturing Organization) business, which undertakes the entire process from the development of manufacturing technologies to contracted synthesis service, in the field of medium-molecular pharmaceuticals such as oligonucleotides and peptides, which are expected to grow significantly in the future. For that purpose, Otsuka Chemical will establish a new multi-purpose API manufacturing plant in Naruto, Tokushima Prefecture, which will start full-scale operations in early 2023.

• **GMP-conforming plant designed for solid-phase and/or flow synthesis, and capable of handling highly potent substances (OEB Category 4)**

The new facility will be a GMP-conforming multi-purpose plant designed for solid-phase and/or flow synthesis, and capable of handling highly potent substances (OEB Category 4) and conjugates, such as modified oligonucleotides.

The plant is also equipped with a non-GMP area, allowing for a multiple and flexible production system and environment. By responding to various production methods, such as process development with a view to smooth technology transfer to GMP, the plant will operate as a facility for the production of intermediates for the manufacture of APIs and reagents for testing and research, such as special amino acids and special amidites, for customers.

In the production of medium-molecule APIs/intermediates, quality stability and impurity control have been major issues. By combining the GMP management know-how that we have developed over 40 years with the state-

of-the-art equipment and quality control technology to be introduced to this plant, we will be able to stably supply high quality medium-molecule APIs.

- **Meets diverse needs with our halogenation technology and our proprietary catalyst development technology.**

Recently, as the needs for medium-molecule pharmaceuticals have diversified, requests for non-natural oligonucleotide monomers, known as special amidites, and special amino acids used in the synthesis of non-natural type peptides have increased. In response to those needs for cutting-edge drug discovery research, we have developed new organic synthesis technologies and purification methods by combining our halogenation technologies cultivated over the span of 60+ years and our proprietary catalyst development technologies, and have achieved a significant reduction in the number of production processes and impurities in special amidites. We have also developed some production methods of intermediates of new special amino acids, enabling the synthesis of more than 100 non-natural type amino acids. We provide 'rapid', 'highly efficient' and 'high-quality' CDMO services for a wide range of exploratory research and drug discovery research, with consistent quality and rapid response from special raw materials to intermediates and medium-molecular APIs.

Otsuka Chemical will explore and develop advanced and proprietary manufacturing technologies to meet the needs of our customers and contribute to the promotion of pharmaceutical development and the further development of the healthcare industry as a whole.

【Image of the new Naruto plant of Otsuka Chemical】



【Overview of the new plant】

- Building: 3 floors above ground, total floor area of approx. 1300 m²
- Main facilities: Automated solid-phase synthesizer of oligonucleotides, reactors for liquid-phase synthesis, equipment for flow synthesis, chromatography equipment, freeze dryer
- Control level: OEB Category 4 (1 – 10 µg/m³), GMP and non-GMP.

【Contact Information】

<https://www.otsukac.co.jp/en/contact/>