

Development and commercialization of manufacturing technologies to reduce the manufacturing process of drug delivery systems including liposomal and lipid-based nanoparticulate formulations

Osaka University and NAGASE / Nagase Medicals to Launch Joint Research Program

Nagase & Co., Ltd. (Tokyo; Kenji Asakura, Representative Director and President) (“NAGASE”) and Osaka University (“OU”) have launched DDS Products Joint Development Research Chair, a course dedicated to research in the development of production methods of liposomal formulations and lipid-based nanoparticulate formulations (“LNP”). Both are drug delivery system (“DDS”) products, which are intended to offer solutions to issues such as metabolism of active pharmaceutical ingredients within the body before reaching the targeted tissues, or acting on tissues that causes adverse effects.

As DDS products, both liposomal and LNP formulations control how a drug functions by encapsulating active pharmaceutical ingredients in lipid particles. While garnering attention as a promising candidate for treatment for some of the refractory diseases that have no effective therapies to date, DDS products have problems before they could be commercialized, such as a complicated and long manufacturing process that results in higher manufacturing cost, and difficulties in increase production yield (i.e. production scale-up).

Associate Professor Takashi Matsuzaki at Department of Cardiovascular Medicine, Osaka University Graduate School of Medicine has invented a technology for the production of liposomal and LNP formulations, with the use of microfluidic device. By applying this new technology, the manufacturing process of these products will become shorter. It will also help overcome the obstacles in achieving production scale-up. OU has already reached agreement with the Japanese regulatory agency, Pharmaceuticals and Medical Devices Agency (PMDA) on the specifications and quality of liposomal formulations and has produced multiple investigational drugs using this technology.

NAGASE Group is introducing manufacturing equipment at one of its group company, Nagase Medicals Co., Ltd. (“Nagase Medicals”). By applying this technology not only to the low-molecular drugs, but also to Oligonucleotide drugs and gene therapy which represent driving force of the next generation medicine, Nagase will further strengthen its contract development and manufacturing (CDMO) business, from formulation development to investigational drug and commercial production.

■ Technology features

- **Potential to shorten the manufacturing process, which would take 4-5 days using a conventional extruder, down to 1-2 days**
- **The same parameters used in the investigational drug production may be used for commercial production, which will make production scale-up simpler**



- **Production with high reproducibility in terms of quality characteristics**
- **Nagase Medicals ensures compliance with the Japanese, US, and EU GMP requirements as well as the PIC/S GMP**
- **Easy transfer from other manufacturing methods has been demonstrated**
- **The technology has already been used in multiple investigational drugs production and supply**

◆ **Inquiries**

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