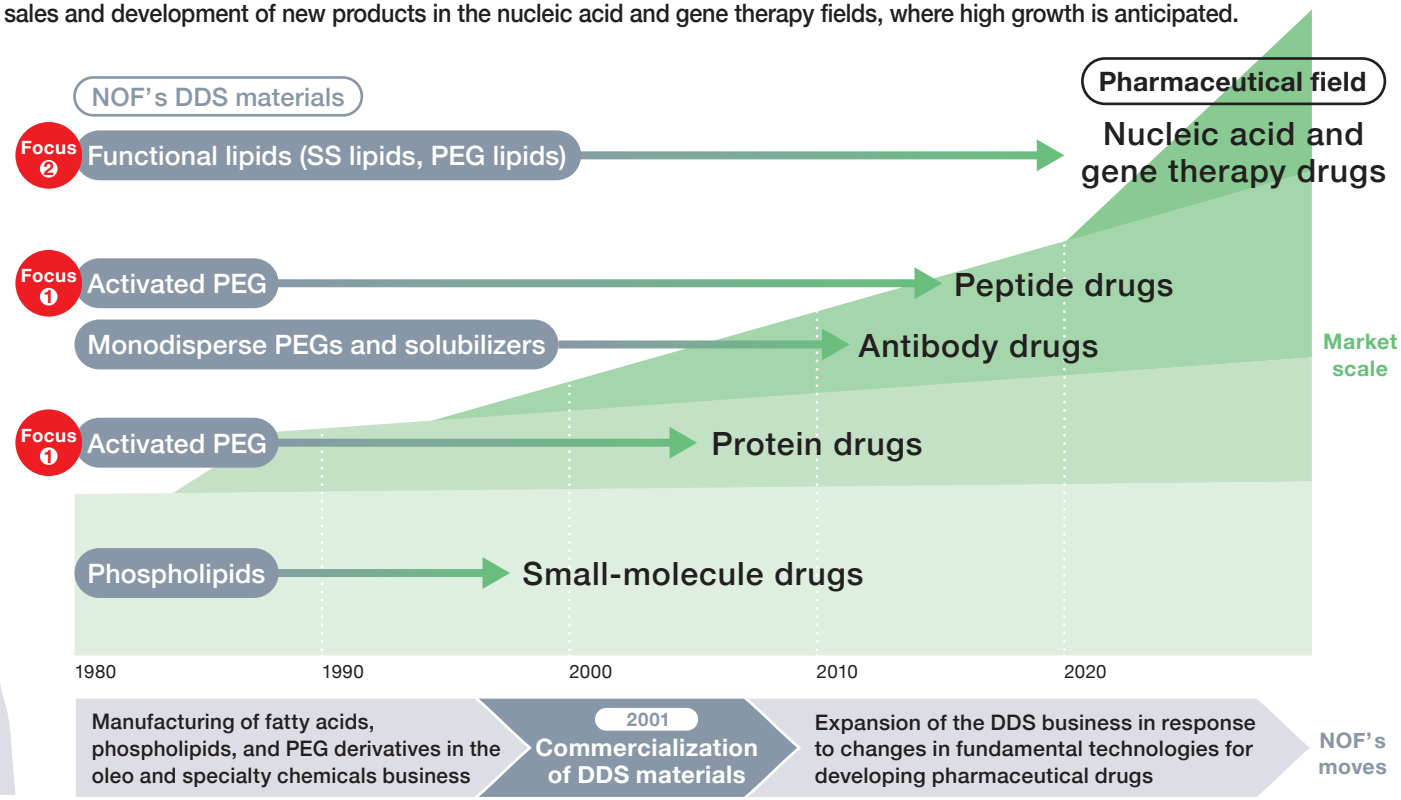
Expanding NOF's DDS materials in the biopharmaceutical field, where major growth is expected

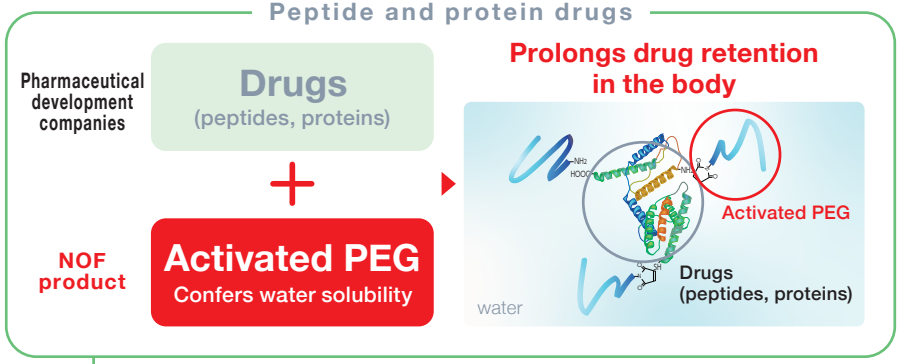
Harnessing the high purification and advanced molecular design technologies we developed in our business thus far, we launched our DDS materials business in 2001. Initially at the time of the business launch, we provided phospholipids for small-molecule drugs and activated PEG for protein drugs. Since then, we have expanded our business by developing new DDS materials in response to shifts in modality, such as antibody drugs, peptide drugs, and nucleic acid and gene therapy drugs. Between 2023 and 2028, the projected average annual growth rate of the market is 5% for small-molecule drugs, 9% for protein-based, peptide, and antibody drugs, and 42% for nucleic acid and gene therapy drugs. The NOF Group is focusing on the expansion of sales and development of new products in the nucleic acid and gene therapy fields, where high growth is anticipated.

What is a drug delivery system (DDS)

A DDS refers to a system designed to deliver drugs to the intended site in the body, at the appropriate timing, and in the necessary amount. These systems enable efficient drug transport to the affected area and enhance therapeutic effects while improving the retention of drugs in the body, thereby reducing the required number of doses. This reduces the burden on patients and improves quality of life.



Focus ❶ Activated PEG



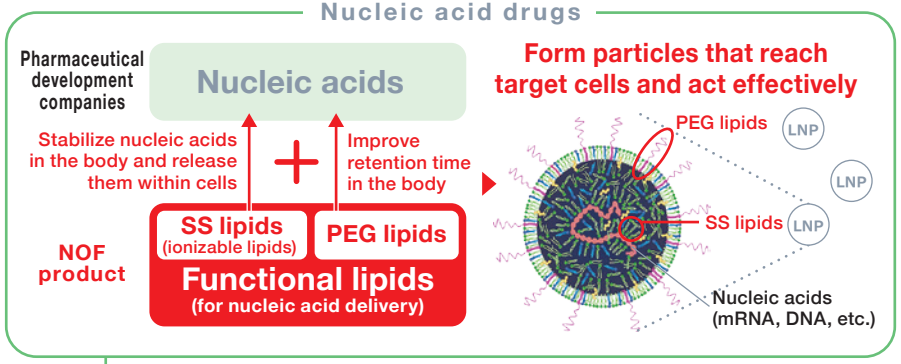
No. 1 share in the world

Activated PEG is hydrophilic and, when chemically conjugated with hydrophobic substances such as peptides or proteins, imparts high water solubility. In addition, peptide and protein drugs modified with activated PEG demonstrate improved retention in the body, enabling more efficient treatment. NOF holds the No. 1 global share in activated PEG, and increasing numbers of biopharmaceuticals have been made using our materials in recent years.

New plant construction and increased production capacity

We completed construction of our new activated PEG manufacturing facility at our Aichi Works, with operations scheduled to begin in fiscal 2025. With its large scale, the facility has about twice the production capacity of the existing DDS facility at our Kawasaki Works. In addition, this state-of-the-art manufacturing facility has three key characteristics: (1) GMP*1-compliant equipment that enables production at larger batch scales*2 than before, (2) Realization of a smart factory through the digital transformation (DX) of manufacturing and quality control, and (3) Contribution to carbon neutrality through the use of solar panels and energy-saving design features.

Focus ❷ Functional lipids (SS lipids, PEG lipids)



Development of proprietary lipids

For nucleic acid drugs and gene therapies to be effective, it is essential to safely deliver nucleic acids such as mRNA and DNA to specific organs. To achieve this, lipid nanoparticles (LNPs), which serve as capsules to transport nucleic acids, are used. The ionizable lipids and PEG lipids offered by NOF are vital components of LNPs and play a crucial role in efficiently delivering nucleic acids in the body. NOF has developed proprietary ionizable lipids called SS Lipids, which feature enhanced degradability within cells.

Start of collaboration with contracted drug development and manufacturing organizations

We have invested in Phosphorex, a contract development and manufacturing organization (CDMO) specialized in LNPs, and are further strengthening our business through this partnership. Until now, our role was mainly limited to supplying lipids. However, this partnership enables us to provide contracted development and manufacturing services for LNP formulations tailored to each customer's stage of development.

*1 Standards for the manufacturing and quality control of drugs, cosmetics, etc.

*2 The amount of material processed per cycle in a specific process stage