Development of monoclonal antibody reference material to support the development and quality control of antibody drug

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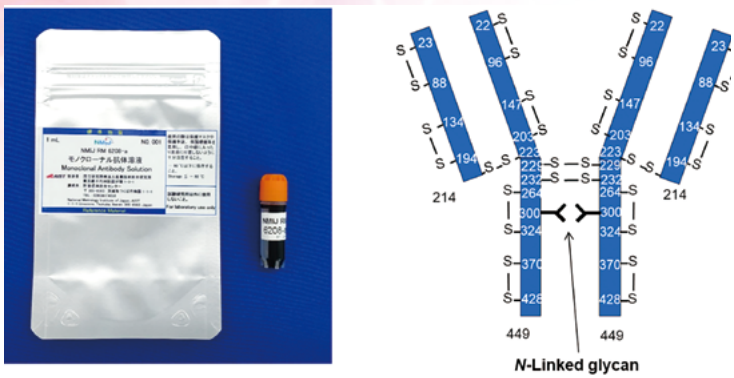
Biopharmaceuticals, especially antibody drugs, have a molecular weight exceeding tens of thousands and are produced using biological processes that lead to structural heterogeneity, including post-translational modifications and the formation of aggregates. In this regard, the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) has published guidelines requiring detailed characterization of the structure and the aggregate, including antibody concentration, for the development and quality control of antibody drugs. To address this, we developed a monoclonal antibody reference material (NMIJ RM 6208-a). The 22 physicochemical properties covering most of those required by the ICH guidelines for this reference material and their measurement conditions are available as a case study, thereby, enabling the use of the material and associated case study as a package. This allows the validation of analytical procedures and instruments for determining the important properties of antibody drugs. Hereafter, regarding properties such as glycosylation, whose results depend on the measurement method, we aim to meet the needs of a wide range of characterization by accumulating case studies through inter-laboratory comparisons with external institutions.



Monoclonal antibody reference material, AIST-MAB (NMIJ RM 6208-a), and its structure.

References:
T. Kinumi et al., *Front. Mol. Biosci.*, 9, 842041, 2022
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