

# CMC R&D Technology (1/3)



(Revised August 7, 2025)

## Formulation Technologies

- Long-acting non-oral formulation technology (LAP)
  - Avoidance of subcutaneous and intramuscular irritation
  - Enabling increased dosage for subcutaneous and intramuscular administration
  - Development of low-cost LAP formulations
- Formulation technology enabling sustained drug release for over one week via oral administration
- Technology to predict the human PK of LAP preparations in a short period of time.
- Long-acting formulation technology that balances sustained drug release and improved absorption
- Technology to improve the stability of products that can be stored at room temperature

# CMC R&D Technology (2/3)



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## Process Development, Manufacturing, and Quality Control Technologies

- Evaluation and control technology for crystal and powder properties of drug substances (small molecules)
- Formulation design and manufacturing technology enabling ligand addition after LNP formation
- Large scale equipment designed to manufacture DS with control of insoluble foreign materials and endotoxins.
- Manufacturing process with quality controlled for depolymerization of polysaccharide compounds over kg scale
- Manufacturing process with quality controlled for dispersion in water of polysaccharides to formulate self-assembled nanogel structure
- High-throughput downstream development via chromatography (non-96-well)
- Automation technology to reduce experimental frequency and accelerate manufacturing
- Universal resin for high-purity protein from BEVS/CHO with minimal process development



# CMC R&D Technology (3/3)



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Cell, Culture, and Expression System Technologies	<ul style="list-style-type: none"><li>● Innovative medium for enhanced biologics cell culture</li><li>● Technology for constructing clonal cell lines that stably achieve high quality and high yield for antibody quality control</li><li>● Transient expression system enabling to supply sufficient amount of API enough for GLP.</li></ul>
Device Technologies	<ul style="list-style-type: none"><li>● Injection device technology that simplifies complex preparation procedures and improves usability by administrating 2 types liquid with one shot.</li></ul>
Analytical and Evaluation Technologies	<ul style="list-style-type: none"><li>● Evaluation technology for understanding the existence states of components in lipid particles and emulsions and the release profiles of them in biological environments.</li><li>● Measuring technology for the particle solidness and membrane fluidity of lipid particles and emulsions.</li><li>● High-throughput SDS-PAGE methods to increase analytical throughput</li><li>● MS-based methods to assess small molecule–protein binding when traditional techniques are limited by protein mobility.</li><li>● Conjugation technology enabling to functionalize favorable cite of antibody without mutation of antibody</li></ul>