Expansion into Late Drug Discovery and Early Development

with Derrick Katayama

The Samsung Biologics contract development organization (CDO) service has focused traditionally on cell line, process, analytical, and formulation development. Samsung Biologics has expanded its scope to support late drug discovery and increase success in early development using the S-CHOsient transient expression system and DEVELOPICK platform, as presented by Derrick Katayama (lead scientist of formulation development at Samsung Biologics). Failure rates in drug development often stem from molecular instability or selection of the wrong candidate. In this expanded program, the S-CHOsient and DEVELOPICK systems provide tools for early evaluation of molecular attributes such as cell productivity, stability risk during processing, physiochemical stability, and solubility.

Katayama's Presentation

The S-CHOsient system produces transiently expressed material and can transition from small- to large-scale manufacturing at comparable efficiency and product quality. The technology is effective across different modalities, including monoclonal antibodies (mAbs), Fc-fusion proteins, and bispecific antibodies, and provides higher productivity compared to a commercial platform with no discernible differences in product quality. The DEVELOPICK program assesses and selects the best molecule for early development activities. The tool can measure attributes such as molecular stability, solubility, and process stability. The system performs short-term analyses using small amounts of material. Automation is used to evaluate multiple candidates side by side.

Workflow: The typical DEVELOPICK workflow begins with material receipt and then moves on to assessment of primary sequences to identify hotspots in the tested molecule. The system software can compare the number of hotspots of different candidates for determination. For example, if the tested molecule is a mAb, the DEVELOPICK platform can evaluate its complementarity-determining region for hotspots and compare those with other tested mAbs. Such evaluations provide insight to minimize pathways of degradation.

After primary sequence assessment, the platform performs biophysical characterizations and basic characterization studies of tested molecules using high-throughput methods. These tests measure parameters such as colloidal and thermodynamic stability. The DEVELOPICK platform can measure the free energy of unfolding through chemical denaturation using guanidine or urea. Such tests can be performed on multiple candidates simultaneously.

Relative solubility studies also can be conducted to assess solution conditions. Typically in this stage of development, limited material availability makes it difficult to assess multiple conditions. To overcome that limitation, the DEVELOPICK platform uses a polyethylene glycol (PEG) precipitation solubility assay to monitor protein concentration. Thus, solution conditions can be compared during the same phase as molecules.

Katayama presented two case studies in selecting the most favorable candidates after testing aggregation, unfolding temperatures, thermal stress, and low-pH treatment. In one of these case studies, the chosen candidate proceeded into drug development, and the client successfully created a formulation.

Questions and Answers

What experience does Samsung Biologics have with the DEVELOPICK platform and its customers? Four drug programs have used the DEVELOPICK platform during early development since its launch in October 2022. I anticipate it being used more in the future because much attention is being given to understanding the properties of lead candidates in early development.

Would you recommend using the S-CHOsient service to conduct DEVELOPICK testing? Yes, I would recommend using the S-CHOsient system for the DEVELOPICK service. The proteins generated have good quality attributes. Early production in the S-CHOsient system also can provide early information on productivity using the S-CHOice stable cell line.

Is it efficient to spend more time conducting additional developability studies? I think that developability assessment is even more important in this fast-paced world of biopharmaceuticals. It enables selection of the correct candidates to proceed to development. Additionally, the information gained from developability assessment minimizes potential delays. Developability assessments can be performed in parallel with other activities early in the process. They do not affect the timeline, because the material used for developability assessments is also generated by the S-CHOsient system. As a result, a development program is set up for success from the start.