BioSpect
the business of Bi
24 years of leveraging the business of Bio
www.biospectrumindia.co

Merck introduces new service for the biotech field

18 July 2019 | News

Adaptive approach to cell line development, analytics and clone selection for emerging biotechs and start-ups



Merck has launched its Plug & Play Upstream Development Service to help emerging biotech and start-up companies optimize the cost and speed of advancing their molecule to the clinical stage. Eliminating the need to work with multiple vendors for upstream development, the new service reduces bottlenecks, lowering time to clinic by two months. With 60 percent of drugs in the pipeline today being developed by emerging biotech companies, Merck's tailored, streamlined service is poised to have a significant impact on drug development efficiency.

The Plug & Play Upstream Development Service includes:

- Cell line development, utilizing CHO cell lines or Merck's proprietary CHOZN® license
- Standard analytics and early material from stable pools
- Stability study and clone selection

In the early stages of upstream development, cell line development and analytical development occur in parallel, allowing molecules to progress faster.

For customers looking to progress at an even faster speed, Merck offers its fast-track process by running process development and clone development steps in parallel, balancing speed and risk without sacrificing quality. The company's robust and automated mini-pool approach allows it to more efficiently generate early material for process development, reducing the timeline by 10 weeks for the first pharmacodynamic experiment at the pre-clinical stage.

Customers are supported by a dedicated project manager and Merck expertise including risk assessment and regulatory expertise. Monoclonality and stability validation is fully documented based on regulatory expectations and a statistical approach. There are no royalty fees and customers have the freedom to technology transfer at any stage, to any partner.

Optional, add-on plug and play services are available, depending on customers' needs, including:

- Off-the-shelf media and feed screening
- Analytical method development
- Complete analytics
- GMP master cell bank (MCB) and cell bank characterization
- MCB storage

Customers also have the option for Merck's BioReliance® Product Characterization team to synthesize data from multiple analytical and bioanalytical methods to help reveal the true identity of the product, ensuring the biotherapy's safety, purity and potency with off-the-shelf mAb-based assay packages or a custom assay tailored for the biologic. Based on the mAbs needs, the product characterization team would recommend vital assays to provide all key physiochemical, binding and functional critical quality attributes and selects the lead clone for the generation of the desired product.