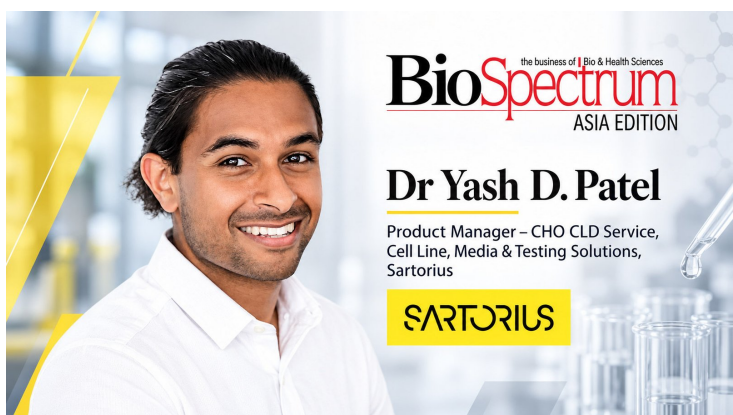


From 200 Antibody Variants to One Winning Candidate: How Sartorius Is Accelerating Biologics Development

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Dr Yash D. Patel of Sartorius Explores How AI-Powered Antibody Prediction, High-Throughput Screening and Early Developability Assessment Could Reduce Risks, Shorten Development Timelines and Transform Biologics Manufacturing by 2027



Artificial intelligence is reshaping biologics development by enabling faster antibody selection, early identification of developability risks and more efficient cell line optimisation. Through its collaboration with MAbSilico, Sartorius is integrating AI-driven molecular predictions with its established CHO cell line development platform, enabling developers to assess up to 200 antibody variants and expression conditions within just 12 weeks. In an exclusive interview with **BioSpectrum Asia**, **Dr Yash D. Patel, Product Manager – CHO CLD Service, Cell Line, Media & Testing Solutions, Sartorius**, discusses how this approach could accelerate the journey from drug discovery to clinical development, minimise costly setbacks and pave the way for AI-enabled bioprocessing and digital twins.

How will combining AI prediction with CHO cell line development accelerate lead optimisation?

By combining the two technologies a drug developer is able to: i) screen a large panel of up to 100 drug candidate amino acid sequences rapidly through AI-powered in silico prediction within a week which allows to identify and select the best antibodies to move to cell line development ii) by using an industry proven CHO cell line development platform and high throughput stable pool screening to perform the empirical/wet lab screen, the drug developer will have indicative performance of the molecule in a technology which can take them to IND-readiness, iii) avoid or limit risk and need of re-engineering of antibody due to liabilities identified during the CLD process. Therefore, the client saves time in screening using AI-prediction but also removing the step of having to screen their molecule in another expression technology as they journey to the clinic.

What advantages does screening up to 200 variants and expression conditions within 12 weeks offer developers?

This would benefit the drug developer as follows:

- To allow them to accurately evaluate a panel of drug candidate variants coming from stages like humanisation and lead optimisation stages during drug discovery by testing these variants in the same CHO

- cell line development platform that could take them to IND-readiness
- They can benefit from screening a large panel of sequence variants, which would be more comprehensive and exhaustive, in turn increasing their probability of finding the optimal variant to take to the clinics and de-risking the remainder of the development process
- By screening such a large number of variants and screens, a client can explore the option of combining screening different drug candidate variants and test different expression conditions i.e. testing different gene/chain ratios, different genetic elements, etc. in the same experiment. Therefore, allowing the drug developer to identify both the optimal lead candidate and the expression conditions to achieve high titers and product quality profile.
- They are adding a filter in their selection process, rational selection while anticipating optimization when needed before moving into CLD process

How are MAbSilico's AI predictions validated against Sartorius' experimental data?

As part of establishing our partnership, MAbSilico and Sartorius performed an internal evaluation to see if the two technologies were synergistic and if MAbSilico predictions translated to observed performance in Sartorius' CHO cell line development technology. This evaluation was performed by taking a known monoclonal antibody which MAbSilico evaluated through their AI algorithm for developability risks and avenues to optimize the molecule and provide a shortlist of sequence variants, as well as a candidate from MAbSilico's discovery campaign. Sartorius then took these variants and expressed them in their CHO cell line development platform up to a stable pool fed-batch evaluations and screen for titer, product quality and select developability criteria. In short, the results between the prediction and the empirical data were comparable and indicated that both our technologies were working well together. We are in the midst of finalising this study into a poster and case study, so watch this space.

Aside of the developability assessment technology highlight in this collaboration, MAbSilico is in business for nearly 10 years as a pioneer of AI-driven solution for antibody drug discovery. They worked on more than 100+ projects for biotech and pharma companies. The POC described above was done to evaluate specifically their solution related to developability of antibodies which was very impressive and led to the partnership.

How effectively can the platform identify developability risks before wet-lab development?

Based on the POC and the use cases provided by MAbSilico, all sequences that pass in silico developability assessment have very good expression profiles in mammalian cells and those who were tested in vitro via DLS, DSF etc also showed good stability.

What does MAbSilico's technology add to Sartorius' existing cell line development capabilities?

By combining MAbSilico's technology with Sartorius' CHO cell line development platform, we are able to more effectively support drug developers at an earlier stage during drug development and become more of a partner than just a service provider when supporting the client from late discovery to IND approval. Similarly, MAbSilico can support a developer with an integrated development process from de novo discovery to an IND-ready high performing clonal cell line encouraging a smooth continuity towards the clinic. Together we derisk transitioning from discovery to cell line development.

Evaluating sequences from our clients before moving to cell line development also helps to anticipate potential clone generation, clone selection and production scaling issues when designing a client study and quotation.

Could this collaboration eventually enable an AI-led design-build-test-learn model for biologics development?

For the big picture and long-term view, absolutely. As we continue to work together and generate more and more data between our two technologies in the background, we start to work towards continually improving our predictability but also to expand the avenues of what other parameters can we predict and validate through empirical data.

About the developability itself and the existing solutions, there is no need of lab-in-the-loop approach, the solutions can be applied on any type of sequences regardless the target. Some discussion about common R&D for the manufacturability are ongoing which might be an opportunity to apply the lab-in-the-loop strategy.

Looking to 2027, what key AI trends will reshape biologics discovery and cell line development?

From a cell line development and bioprocessing perspective, we already see the implementation of AI/ML prediction for high producing clones during single cell cloning and clone selection and anticipate that more steps along the bioprocess

could be modeled in the near future. With the goal to eventually develop digital twins.

From the antibody design perspective, applying AI on existing biological data (or antibody sequence) is getting mainstream (like following a selection by phage display). The complete de novo design remains one key milestone not yet achieved. We can also see an increase in the complexity of modalities such as pH dependency, multi-specificity format or post-translated modified epitope.