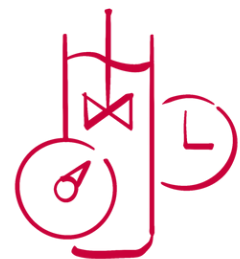




From Complexity to Clarity: Tailoring Downstream for a Tricky Bispecific

*Developing a Cost-Effective Purification
Process for a Hydrophobic Bispecific IgG2
Antibody*



Process Development

Project Background

The client engaged FyoniBio for a comprehensive development project — spanning **cell line development**, **upstream**, and **downstream process development** — for a bispecific IgG2 antibody candidate. This end-to-end responsibility gave us a deep understanding of the molecule and the flexibility to adapt our strategies quickly.

During downstream development, we faced an unexpected challenge: designing a **cost-efficient, rapid purification strategy** for a **highly hydrophobic bispecific** that didn't behave as anticipated. The molecule, for example, failed to elute from a mixed-mode ion exchange column under high salt conditions — **rendering standard platform approaches ineffective**.

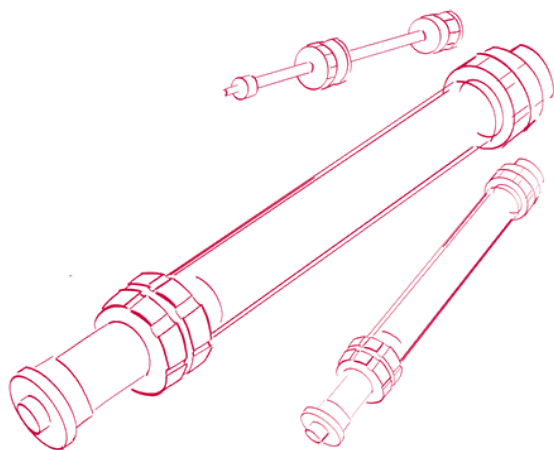
Our Approach

Rather than forcing a standard platform onto a molecule that didn't fit, we took a **flexible, data-driven approach**. Our team ran a broad screening of chromatographic resins with diverse properties to better understand the behavior of this **challenging bispecific IgG2**. This gave us the insight needed to design a **tailored purification strategy** around the molecule – not the other way around.

The result was a **three-step chromatographic process** that required minimal handling:

- **Two flow-through steps,**
- **One rebuffering step** into formulation buffer.

Because each step aligned cleanly with the next, the process ran **seamlessly**, cutting down on rework and reducing turnaround time. We developed the workflow at a **1–20 mL scale** and scaled it up to **75–400 mL** with **high reproducibility in both yield and purity** – a practical, reliable solution ready for handover.



Results and Outcomes

This project moved quickly thanks to our **tight-knit Downstream Process Development & Quality Control team**, who worked side by side to align analytics and cleaning strategies. With **no external partners involved**, communication remained simple and decisions could be made without delay – a setup that kept the project on track.

The outcome was a **robust three-step purification process**, meeting the required **purity and yield targets** and **ready for transfer** to a Contract Manufacturing Organization. The **low impurity content** in the final material exceeded expectations and confirmed the process's reliability.

The client's feedback said it best: the development report **"will be a pleasure to use for the IMPD."**

Tailored Support

We focused on making the process as **lean and practical** as possible – not just scientifically sound, but also **efficient in real-world application**. By aligning the steps to work seamlessly together, we **minimized rebuffering** and kept operational complexity low.

This not only saved time but also **reduced material use and handling**, making the process **more cost-effective**. Because the **eluate from each step could feed directly into the next**, there was no need for major adjustments along the way – a clear advantage when speed and scalability matter.

Every molecule has its quirks – and we're used to working with them. Reach out to explore how we can tailor our support to your project.

FyoniBio offers high quality ISO-9001 compliant services. For more information please contact us.



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