

Bioprocessing Applications Lab (BPAL): A Partner-Focused Case Study in Solving Downstream Purification Challenges

How Ecolab's BPAL combines specialist equipment, development expertise, and practical problem-solving to help our help partners overcome purification challenges they cannot resource alone.



The Challenge

Our customer needed to improve purification of a difficult, aggregation-prone monoclonal antibody. The existing platform approach - Protein A capture followed by polishing - was not sufficiently tuned to the molecule, leaving aggregation risk during capture and elution and limiting confidence in overall process robustness. The challenge was to determine whether a more tailored downstream strategy could reduce that risk, while remaining practical and developable.

Rather than run a narrow troubleshooting exercise, the BPAL team at one of our BPAL sites designed a focused development study to assess capture and polishing options systematically and identify a more robust purification path. BPAL strengthens development efforts by combining scientific expertise, dedicated development infrastructure, and a structured approach to problem-solving, helping teams move from complex technical questions to practical development programs.

How BPAL Supported the Program

A staged development program moved from rapid screening to representative column studies, allowing the team to evaluate capture and polishing options systematically while conserving valuable material. By combining high-throughput screening with lab-scale confirmation, the study balanced speed with process relevance and provided a strong foundation for refining the purification strategy.

The team evaluated multiple Protein A capture conditions, including milder elution approaches designed to reduce the process stress that can contribute to aggregation.

ANNUAL SAVINGS



TIME SAVED
ca. 10% over legacy process



PRODUCT RECOVERY
41% increase



PRODUCTIVITY
Enabling > 99% monomer purity



TOTAL VALUE DELIVERED
Higher first-pass purity with less process complexity – reducing rework risk, waste, and facility time while helping customers deliver high-quality product more efficiently.

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From there, the work expanded into polishing studies, assessing both anion exchange and cation exchange options. Data generated at each stage informed the next phase of development, creating a structured, evidence-based approach to optimizing the purification process.

The result was rapid early data generation grounded in practical process understanding, rather than screening data alone.

Equipment and Capability Available Through BPAL

BPAL's specialist equipment enabled both speed and depth of evaluation. Automated high-throughput tools, including Tecan Fluent liquid-handling systems and RoboColumns, screened chromatography conditions efficiently while conserving valuable feed material. This allowed a broader experimental space to be explored than would typically be practical in a one-factor-at-a-time study.

Selected conditions were then confirmed on lab-scale chromatography systems and supported by analytics, including size-exclusion chromatography and impurity-related testing. Together, these capabilities allowed BPAL to move beyond simple screening and develop a practical view of how the purification sequence could be configured for a challenging molecule.

For our partners, BPAL provides access to an established development environment without requiring them to build the same equipment base or specialist chromatography capabilities internally.

The Work BPAL Completed

BPAL's work focused on identifying a purification strategy better suited to the molecule's aggregation profile. Early studies showed that capture conditions had a significant impact on product quality, leading the team to refine the Protein A capture step using milder elution conditions and resin options that reduced process stress during recovery.

The polishing phase further demonstrated that aggregate removal performance varied significantly across chromatography approaches. By evaluating multiple anion and cation exchange strategies, BPAL identified conditions that improved impurity clearance while maintaining a practical and scalable process sequence.

The resulting data enabled the customer to move beyond a standard platform process and adopt a downstream strategy tailored to the molecule's specific behavior. By the end of the study, the recommended process incorporated a better-defined capture step and polishing sequence, delivering improved recovery, higher monomer purity, and a more robust foundation for continued development.

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What BPAL Brings to Partners

This study demonstrates how BPAL helps partners solve purification challenges that may be difficult to resource internally. BPAL gives partners access to the specialized capabilities and scientific expertise needed to investigate complex downstream challenges and translate findings into practical development strategies.



**Faster troubleshooting and
process optimization**



**Efficient evaluation of multiple
development pathways**



**Access to specialist equipment
and development expertise**



**Data-driven recommendations
that support confident decision-
making**



**Greater experimental capacity
without additional internal
infrastructure**

In this program, BPAL enabled the partner to evaluate multiple downstream options, identify a more robust purification strategy, and establish a clearer path forward for process development. The output extended beyond a collection of experimental results, providing a structured development path that translated technical findings into practical next steps.

Whether the challenge involves complex molecules, limited material availability, aggressive timelines, or gaps in internal resources, BPAL provides a flexible and experienced extension of a partner's process development team.

For readers interested in the underlying technical data, a companion Application Note, Design and Optimization of a Three-Step Monoclonal Antibody Purification Workflow to Improve Yield and Reduce Aggregation, provides detailed development data from this program, including chromatography screening results, process optimization methodology, impurity clearance performance, and analytical outcomes that supported the final purification strategy.

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