



3M™ Harvest RC Chromatographic Clarifier Beta Testing Series

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Frost & Sullivan invited a panel of industry leaders and key opinion leaders in pharmaceutical bioprocessing to participate in a new and unique thought leadership forum, our Virtual Think Tank (VTT) Early Access series. Each VTT panel, comprising professionals from pharmaceutical companies, contract development and manufacturing organizations (CDMOs), and 3M Company, discussed the new 3M™ Harvest RC Chromatographic clarification technology following participation in a beta test program that allowed them early access to work with the product and provide hands-on feedback.

Panelists:

- ▶ **AARON ALMEIDA**
Manager,
Manufacturing Process Optimization,
Catalent Pharma Solutions
- ▶ **RYAN DAVIS**
Senior Scientist,
Downstream Process Development,
Ology Bioservices
- ▶ **JACOB NUHN**
Process Development Scientist,
I - Upstream,
KBI BioPharma
- ▶ **HENRIK OLSEN**
Vice President (VP), Drug Discovery,
Gliknik Inc.
- ▶ **HENDRI TJANDRA**
Associate Director,
Bayer Healthcare LLC
- ▶ **HELENA MAKAGIANSAR**
VP, Development and Manufacturing,
Mapp Biopharmaceutical, Inc.
- ▶ **GUNTER KREISMAYR**
Head of Production, Upstream,
Polymun Scientific
- ▶ **ANDREW BARMASSE**
Process Development Engineer, Regeneron
Pharmaceuticals, Inc.
- ▶ **PETER LUI**
Senior Scientist,
Downstream Process Development,
Merck
- ▶ **ANGIE MORENO**
Scientist,
Downstream Process Development,
Alexion Pharmaceuticals
- ▶ **REGINE VAN MOL**
Senior Research Associate,
Genmab
- ▶ **MIKE CAVALIER**
Senior Director, Manufacturing,
XBiotech

Introduction

The global biologics market is expected to grow at a 10.8% compound annual growth rate (CAGR) leading up to 2028¹. COVID-19 vaccines and therapeutics will further drive this growth during the next 5 years. However, manufacturing monoclonal antibody therapies (mAbs) at a commercial scale is a costly, complex, and time-consuming process.

The 3M™ Harvest RC is a new chromatographic Chinese hamster ovary (CHO) cell culture harvest product. It is a single-stage, single-use chromatographic purification solution for recombinant protein therapeutics manufacturing that replaces the centrifugation and depth filtration operations of the protein purification process. It unifies multiple steps of the upstream process into a single step for various particle sizes and, as a result, thereby reducing the footprint and operating complexity. 3M™ Harvest RC is a next-generation solution to help manufacturers simplify and intensify the process.



1 Businesswire, Global Biologics Market (2021 to 2028)

Benefits of Adopting 3M™ Harvest RC Chromatographic Clarifiers

- Replaces primary, secondary, and guard membranes with single-stage chromatographic clarification
- Removes soluble and insoluble contaminants in various sizes
- Maintains higher product recovery than existing processes
- Demands a smaller footprint

The 3M™ Harvest RC replaces the primary, secondary, and guard membrane filters with single-stage chromatographic clarification. **Jacob Nuhn**, Process Development Scientist at KBI BioPharma, stated, “I think the biggest thing that stands out to me is the single type (single grade) of filter, not having to evaluate primary [or] secondary depth filters. And our manufacturing suite only requiring 1 type of filter instead of 2 stages would allow for a flexibility that we don’t currently have.”



3M™ Harvest RC Chromatographic Clarification's separation capabilities are unique in the industry. It can remove soluble and insoluble contaminants of various sizes, from cells to DNA. Combined with the single-stage approach—compared to the traditional 2- to 3-filter method—it provides an economical and simplified process.

Henrik Olsen, VP of Drug Discovery at Gliknik Inc., explained, “What we are [currently] doing is we are normally harvesting by centrifugation and then we are taking it to a 0.2-micron filter and then we are actually taking it to a small scale 3M™ Emphaze™ [AEX Hybrid Purifier] filter. If we could combine that process into just taking [it] through a filter like this, then we would save both time and money.”

The 3M™ Harvest RC achieves higher concentrations, condenses processing timelines, and increases the mAb purity and recovery into a streamlined process, which results in higher throughput. **Hendri Tjandra**, Associate Director at Bayer Healthcare, explains, “you are getting twice as much of the throughput per meter square of your total depth filter.”

3M™ Harvest RC demands a smaller footprint due to its vertical format, which reduces facility space requirements while providing a higher capacity without compromising quality.

Aaron Almeida, Manager of Manufacturing Process Optimization at Catalent, said, “the capacity of this [Harvest RC] is really enabling going from a fairly large number of cycles to get through clarification to a smaller number.”

Andrew Bermasse, Process Development Engineer at Regeneron Pharmaceuticals, was pleased to learn of the pre-use integrity tests. He explained his reasoning: “With the current depth filter technology, there is no way to really know if you have a bad lot until you run the system, and you run the process, and it fails. This is having a built-in check beforehand.”



Benefits of Adopting 3M™ Harvest RC Chromatographic Clarifiers in Production Processes

- Scalability
- Utility in discovery and early-stage development
- Streamlined process and smaller footprint

Various processes benefit from the adoption of the 3M™ Harvest RC as it combines multiple stages of harvesting clarification and makes scalability easy. **Guenter Kreismayr**, Head of Production for Upstream at Polymun Scientific, said, “when you do scale up in small scale, you can use the Harvest RC without headache.” Kreismayr added, “this is a 1-step purification with a good NTU (nephelometric turbidity unit; low turbidity) at the end. It could probably replace other small filter types where [multiple stages of depth filter grades are deployed] for commercial-scale.”

Many experts on the panel are utilizing the 3M™ Harvest RC in discovery and early-stage development to simplify their harvest process. **Ryan Davis**, Senior Scientist for Downstream Process Development at Ology Bioservices, stated, “I would typically default to this given the single grade needed for clarification [and] the performance improvements that we saw through the clarification impurity profile.”


After the product is adopted in the early stage, it gets commercialized and can be adopted at a commercial scale. **Helena Makagiansar**, VP of Development and Manufacturing at Mapp Biopharmaceutical, stated, “We are a small company, so we are very lean. I think it makes sense for our pilot operation to just install 1 instead of 3 filters. So, that is part of the plan already.”

Nuhn added, “As we continue to see increased cell growth, as clients continue to bring in higher, better growing cells, and as it fits well within the framework of the platform processes we currently have, I could see us, in the future, moving to this.”

Conclusion

3M™ Harvest RC is a single-stage, single-use chromatographic clarification solution with multiple benefits driving its industry adoption. It overcomes the time- and cost-related challenges associated with legacy processes, has an increased rate of mAb product recovery, and reduces turbidity while maintaining protein purification consistency. During Frost & Sullivan's VTT Early Access series, respondents made it evident that they believe adopting the 3M™ Harvest RC in commercial manufacturing will eliminate these key challenges in the harvest process.

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