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Commentary Article

Affinity Chromatography: An Enabling Technology for Large Scale Bioprocessing - How does it get to the Developing World

Frank Riske [1*] and Brendan Riske [2]

[1] Ph. D., BPTG, BDO, One International Place, Boston, MA 02110

[2] M.S., Department of Entomology, University of Arizona, Tucson, AZ, 85721

Corresponding author: Frank Riske, Ph. D., BPTG, BDO, One International Place, Boston, MA 02110.

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Abstract

Affinity chromatography was initially used to describe chromatographic biological interactions such as lectin-glycoprotein, antibody -antigen and enzyme-inhibitor. This definition has expanded to include the specific interaction between a target and a ligand. The use of affinity chromatography has reached a zenith with the explosion of Mab therapeutics and the use of Protein-A chromatography for antibody capture. Now, affinity chromatography has moved to non Mab proteins. This can result in the same economic advantages as Mab, by enabling the standardization of process development and manufacturing processes in flexible multiproduct production sites. The output is improved product throughput, higher target recoveries, and potentially less expensive drugs. These advantages are available to the developed world but how do we make this technology available to the developing world?

Key words: affinity chromatography, affinity ligands, custom resins, platform process, developing world, biological facilities

Abbreviations:

cGMP – current Good manufacturing Practice

FTE – full time equivalent

ROW – rest of world

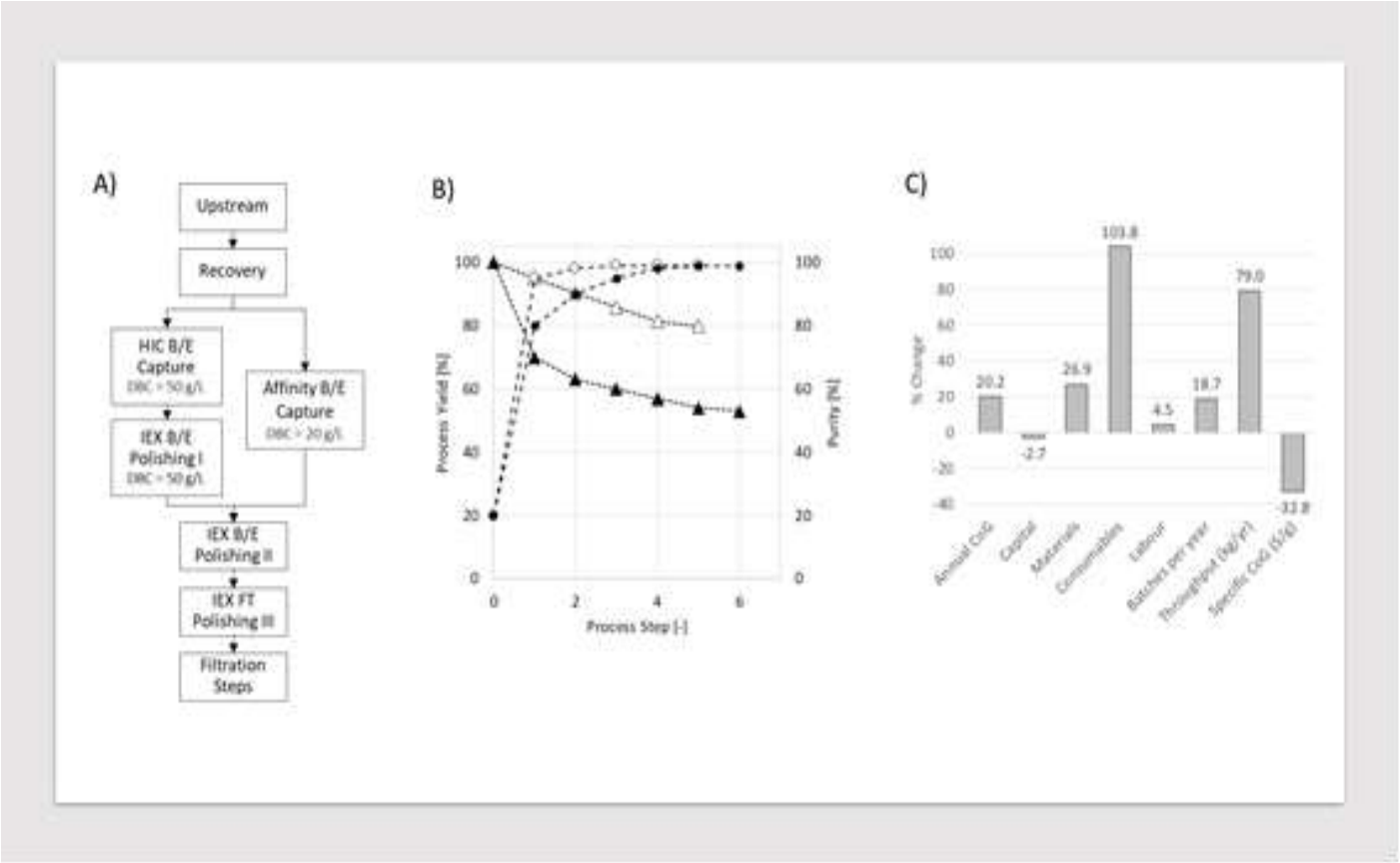
COG – cost of goods

Introduction

World-wide access to high quality biologics is often limited due to the high cost of building, operating, and maintaining facilities to produce cGMP drugs. Furthermore, the total number of FTE's associated with process development for a recombinant protein can be as high as 36 FTE's totaling a cost of several millions of dollars [1]. One solution has been for the developing world to build, operate, and profit from a facility for a fixed time period and then transfer that facility to the country of operation (and retain a percentage of the profits). But even with lower wages and reduced building costs, the challenges to producing cost efficient biologics are daunting. Methods to simplify and standardize processes are needed to reduce biologics costs. Custom affinity chromatography, which may take only 3-5 months to develop (personal communication with Avitide), can provide that simplicity and standardization. However, discovering and developing the appropriate ligand requires specialized labs and equipment which may not be available in all parts of the world. Perhaps, the custom affinity ligands would be developed in the US or Europe and then made available to the ROW. This may require government(s) consortiums to pay for that development or provide fair payment to companies for access to platform processes using affinity ligands.

Discussion

Ligands (synthetic or natural) used in bioprocess affinity chromatography, must exhibit high selectivity, relatively high affinity, chemical stability and the reversible binding to the target yielding target elution under relatively mild conditions. Many affinity ligands to protein exist [2-5]. Several companies operate in this space; e.g., Affilogics, Aptamer group, Avacta, Avitide, Prometics, Navigo, and Thermo Fisher. Affinity chromatography processes show a lower specific COG in comparison to conventional processes (Figure below).



Courtesy of Biotech J.

Panels: A) simplified process layout for Process I (affinity, open symbols) and Process II (conventional, closed symbols); B) Cumulative process yields (triangles) and purity (circles) after each downstream processing step in Process I (open symbols) and Process II (closed symbols); C) Changes in typical process economy indicators expressed in percent change of Process II values.

Affinity chromatography COG is lower because one can typically reduce the number of unit operations in a downstream process to achieve the requisite purity. This reduces development time and plant time. Furthermore, with the appropriate ligands a platform process can be developed for diverse biomolecules.

The biotechnology industry continues to expand into the developing world. Developing nations are both markets with a high demand for pharmaceutical products and potential manufacturing locations. There has been increasing interest in setting up and running biotech production facilities in these locations. Successful recent examples include domestic insulin production in Egypt, the development of Covid vaccines by Cuba [1], and the production of transgenic crops for agriculture in Kenya [1] (Kingiri, et al, 2021). It is increasingly clear that these nations have the human capital and capacity to take part in the industry. This ligand technology provides new opportunities, as it could streamline and lower the cost of production for many types of biological product.

Biotechnology production in developing markets is becoming increasingly attractive. Costs such as land and labor are significantly lower in these countries, and infrastructure improvements have made supplying these facilities and exporting from them more feasible. Two key elements in any of these projects are government support and partnerships with multinational companies. Government assistance with funding and other policy support is necessary to make viable projects. Partnerships with large companies creates opportunities for facilities to get access to technology, as well as find good suppliers and customers. In the case of this technology transfers or leasing will play a critical role. By giving companies in these regions access to protocols and materials which have been already developed, they can rapidly get them online manufacturing desired products. This can allow firms to compete in local markets.

References

1. Shukla, B. Hubbard, T. Tressel, S. Guhan, D. Low, (2007) Downstream processing of monoclonal antibodies--application of platform approaches *J Chromatogr B Analyt Technol Biomed Life Sci. 848*, 28.
2. Mouratou, G. Behar, F. Pecorari, (2015) Artificial affinity proteins as ligands of immunoglobulins. *Biomolecules*, 30;5(1):60-75.
3. M. Lonne, S. Bolten, A. Lavrentieva, F. Stahl, T. Scheper, J.-G.Walter, (2015) Development of an aptamer-based affinity purification method for vascular endothelial growth factor. *Biotechnol. Rep. 8*, 16.
4. Forier, E. Boschetti, M. Ouhammouch, A. Cibiel, F. Duconge, et al. (2017) DNA aptamer affinity ligands for highly selective purification of human plasma-related proteins from multiple sources, *J. Chromatogr. A 1489*, 39.
5. S. Miyakawa, Y. Nomura, T. Sakamoto, Y. Yamaguchi, K. Kato, S. Yamazaki, Y. Nakamura, (2008) Crystallization and preliminary X-ray diffraction studies of an RNA aptamer in complex with the human IgG Fc fragment *RNA* 2008, *14*, 1154.
6. Gorry MA. (2020). *MEDICC Review* 2020, 22 (4).
7. A.N. Kingiri, *Innovation and Development* 2021, 0(0), 1–20.