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Editorial

Editorial on "Technology trends in antibody purification" by P.S. Gagnon

Some of the blockbuster drugs are monoclonal antibodies, and the number is growing. In 2008, the revenues from monoclonal antibodies in the United States alone were over $15 billion. Most of the antibody drugs are used to treat cancer and autoimmune diseases, and many of the rest are used to treat orphan and infectious diseases.

Unfortunately, antibodies are proteins. This of course means that they are complex in all sorts of ways, which makes it challenging to purify and characterize them sufficiently so that they meet the rigid requirements of a therapeutic. While antibodies share some structural characteristics, each antibody has unique properties that can play a role in the purification process.

Therapeutic antibodies come in different genetically engineered forms such as bispecific (the antibody has two different binding sites with different antigenic targets) and humanized (mixture of murine and human sequences to various degrees, especially to minimize immune response to the antibody in the patient). They can also be engineered in other ways, e.g. in glycan content and sequences that minimize aggregation. Sometimes a change in sequence that reduces aggregation simultaneously increases immunogenicity. The antibodies may be conjugated to another kind of drug. Because of the inherent and engineered variations in therapeutic antibody structures there is no "one size fits all" when it comes to techniques for their purification. The closest to this is protein A affinity chromatography, which is widely used. However, it is expensive, susceptible to degradation by proteases, and not fully stable to column washing and elution conditions.

The market for therapeutic monoclonal antibodies drives and justifies extensive tuning and understanding of the schemes for their purification. Clearly the field is advanced, considering that about 30 antibodies over the past 25 years have been brought to market. Nevertheless, further advances in purification are needed, especially to lower production costs and thereby, hopefully, the costs of these medications for the patient.

The review by Peter Gagnon gives us a perspective on the field of therapeutic antibody purification, covering the broad variety of techniques that are being used and studied.

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