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## Current Trends in Monoclonal Antibody Development and Manufacturing



Publication Date: 2009-11-12

Edited by Steven J. Shire, Wayne Gombotz, Karoline Bechtold-Peters, and James Andya

Monoclonal antibodies represent one of the fastest growing areas of new drug development within the pharmaceutical industry. Several blockbuster products have been approved over the past several years including Rituxan, Remicade, Avastin, Humira, and Herceptin. In addition, over 300 new drugs are currently in clinical trials. With both large, established biotechnology companies and small start-ups

involved in the development of this important class of molecules, monoclonal antibodies products will become increasingly prevalent over the next decade. Recently the regulatory review of monoclonal antibodies has been moved from Center for Biologics and Research to the Center for Drug Evaluation and Research (CDER) division of the U.S. Food and Drug Administration. It is anticipated that CDER will expect a certain minimal amount of data to be provided as more of these products move through the regulatory pipeline. *Current Trends in Monoclonal Antibody Development and Manufacturing* will provide readers with an understanding of what is currently being done in the industry to develop, manufacture, and release monoclonal antibody products and what will be required for a successful regulatory submission.

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