

Therapeutic antibodies

Therapeutic antibodies represent the first, and the major, category of a class of biopharmaceuticals that function by recognizing and binding to a ligand within the body (for example a cellular receptor, a cytokine or other soluble factor, or an epitope on a pathogen). Therapeutic antibodies can exert their effect in a number of ways: by blocking ligand:ligand interactions; by delivering a signal through a receptor after binding; by delivering an effector payload (such as a drug or radioisotope) to a specific location, or by recruiting other elements of the body's immune system.

Since the discovery of monoclonal antibodies in the mid 1970s, and the approval in 1986 of the first monoclonal antibody product, OKT3, 28 therapeutic antibodies of various formats have been approved around the world (5 murine, 5 chimeric, 14 humanized and 4 recombinant human). An even larger number are in clinical studies. These products have combined annual sales in excess of \$25B world-wide, including the blockbuster sellers Remicade (\$5B, 2007), Rituxan (\$4.6B in 2007), Herceptin (\$4B, 2007) and Avastin (\$3.4B, 2007).

Here at Ithaka we have first-hand experience in the design and manufacture of such molecules and in the preclinical and clinical development process leading to product approval. We maintain awareness of developments in the field and can provide advice and assistance in the development of therapeutic antibody products from inception to the clinic. Team members with direct experience include John Adair, Malcolm Rhodes and Grahaem Brown

John Adair has an extensive background in antibody R&D, including bench research at Celltech, leading to the development of a significant intellectual property portfolio and, currently, two licensed products. In addition he has experience in the management of research and pre-clinical development of biopharmaceuticals (including early stage cell line development and production) at Celltech and Scotgen Biopharmaceuticals and in consultancy work for a number of UK antibody-based companies including Aeres Biomedical, Antisoma, Cambridge Antibody Technology, Celltech, Haptogen and the Medical Research Council.

Malcolm Rhodes has extensive experience in process development, product development and manufacture of antibodies for clinical trials, and licensed therapeutic and diagnostic applications at Celltech (now Lonza Biologics) and Bioscot (now Millipore). He has developed numerous clinical products including several now marketed. He has also advised venture capital companies and law firms and academic researchers on non-clinical development programmes for antibody products.

Dr Grahaem Brown, a specialist in Internal Medicine, is a consultant to the Pharma, Biotech and Venture Capital Industries, having previously held senior R&D positions in Glaxo, Novartis, Pharmacia and UCB/Celltech. Grahaem has 20 years experience of driving global development of small molecules and biologicals, from discovery through development to product launch and life cycle management. He has experience in assessing potential collaboration opportunities and conducting due diligence. He has worked on the clinical development of IL-1, TNF α , CD22, VEGF and dsDNA antibodies