

# Advances in Bio-Separations

## Biologics Characterisation from Cradle to Grave

### 12th – 13th May 2015 at MedImmune, Cambridge

*Dr Chris Bevan*

*Events Coordinator for The Chromatographic Society*

#### THE SUBJECT OF THE SYMPOSIUM

The Chromatographic Society strives to present leading edge Separation Science in-context. This symposium is devoted exclusively to examining the challenges facing chromatographers by the rapidly emerging field of therapeutic biologics development.

#### BIOLOGICS

Biologics can be composed of sugars, proteins or nucleic acids and/or complex combinations of these substances, or may be living entities such as cells and tissues. Biologics are isolated from a variety of natural sources and may be produced by biotechnology methods and other technologies. Gene-based and cellular biologics are often at the forefront of biomedical research being used to treat a variety of medical conditions for which no other treatments are available.

In most cases, the term 'biologics' is reserved for a class of therapeutics produced by means of biological processes involving recombinant DNA technology. These medications are usually one of three types, namely:

- Substances that are almost identical to the body's own key signalling proteins. An example is the growth-stimulating hormone named generally as 'growth hormone' or biosynthetic human insulin and its analogues.
- Monoclonal antibodies similar to the antibodies that the human immune system uses to counter bacterial and viral infections, being 'custom-designed' to specifically counteract or block a given substance in the body, or to target a specific cell type.
- Receptor constructs (fusion proteins), usually based on a naturally-occurring receptor linked to the immunoglobulin frame.

#### THE CHALLENGE FOR THE ANALYTICAL CHEMIST

Compared with small molecules (say of Mol Wt <500) which consist of chemically identical active ingredients, biologics are vastly more complex and may consist of a multitude of sub-species. Due to their heterogeneity and the high sensitivity to their production process conditions, neither originators nor follow-on manufacturers find it easy to produce completely constant and consistent quality profiles over time.

The process variations are monitored by modern analytical tools such as liquid chromatography, immunoassays and mass spectrometry, which serve to describe a unique 'design space' for each biologic and form the core theme of this symposium.

The complete characterisation of proteins and peptides is now



becoming essential across a wide range of industries and applications as specifications are tightened and enforced.

Thus, the emergence of protein based biologics and bio-pharmaceuticals has resulted in an increased reliance on the chromatographic and spectrometric techniques used to determine the key quantitative and qualitative attributes of such highly complex therapeutic entities.

This meeting aims to highlight key advances and current practises in the separation and detection techniques used to analyse peptides and proteins.

#### THE LECTURE PROGRAMME

This highly topical subject area has attracted contemporary international specialists and pharma experts who will be describing their work and revealing the analytical challenges they face and their solutions to some of these complex problems.

Notable amongst these currently, we have:

**Dr Alexander Makarov (ThermoFisher Scientific, Germany)**

Bio-Chromatography with Orbitrap detection: past, present and future

**Prof Gary Walsh (University of Limerick, Ireland)**

Bio-similar characterisation for regulatory approval

**Dr Koen Sandra (Research Institute for Chromatography, Belgium)**

Chromatographic and mass spectrometric information available at the protein, peptide, amino acid and glycan levels

**Dr Davy Guillarme (University of Geneva, University of Lausanne, Switzerland)**

Size exclusion and Ion Exchange chromatography for bio-molecule characterisation

**Dr Alistair Kippen (MedImmune, Cambridge)**

Introduction to Biopharm Development & Characterisation of Biologics

**Dr Vivian Lindo (MedImmune, Cambridge)**

Mass Spectrometry and the Characterisation of Biologics

**Stuart Phillips (Shimadzu, Milton Keynes)**

Supporting biologic molecules development using the latest separation and mass spec techniques

**Dr Milena Quaglia (LGC group)**

An experimental design protocol for hydrogen deuterium exchange mass spectrometry experiments and the role of chromatography

**INSTRUMENT EXHIBITION**

Complementing the lecture programme an exhibition of scientific equipment and consumables relevant to the analysis of biologics and their purification will be held as an integral part of the symposium together with relevant specialised technology presentations from our list of supporting companies.

These companies currently include

PHENOMENEX; CRAWFORD SCIENTIFIC; SHIMADZU; HICHROM; THERMOFISHER SCIENTIFIC & EUROPA BIOPRODUCTS

**THE VENUE**

The Chromatographic Society is privileged to partner with MedImmune laboratories at Cambridge to host this symposium and to offer their facilities and lecture presentations from senior scientific staff members on their work.

MedImmune (formerly Cambridge Antibody Technology) is the worldwide biologics R&D arm of AstraZeneca, a global, innovation-driven biopharmaceutical business that focuses on the discovery,

development and commercialisation of small molecule and biologic prescription medicines. MedImmune is pioneering innovative research and exploring novel pathways across key therapeutic areas, including respiratory, inflammation and autoimmunity; cardiovascular and metabolic disease; oncology; neuroscience; infection and vaccines.

**REGISTRATION:****HOW TO ATTEND AS AN EXHIBITOR AND/OR AS A DELEGATE SPONSORSHIP AND EXHIBITION COSTS****GOLD LEVEL SPONSORSHIP £1750**

- Table top exhibition stand & 20 mins lecture time integrated into the programme
- 3 free delegate admission places

**SILVER LEVEL SPONSORSHIP £1250**

- Table top exhibition stand & 10 mins lecture time integrated into the programme
- 2 free delegate admission places

**BRONZE LEVEL SPONSORSHIP £750**

- Table top exhibition stand and 1 free delegate admission place

**DELEGATE ADMISSION PRICES**

Member of the Chromatographic Society or affiliated societies (BMSS, ELRIG or RSC)	£150
Promotional rate for non-members which includes ChromSoc membership for remainder of 2015	£170
Non members	£180
Bona fide student	£75

NOTE: VAT at 20% is additionally charged on all prices

**SPONSORSHIP, LECTURE CONTENT & EXHIBITION STAND ENQUIRIES**

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