SGS M-SCAN OPEN DAY

BIOPHARMACEUTICAL CHARACTERISATION

VENUE:
DEVERE WOKEFIELD PARK HOTEL
GOODBOYS LANE, MORTIMER
READING BERKSHIRE, UK RG7 3AH

DATE: JUNE 19, 2012

M-Scan

SGS

Join SGS M-Scan for a one-day seminar to stay abreast of the current regulatory environment and to learn about optimizing your Biopharmaceutical development. The day will include a selection of scientific talks, case studies and face-to-face meetings with some of our experts and key industry players who will discuss:

- The Biologics R&D Market and Trends: a presentation by Frost & Sullivan
- Biophysical Analysis
- Extractables & Leachables
- Antibody Characterisation
- Methods for Characterisation of Protein Glycosylation
- Regulatory/technical Issues for Biopharma & Biosimilar products

We look forward to seeing you at DeVere Wokefield Park Hotel.

PROGRAM

REGISTRATION AND COFFEE	10:00 – 10:30	
WELCOME AND INTRODUCTION	10:30 – 10:45	SGS Life Science Services
MARKET OUTLOOK FOR OUTSOURCING IN BIOPHARMA	10:45 – 11:05	K. Srinivas Sashidhar Senior Research Analyst - Life sciences Frost & Sullivan
BIOLOGICAL ASSAY DEVELOPMENT: A STATISTICAL APPROACH	11:05 – 11:35	Samantha Dowse Director Nathan Consulting Ltd.
REGULATORY ISSUES FOR BIOPHARMA AND BIOSIMILAR PRODUCTS	11:35 – 12:15	Dr. Fiona Greer Global Director for Biopharma Services Development SGS M-Scan
DISCUSSION AND QUESTIONS	12:15 – 12:30	
LUNCH & MEET THE SGS M-SCAN SCIENTISTS	12:30 – 14:00	
BIOPHYSICAL ANALYTICAL TECHNIQUES: SCOPE AND APPLICATIONS ON BIOPHARMACEUTICALS	14:00 – 14:25	Dr. Iñigo Rodriguez-Mendieta Senior Scientist in Biophysical Analysis SGS M-Scan Ltd.
STRUCTURAL CHARACTERISATION OF MONOCLONAL ANTIBODIES	14:25 – 15:30	Dr. Andrew Reason Group Manager SGS M-Scan (Europe)
EXTRACTABLES AND LEACHABLES ANALYSIS	15:30 – 16:00	Dr. Chris A. J. Harbach Chemical Services Manager SGS M-Scan Ltd.
DISCUSSION & QUESTIONS	16:00	

SPEAKERS ABSTRACTS AND BIOGRAPHIES

ANALYTICAL LABORATORY TESTING MARKETS FOR BIOLOGICS AND BIOSIMILARS

K. SRINIVAS SASHIDHAR
Senior Research Analyst - Life sciences, Healthcare Practice, Frost & Sullivan

ABSTRACT

A significant increase in the number of analytical testing laboratories is being witnessed worldwide. Much of this is being attributed to an increase in product testing numbers and diversification of products. The European biosimilars market will continue to grow from approximately $172.0 million in 2010 to $3,987.0 million in 2017 at a CAGR of 56.7%. There is a huge opportunity for biopharmaceutical testing services as new biologics and biosimilars are expected to emerge in the future.

AREAS OF FOCUS:

- Overview of the Analytical Laboratory Testing Markets – Current Scenario
- Sneak peak of the Biologics and Biosimilars Markets
- Trends and opportunities in Analytical Testing Markets for Biologics, Biosimilars and small molecules
- Strategic recommendations for market players

BIOGRAPHY

FUNCTIONAL EXPERTISE

K. Srinivas Sashidhar worked on various market research reports focusing on market analysis, such as: identification of key challenges, drivers & restraints, market trends, competitive analysis, revenue forecasts and business models.

INDUSTRY EXPERTISE

Prior to joining Frost & Sullivan Sashidhar gained expertise in the Life Science markets, including pharmaceutical and biotechnology, clinical diagnostics and drug discovery tools, with specific experience in biosimilars, diabetes and In-Vitro Diagnostics as well as DNA analysis and HLA typing for transplants.

BIOLOGICAL ASSAY DEVELOPMENT: A STATISTICAL APPROACH

SAMANTHA DOWSE
Director, Nathan Consulting Ltd.

ABSTRACT

A strategic approach to assay validation is required to support the move from a biopharmaceutical product in pre-clinical development, through the phased clinical trials then into commercial settings. This talk intends to summarise a staged analytical development strategy using a statistical approach to qualification, development, transfer and validation of a biological assay.

BIOGRAPHY

Samantha Dowse is the owner and founder of Nathan Consulting Limited.

With over 10 years' experience working in Analytical Development for Biopharmaceutical Companies, Samantha has become an Analytical consultant who specialises in all aspects of Analytical Development with a focus on biological assays. Consulting roles and previous experience has allowed Samantha to provide strategic input and manage Product Stability Programmes and Stability Studies and to develop strategies and manage Assay Development and Validation Programmes for complex biological vaccines, therapeutics and biosimilars. Samantha is versed in contributing to the CMC sections of the relevant submissions to regulatory authorities in Europe, USA and China for vaccines and therapeutics in the form of Clinical Trials Application Dossiers, Investigational New Drug Applications, Investigational Medicinal Product Dossiers and Requests for Scientific Advice.

Fields of expertise include assay qualification, development, validation and transfer (inter-laboratory and site) with a focus on the use of statistics to allow Quality by Design, along with stability studies program development, study management and evaluation, contribution to the CMC sections of regulatory submissions and general CMC project outsource management from selection through implementation.

REGULATORY/TECHNICAL ISSUES FOR BIOPHARMA & BIOSIMILAR PRODUCTS

DR. FIONA GREER
Global Director for Biopharma Services Development, SGS M-Scan.

ABSTRACT

Update on technical regulatory guidelines for analytical characterisation of bioproducts including mAbs. Overview of international biosimilar status and presentation of integrated capabilities.

BIOGRAPHY

Following a Ph.D. in Protein Biochemistry from Aberdeen University, she joined M-Scan Ltd in 1984 to found the Biochemical Services Department. Here, she pioneered and applied developments in Mass Spectrometry for structural characterisation. She was appointed Director of Biochemical Services in 1988. At the same time, she was instrumental in establishing a facility in the United States where she was appointed Vice President. Dr Greer was responsible for establishing the Quality Management Systems and for directing Quality Assurance across the four M-Scan laboratories.

With over 30 years experience in the structural analysis of glycoproteins using instrumental techniques, she has published many articles on the use of mass spectrometry to fulfil regulatory characterisation requirements. She is regularly invited to give presentations at international meetings and has designed and presented various training courses. She is now Global Director for Biopharma Services Development, SGS M-Scan.

BIOPHYSICAL ANALYTICAL TECHNIQUES -SCOPE AND APPLICATIONS ON BIOPHARMACEUTICALS

DR. IÑIGO RODRIGUEZ-MENDIETA
Senior Scientist in Biophysical Analysis, SGS M-Scan Ltd.

ABSTRACT

Proteins are inherently unstable from a physical structural point of view so analytical techniques that determine their higher order structure are key analytical tools to understand the critical parameters that govern the physical stability of protein materials at the developmental and manufacturing stages as well as determining product shelf life.

Biophysical Analysis addresses this concern: using a selection of biophysical techniques that report on the secondary, tertiary and quaternary structure of proteins permits monitoring of the conformational and aggregation state of proteins at key developmental stages such as pre-formulation and forced degradation stability programs. Additionally, use of Biophysical Analysis is becoming widespread in other stages of the production cycle *i.e.* GMP manufacturing and real time stability studies where their benefits and added value are being rediscovered.

Techniques like CD, FTIR ,fluorescence and DSC are flexible spectroscopic and calorimetric techniques that accurately report on the conformational and thermal stability of proteins. When used in conjunction with powerful techniques like SV-AUC, DLS and SEC-MALS, a comprehensive picture of the physical stability of the materials under study can be fully appreciated.

This presentation will discuss in detail the technical aspects of key biophysical analytical techniques, their applications, benefits and limitations together with some examples from our expert group in the Biophysical Centre of Excellence at the SGS M-Scan facilities in Wokingham.

BIOGRAPHY

Iñigo joined SGS M-Scan Ltd. in January 2012 as a Senior Scientist in Biophysical Analysis to support the provision of Biochemical Services. He obtained his degree in Biochemistry at the University of the Basque Country and his PhD at Leeds University developing ultrafast mixing technology for rapid kinetics of proteins using UV Resonance Raman spectroscopy. Following his doctorate studies, Iñigo joined a small CRO where he was in charge of the development of biophysical analysis services for the Biopharmaceutical industry. After this, he returned to academia for a short period of time before becoming a freelance consultant to the biopharmaceutical industry in the field of biophysics and pre-formulation. Iñigo has extensive experience in the characterisation of proteins in solution using biophysical techniques such as CD, FTIR, Raman, UV Raman, SV-AUC, DLS, DSC and fluorescence spectroscopy among others. He actively applies his expertise in biophysics in the development and provision of analytical services offered by SGS M-Scan Ltd.

STRUCTURAL CHARACTERISATION OF MONOCLONAL ANTIBODIES

DR. ANDREW J REASON
Group Manager of SGS M-Scan (Europe)

ABSTRACT

Five of the top seven and six of the top twenty biological products in 2010 (in terms of revenue) were monoclonal antibodies. A number of new monoclonal antibody products and monoclonal antibody biosimilars are in development, all require extensive characterisation in order for the product to obtain the necessary agreements for clinical trials to proceed and eventually release onto the market. An overview of the structural characterisation requirements for monoclonal antibodies will be delivered.

BIOGRAPHY

Following a Ph.D in "Characterisation of O-linked GlcNAc in nucleoplasmic and cytoplasmic glycoproteins" and a short period of postdoctoral research at Imperial college, Andrew joined M-Scan in 1994 as a biochemist, and rose to become managing director of the M-Scan Limited and GmbH. Shortly after the acquisition of M-Scan by SGS, Andrew was appointed Group Manager of SGS M-Scan (Europe). In addition to his managerial duties, Andrew has contributed to many industry publications and is a regular presenter at regional conferences.

EXTRACTABLES AND LEACHABLES (E&L) - DRUG PRODUCT DEVELOPMENT CHALLENGES

DR. CHRIS A. J. HARBACH
Chemical services manager SGS M-Scan Ltd.

ABSTRACT

Extractables and Leachables (E&L) issues represent some of the most significant challenges facing a drug product development team today. Unwanted chemical species may migrate from process equipment, packaging or delivery systems into the drug product during production or during the product's shelf life. These species may alter the product's identity, efficacy, purity or safety, potentially rendering the drug product ineffective or harmful to the patient. Regulators are increasingly expecting drug manufacturers to assess this risk through properly designed E&L studies. The E&L risk varies depending on the product, the dosage form, patient population and dosing regimen.

SGS M-Scan Limited has developed detailed analytical programmes for the investigation of extractables in container / closure systems and for the investigation of leachables in final product formulations. This presentation will discuss the issues surrounding E&L, the analytical programmes that have been developed and some results.

BIOGRAPHY

- Honours graduate in Natural Sciences (Chemistry) of Cambridge University, England. He obtained his Ph.D. in the Chemistry Department at Cambridge University.
- Joined M-Scan Limited in 1990 as Senior Mass Spectroscopist.
- Promoted in 2002 to Manager, Chemical Services with responsibility for the Chemical sector of the company's business.
- Currently Manager, Chemical Services with responsibility for Chemical, Oil and Environmental services within SGS M-Scan Limited
- Areas of special interest include extractables & leachables, impurities & residuals in pharmaceuticals, polymers, surfactants and odours.

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COST & ACCOMMODATION

The seminar is offered free of charge. However, only pre-registered attendees will be admitted.

For information on travel and discounted accommodation please contact Mrs. Christine Turner.

SGS M-SCAN OPEN DAY 2012

JUNE 19 - WOKEFIELD PARK - READING, UK

TO REGISTER PLEASE COMPLETE THIS FORM (IN CAPITAL LETTERS) AND RETURN IT TO SGS M-SCAN EMAIL: UK.ADMIN.M-SCAN@SGS.COM OR FAX +44 (0) 118 989 6941

PLEASE TICK AS REQUIRED

☐ I hereby register to attend the SGS M-Scan Open Day 2012 which will be held on 19 June 2012 in DeVere Wokefield Park Hotel, Reading, UK from 9:30 hrs to approx. 16:30 hrs.

Attendance is free of charge, refreshments and lunch will be provided during the day.

☐ I will also be bringing ____ colleagues:

_____ _____

Title, Surname, Name Email

_____ _____

Title, Surname, Name Email

☐ Unfortunately I cannot attend the SGS M-Scan Open Day 2012 but would be interested in a future date.

Surname	Title
First Name	
Job Title	
Company/Organisation	
Work Address	
Post Code	Tel No:
Country	Fax No:
e-mail	

Date: _____ Signature: _____

COMMENTS:

A confirmation of your participation and further details of the location will be provided in advance. Please note the number of participants is limited. For information on travel and accommodation, please contact Mrs. Christine Turner at +44 (0) 118 989 6940 or uk.admin.m-scan@sgs.com

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WHEN YOU NEED TO BE SURE

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