



Annual International Conference and Dinner

INJECTABLE DRUG DELIVERY

Devices, Technology & Development

EXHIBITORS:

medisize
CREATING SMARTER SOLUTIONS



Presentations to Include:

- **New Developments in Injectable Drug Delivery**
- **New Drugs for Auto Injectors**
- **Market Trends in Injectable Drug Delivery and the Merger of the Device and Drug World**
- **DosePro™ – From Idea to Approval: A Single Use, Disposable, Needle-Free Drug Delivery Device**
- **Glide SDI® – Injecting Vaccines and Drugs in a Solid Dosage Form**
- **The Use of New Biotech Drugs with Injectable Drug Delivery Systems**
- **Advances in Injection Technology**
- **Market Assessment of the Value of Injection Devices**
- **New Requirements and Approaches on Standards for Pen and Auto Injectors**
- **Delivery of H1N1 Vaccines Using PharmaJet Technology**
- **Challenges with Combination Drug Delivery Systems: Pre-Filled Syringes and Auto Injectors**
- **EU and Global Regulatory Approach for Needle-Free, Pen and Auto Injector Combination Products**

Chairman

Dr Gregory Berman Medical Products Group Leader, PA Consulting Group

With an international panel of speakers

Increase your networking opportunities by attending the conference dinner which is included in the conference package

**PLUS: Post-Conference Seminar
DRUG/DEVICE AND DEVICE/DRUG
COMBINATIONS IN THE EU**

24 March 2010, The Cavendish Hotel, Piccadilly, London



**22 & 23 March 2010
Le Meridien Hotel, London**



INTRODUCTION

The period since the last Injectable Drug Delivery conference has been economically turbulent and characterised by continued cost cutting with resultant job losses in many pharmaceutical companies. It has also seen a new round of mergers with Pfizer's acquisition of Wyeth, Roche's acquisition of the outstanding Genentech equity, and Merck's deal to merge with Schering-Plough for a consideration over \$40 billion. These deals will have an effect on injectable drug delivery device developments and platform requirements. Departments will likely be merged and delivery platforms rationalized.

Elsewhere the industry continues to face patent expiry of its biggest sellers combined with a decline in the number of small molecule drugs (new chemical entities, NCE's) gaining approval. Biological pipelines (new molecular entity, NME) remain more buoyant.

Biopharmaceutical product developments and vaccination programmes mean that increasing numbers of drugs on the market have to be administered by injection, despite most patients' preference for oral administration. For example, the injected H1N1 flu vaccine is expected to boost GSK's sales during the year by a billion pounds.

To make injections more convenient and more acceptable to patients, the industry is using injection devices which automate some or all of the parenteral delivery steps or completely change conventional delivery modalities associated with the needle and syringe.

Taken together, the emphasis within the industry is increasingly on using drug delivery technology to differentiate products and provide lifecycle management opportunities. The surge in biosimilars is triggering the generics companies to develop advanced injection devices to differentiate their products in the marketplace from the branded originals.

Advances in auto injector design and needle-free injectors are helping pharmaceutical companies to market their drugs and to compete more effectively by providing gains in market share, allowing greater penetration of markets, helping patients to comply with dosage regimes and providing safer injections. Indeed, injection devices were once considered as an afterthought, but now in some product categories they are becoming an entry ticket; an essential part of the drug's presentation to the market, without which they would fail to attract patients. Pharmaceutical companies are developing injectors in parallel with their new drugs, in the knowledge that a device will be needed at product launch.

Injectable Drug Delivery Technologies are advancing both commercially and technically. In the last year we have seen the launch of the SmartJect for delivery of Simponi, Centocor's new RA drug. This advanced device is the first pre-filled, single use, disposable auto-injector which fully automates the injection cycle. It inserts the needle, delivers the drug and withdraws the needle at the end of the injection. Other devices leave the needle in at the end of the injection, relying on the patient to remove the needle from the injection site. It is also thought to be the first new drug co-developed with an advanced autoinjector.

THREE REASONS TO ATTEND THIS EVENT

- **An extremely valuable update on the advances in injection technology**
- **An opportunity to keep abreast of business opportunities in the market**
- **The chance to develop significant business partnerships**

PROGRAMME

DAY ONE

- 09.30 ▶ **Chairman's Welcome and Introduction**
Dr Gregory Berman PA Consulting Group
- 09.40 ▶ **New Developments in Injectable Drug Delivery**
- Market trends and industry news
 - Future drivers for injectable delivery platforms
 - Outlook
- Mathias Romacker** Amgen Inc.
- 10.20 ▶ **The Use of New Biotech Drugs with Injectable Drug Delivery Systems**
- Delivery devices for Biotech drugs
 - New launches in the diversified biotech market
 - Anticipating the future attributes and features of delivery devices: Pens, Auto Injectors, Needle-free, Pumps
 - Key success factors for a new delivery device
- Joël Cotten** BD Medical Pharmaceutical Systems



- 11.00 ▶ **Discussion**
- 11.10 ▶ **Coffee and Exhibition Viewing**
- 11.30 ▶ **Market Trends in Injectable Drug Delivery and the Merger of the Device and Drug World**
- From “the filed” view of what are the drug companies future needs?
 - The difference in mind set between device and drug company
 - How to achieve a successful cooperation between the device and drug company
- Frank Isaksson** SHL
- 12.10 ▶ **Life Cycle Management for Biopharmaceuticals Using Injection Devices**
- Don Rogers** Genentech USA
- 12.50 ▶ **Discussion**
- 13.00 ▶ **Lunch**
- 14.10 ▶ **The Future has *Finally* Arrived! From Idea to Approval – Development of the Worlds’ First Single Use, Disposable, Needle Free Drug Delivery Device – DosePro™.**
- The DosePro delivery system is truly unique and has been in development for many years and has encountered and overcome many technical and business hurdles to become a commercial reality. History in the needle free injection field was made in July 2009 when the Sumavel™ DosePro (sumatriptan injection) New Drug Application (NDA) was approved by the U.S. FDA as a first-of-its-kind pre-filled, single use, disposable, needle-free injection system for subcutaneous delivery of sumatriptan for migraine therapy.
- Jonathan M. Rigby** Zogenix Inc.
- 14.50 ▶ **Glide SDI® – Injecting Vaccines and Drugs in a Solid Dosage Form**
- An overview of the Glide SDI (Solid Dose Injector) technology
 - Benefits and key applications
 - Status of clinical development programs
 - Partnered programs and collaborations for the injection of proprietary peptides, proteins and vaccine
- Dr Charles Potter** Glide Pharma
- 15.30 ▶ **Discussion**
- 15.40 ▶ **Tea and Exhibition Viewing**
- 16.00 ▶ **Understanding Patient Preference in Order to Identify Opportunities to Develop Products that Lead to Improved Patient Compliance**
- A patient study based on Human Factors engineering to understand compliance drivers in paediatric patient groups
 - Identifying opportunities for building on and improving on the “state of the art” injection device technologies
- Andy Pidgeon** Cambridge Consultants
- 16.40 ▶ **Advances in Injection Technology**
- Meeting the needs of new biological drugs
 - Designing for user needs
 - Opening doors to new markets and therapies
- Matthew Young** Oval Medical Technologies
- 17.20 ▶ **Discussion**
- 17.30 ▶ **End of Day One**
- 19.30 ▶ **Drinks Reception Followed by Dinner for Delegates and Speakers at The Cavendish Hotel, Jermyn Street, Piccadilly, London**

- 09.00 ▶ **Review of Day One**
Dr Gregory Berman PA Consulting Group
- 09.10 ▶ **Update from Ypsomed**
Ian Thompson Ypsomed
- 09.50 ▶ **SmartJect™ Auto Injector**
John Zowtiak Centocor
- 10.10 ▶ **The Use and Selection of Injection Technologies in the NHS**
Bob Sharp, Nuffield Hospital
- 10.30 ▶ **Discussion**
- 10.40 ▶ **Coffee and Exhibition Viewing**
- 11.10 ▶ **Market Assessment of the Value of Injection Devices**
- The importance of device strategy to biopharmaceutical companies
 - The evolving relationship between device manufacturers and biopharmaceutical companies - creating combination products together
 - Innovating injectable products to meet patients and physicians needs
- Pavan Handa Antares Pharma
- 11.50 ▶ **New Requirements and Approaches for Pen and Auto Injectors**
- ISO 11608 Update on status and directions
 - FDA draft injector guidance
- Lee Leichter, P/L Biomedical
- 12.30 ▶ **Discussion Followed by Lunch**
- 14.00 ▶ **Delivery of H1N1 Vaccines Using PharmaJet Technology**
- Overview of the PharmaJet technology
 - Public Health campaign
 - Preparing for a pandemic situation
 - Feedback and conclusions
- Kathy Callender PharmaJet Inc.
- 14.40 ▶ **Challenges with Combination Drug Delivery Systems: Pre-Filled Syringes and Auto Injectors**
- The growth of pre-filled syringes in certain therapeutic classes has increased the demand for secondary injection systems as a means of offering safety and/or ease of administration to the end user. These systems create new demands and challenges for the existing process limits of pre-fillable syringe systems. Designing flexibility into the secondary system is one way to overcome these issues and offer a more reliable injection system. Another option is to adopt pre-filled syringe technology that lends itself to consistency in dimensions and functional forces. This presentation reviews how these options address the currently ongoing industry issues.
- Glenn Thorpe West Pharmaceutical Services
- 15.20 ▶ **EU and Global Regulatory Approach for Needle-Free, Pen and Auto Injector Combination Products**
- Overview of combination products
 - Regulatory status of injection-based products
 - Handling safety issues
 - Life Cycle management
 - Future regulatory developments
- Dr David Jefferys Eisai R & D Company
- 16.00 ▶ **Discussion and Chairman's Closing Remarks**
- 16.15 ▶ **Close of Conference and Tea**

CHAIRMAN

Dr Gregory Berman leads the Medical Products Group in PA's Product and Process Engineering Practice, PA Consulting Group, UK

SPEAKERS

Kathy Callender, President, PharmaJet Inc., USA

Joël Cotten, European Product Manager / Marketing, BD Medical – Pharmaceutical Systems, France

Pavan Handa, Vice-President Business Development Antares Pharma, USA

Frank Isaksson, General Manager, Scandinavian Health Ltd (SHL), Taiwan

Dr David Jefferys, Vice President, Global Regulatory, Eisai R & D Management Co. Ltd., UK

Lee Leichter, President, P/L Biomedical, USA

Andy Pidgeon, Senior Consultant, Cambridge Consultants, UK

Dr Charles Potter, CEO, Glide Pharma Ltd, UK

Jonathan M. Rigby, Co-Founder and Vice President, Business Development, Zogenix Inc. USA

Mathias Romacker, Drug Product & Device Development, Amgen Inc USA

Don Rogers, Associate Director, Device Development, Genentech, USA

Bob Sharp, Consultant Orthopaedic Surgeon, Nuffield Hospital, UK

Ian Thompson, Manager, Business Development, Ypsomed, Switzerland

Glenn Thorpe, Vice President & General Manager of Advanced Injection Systems, West Pharmaceutical Services Cornwall Ltd, UK

Matthew Young, Oval Medical Technologies, UK

John Zowtiak, Director, Device Development & Engineering, Centocor R&D, USA

Register on-line at www.management-forum.co.uk or telephone +44 (0) 1483 730071

MEDIA PARTNERS

ONdrugDelivery

ONdrugDelivery is rapidly establishing itself as the leading provider of truly specialised information on drug delivery to the global pharma, biotech, speciality pharma and drug delivery industries. <http://www.ondrugdelivery.com>

InPharm.com

InPharm.com - providing executives in the biopharmaceutical and healthcare industries with relevant information services such as news, articles, jobs, directories of services and thousands of links out into the Net. <http://www.inpharm.com>

Network Pharma

Network Pharma provides instant access to a unique database of specialist information which is particularly relevant to individuals working within the medical and pharmaceutical industries around the world. <http://www.NetworkPharma.com>

POST-CONFERENCE SEMINAR DRUG/DEVICE AND DEVICE/DRUG COMBINATIONS IN THE EU

24 MARCH 2010

With:

Dr David Jefferys, Vice President, Global Regulatory, Eisai R&D Management Co. Ltd, UK

Dr Brian James, Managing Director, Interface International Consultancy, UK

Introduction/Aim

This seminar will focus on the EU regulations for drug/device and device/drug combination products including needle-free, pen and auto injectors in addition to other combination products. It will provide an excellent opportunity for delegates to understand the complex regulations and will assist in establishing the best regulatory route for their product to achieve success in the European market.

Delegates will have the opportunity to send specific queries in advance of the event to ensure they are addressed at the seminar.

PROGRAMME

Welcome and Introduction

EU Regulatory Framework and Guidance

Roles of Key Bodies

- Notified Body expectations
- Member States
- EMEA's view point

Defining the Regulatory Approval Route for Your Product

Differences in Documentation

- Device
- Drug and device
- Device and drug

Quality Systems for Combination Products

- Quality, pre-clinical and biocompatibility issues: how to address these for combination products
- What kind of non-conformance can we expect if you combine a drug and device?

Clinical Trial Considerations

Vigilance vs Pharmacovigilance

European Approvals Outside the EU

- Life Cycle management
- Global structure
- Using the EU as part of a wider global strategy

Close of Forum



ANNUAL INTERNATIONAL CONFERENCE AND DINNER INJECTABLE DRUG DELIVERY

22 & 23 MARCH 2010 – N3-8010

DRUG/DEVICE AND DEVICE/DRUG COMBINATIONS IN THE EU

24 MARCH 2010 – N3-8110

APPLICATION TO REGISTER

22 & 23 March 2010, Conf. No. N3-8010
24 March 2010, Conf. No. N3-8110

Please PRINT your details:

Title..... First name.....

(Dr, Mr, Mrs, etc)

Family name

Position

Department.....

.....

Company

Address.....

.....

City.....Post Code

Country

Tel No..... Fax No.

E-mail

Secretary's name.....

Signature

Substitutions may be made at any time at no extra charge

Payment by either: VISA MASTERCARD AMEX

Card No.

Card Security No. / AMEX

Expiry date...../.....

Cheque enclosed payable to Management Forum Limited

Bank transfer on receipt of invoice

W

YOU MAY REGISTER BY:-

+44 (0) 1483 730008

Management Forum Ltd, 98-100 Maybury Road,
Woking, Surrey GU21 5JL, UK

www.management-forum.co.uk

E-mail: registrations@management-forum.co.uk

If you have NOT received confirmation seven days after
registering, please contact Registration Department.

If you do not want to receive future mailings from Management Forum please contact nick@management-forum.co.uk
If you do not wish to receive selected third party mailings please contact nick@management-forum.co.uk

REGISTRATION INFORMATION

INJECTABLE DRUG DELIVERY – 2010

Dates 22 & 23 March 2010

Times 22 March 2010 Start 09.30 – Finish 17.30
Conference Dinner Start 19.30
23 March 2010 Start 09.00 – Finish 16.15

Post Conference Seminar
DRUG/DEVICE COMBINATIONS IN THE EU
24 March 2010 Start 09.00 – Finish 17.00

Registration & Coffee
Conference: 22 March 2010 09.00
Post Conference Seminar: 24 March 2010 08.30

Venue for Conference

Le Meridien Hotel, Piccadilly, London. Tel: +44(0)20 7437 9090.

Venue for Conference Dinner and Post Conference Seminar

The Cavendish Hotel, 81 Jermyn Street, Piccadilly, London.

Hotel Tel: +44(0)20 7930 2111.

Hotel Fax +44(0)20 7839 4369.

Email: Reservations@thecavendishlondon.com

Accommodation

A limited number of bedrooms have been reserved at the
The Cavendish London, 81 Jermyn Street (main entrance in
Duke Street), St James's, London SW1Y 6JF, at a special rate
of £178.73 + VAT – inc. full English breakfast, subject to
availability.

Hotel Tel: +44(0)20 7930 2111.

Hotel Fax: +44(0)20 7839 4369.

Email: Reservations@thecavendishlondon.com

OR

Flemings Mayfair Hotel, Half Moon Street, Mayfair, London,
W1J 7BH. Hotel Tel: +44(0)20 7930 2111.

Email: reservations@flemings-mayfair.co.uk

**All bookings should be made directly with the hotel
quoting Management Forum and your credit card number.**

Conference Fees:

Please tick

**Injectable Drug Delivery – N3-8010 = £1,295 + VAT
(including conference dinner)**

Post Conference Seminar – N3-8110 = £545 + VAT

Both Events N3-8010 and N3-8110 = £1,760 + VAT

Discounted Rates

Available on application for personnel from non-profit making
organisations and registered charities.

Group discount available on request.

Cancellation Policy:

Over 14 days prior to the Seminar: Cancellation fee of £75.
7/14 days prior to the Seminar: 50% of the fee. Fewer than 7
days or if no notification received: Registrant liable to pay
FULL seminar fee.

**NB: Cancellations must be received in writing by
lesley@management-forum.co.uk.**

In the event of circumstances beyond its control, Management
Forum reserves the right to alter the programme, the speakers,
the date or the venue.

Exhibition spaces and promotional opportunities will be available at this meeting.

For further information please contact Vicki Elliott

(email: vicki@management-forum.co.uk)

MANAGEMENT FORUM LTD., 98-100 Maybury Road, Woking, Surrey GU21 5JL, UK

Tel: +44 (0)1483 730071 Fax: +44 (0)1483 730008 Website: www.management-forum.co.uk