DATA PROTECTION ISSUES IN THE PHARMACEUTICAL INDUSTRY

29 November 2004, A11-4404 **W**

MANAGEMENT FORUM

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If you have NOT received confirmation seven days after registering, please call **+44(0) 1483 570099** and ask for Registration Department.

REGISTRATION INFORMATION

Date 29 November 2004

Times Start: 09.30 Finish: 17.00

Registration & Coffee 09.00

Venue
Harrington Hall Hotel, 5-25 Harrington Gardens, London SW7.

Directions
Nearest Underground station: Gloucester Road.
Map available on Website under Hotels and Venues.

Accommodation
A limited number of bedrooms have been reserved at the Harrington Hall Hotel, 5-25 Harrington Gardens, London SW7, at a special rate of £119.15 inc. continental breakfast, excl. VAT, only valid up to 14 days before the conference – subject to availability.
Hotel Tel: +44(0)20 7396 9696
Hotel Fax: +44(0)20 7396 9090
All bookings should be made directly with the hotel quoting Management Forum and your credit card number.

Fee
£510 +17.5% VAT. The fee includes course documentation as well as mid-session refreshments and lunch. Invoice and confirmation will be forwarded to you.

Conference No. A11-4404

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

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 to Lesley Vincent.

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

The information you provide will be held on our database and will not be used for third party mailings.
If you wish your name to be deleted from our database please contact Vicki Elliott at Management Forum. Email: vicki@management-forum.co.uk

MANAGEMENT FORUM LTD., 48 Woodbridge Road, Guildford, GU1 4RJ, UK
Tel: +44 (0)1483 570099 Fax: +44 (0)1483 536424
Website: www.management-forum.co.uk

DATA PROTECTION ISSUES IN THE PHARMACEUTICAL INDUSTRY

Topics to be covered at this meeting include:

- Data Protection Principles – Overview of European Data Protection Legislation
- Impact of Legislation on Drug Development and the Industry
- Data Processing and Data Export
- International Issues – Global Development Programmes, Exporting Data
- Data Protection, the Patient and Medical Ethics

Chairman:
Dr Peter Feldschreiber 4 New Square, Lincolns Inn

Speakers:
Dr Grant Castle Covington & Burling
David Evans Information Commissioners Office
Dr Darren Shickle University of Sheffield

29 November 2004
Harrington Hall Hotel, London

MANAGEMENT FORUM

INTRODUCTION

Legislation on data protection is having a significant impact on the work of the Pharmaceutical Industry. The seminar will examine the effects European and UK Laws will have on clinical development, market support of new medicines and pharmacovigilance. Topics will include the philosophy and objectives of the European Data Protection Directive, the UK Data Protection Act, the concepts of consent, processing, sensitive data, safe havens, the types of research affected by data protection as well as strategies for the future. The relationship between data protection and intellectual property will also be covered.

WHO SHOULD ATTEND

This meeting will be of relevance to personnel working within the Pharmaceutical Industry, including Medical and Clinical Research Directors, Regulatory Affairs Directors/Managers, Clinical Research personnel, such as CRO Managers, Senior Monitors as well as in-house Legal Counsel, Data Management and IT Personnel.

DOCUMENTATION

Delegates will receive a course material folder containing comprehensive documentation provided by the speakers, which will be a valuable source of reference for the future.

FORTHCOMING EVENTS

For a full list of forthcoming conferences and seminars please visit our website at: **www.management-forum.co.uk**.
You may make a registration and request a brochure on-line.

A Certificate of Attendance for Professional Development will be given to each participant who completes the course.

CHAIRMAN

Dr Peter Feldschreiber is a barrister at 4 New Square, Lincolns Inn specialising in Medical Law. He is also a physician and has held international medical director posts in research and development in the Pharmaceutical Industry. Currently he holds appointments as medical assessor to the Medicines and Healthcare products Regulatory Agency (MHRA) and special litigation co-ordinator to the Committee on Safety of Medicine (CSM).

SPEAKERS

Dr Grant Castle is an Associate at Covington & Burling. His practice covers the regulation of pharmaceuticals, medical devices and chemicals under European Community law and the national laws of the EC Member States. Grant received a BSc in Chemistry with first class honours from Imperial College of Science, Technology and Medicine in London in 1991 and a PhD in Organic Chemistry from Trinity College, University of Cambridge in 1994. He is a Chartered Chemist, a Member of the Royal Society of Chemistry and a Member of the Law Society of England and Wales.

David Evans is Healthcare Compliance Manager, Office of the Information Commissioner's Office (formerly the Office of the Data Protection Commissioner). The main issues for the Health Sector include the use and disclosure of medical data, accuracy issues and subject requests.

Dr Darren Shickle is Clinical Senior Lecturer for the Public Health Section at the School of Health and Related Research at the University of Sheffield. He is also an Honorary Consultant at North Eastern Derbyshire PCT. He has recently completed a major research project funded by the Department of Health examining public attitudes to privacy and use of personal health information.

PROGRAMME

Chairman's Welcome and Introduction

Dr Peter Feldschreiber 4 New Square

Introductory Overview – The Areas and Purpose of the Law, Human Rights and the Balance between Patients and Research and Industry

- Introduction to Data Protection in the Pharmaceutical Industry
- Overview of European and UK law
- Areas of law that specifically impact on drug development and the industry
- Sensitive data
- Data processing and data export
- Medical records

Dr Peter Feldschreiber 4 New Square

Detailed Review of the Data Protection Legislation and its Mechanics

- The Data Protection Directive
- National implementations
  - The Data Protection Act
  - Other examples
- The Safe Harbor Agreement
- Clinical Trials
  - The Clinical Trial Directive
  - Study sponsors
  - Anonymisation of data
  - Rights of access
  - Further research
  - Consent
  - Contractual arrangements
- Pharmacovigilance
  - Follow-up issues
- Other research
- Potential liability issues
- Data Protection case studies

Dr Grant Castle Covington and Burling

Data Protection Principles

- Fair and lawful processing
- The research exemption
- Security of personal data
- Overseas transfers

David Evans Information Commissioners Office

Data Protection, the Patient and Medical Ethics

- What do the public think about the use of their personal health information by the Pharmaceutical Industry?
- Empirical quantitative and qualitative research findings on public attitudes to use of personal health information
- Specific public response to issues within the Source Informatics case
- Willingness of the public to allow access to their information, even by commercial organisations, provided it is in the public interest
- Implications for the Pharmaceutical Industry

Dr Darren Schickle University of Sheffield

Panel Discussion

Close of Meeting