Intensive Practical Course

MANAGEMENT FORUM

SUCCESSFUL MEDICAL WRITING

- Enhancing Writing Skills
- Being Kind to Your Reader
- Writing the Investigator's Brochure, Clinical Study Reports and Publications
- Writing Clinical Summaries, Clinical Overviews and Global Submission Dossiers
- Tables, Graphs and Flowcharts
- Statistics for Medical Writers

With

Dr Stephen de Looze Accovion GmbH
Dr Barry Drees Trilogy Writing & Consulting
Alistair Reeves Ascribe Medical Writing and Translation

Our courses can be tailored to your requirements and delivered in-house. For more information please contact: josephine.leak@management-forum.co.uk

You can register online at www.management-forum.co.uk or by phone on +44 (0)1483 730071, fax 730008

CPD CERTIFIED
The CPD Certification Service
Collective Mark

28 - 30 September 2011
The Rembrandt Hotel, London

INTRODUCTION

Success in the pharmaceutical industry depends on the speed and efficiency of new drug approvals. This process largely relies on the quality of documentation submitted to the regulatory authorities, and a high standard of medical writing plays a vital role in ensuring success. This intensive practical medical writing course will benefit participants by enabling them to achieve this standard.

WHO SHOULD ATTEND

This three-day course will be of interest to all those in the pharmaceutical industry who prepare research reports and documentation intended for regulatory authorities. Although the focus of the seminar is on clinical research documentation, many of the principles will also apply to other types of reports, including pre-clinical, CMC and veterinary documentation. The practical training will benefit not only those new to medical writing, but also those wishing to perfect their existing writing skills, including full-time medical writers and those who only occasionally write research documentation or regulatory submissions.

AIMS AND OBJECTIVES

This intensive and interactive course combines lectures with practical exercises to provide a thorough introduction to the basics of medical writing that goes beyond the usual 'overview' courses. It will provide in-depth training in general writing and data presentation skills, and specifically in the kind of documents most frequently encountered in clinical research.

Participants will learn both the theoretical and practical aspects of writing for regulatory authorities as well as the sensible use of international guidelines, standards and useful writing tips. Many illustrative examples will be used, drawn from the seminar leaders' wide experience of the pharmaceutical industry.

ATTENDANCE LIMITED – EARLY REGISTRATION RECOMMENDED

This limitation, a unique feature of all MANAGEMENT FORUM seminars, will give participants the opportunity for a thorough discussion of the complex issues to be covered by the programme.

Reserve your place at the course by registering online now at www.management-forum.co.uk or by fax +44 (0)1483 730008

Any questions?
e-mail josephine.leak@management-forum.co.uk

COURSE LEADERS

The three course leaders have worked for many years in Medical Writing and related fields and hold the certification 'Editor in the Life Sciences' from the Board of Editors in the Life Sciences, Highlands, USA. They are all active as teachers in international medical writing organisations, notably the European Medical Writers Association (EMWA).

Dr Barry Drees holds a BSc in molecular biology from the University of California, Santa Barbara and a PhD in Genetics at University of California, San Francisco. After working as a postdoctoral fellow of the American Cancer Society at the University of Freiburg, Germany, he joined Hoechst AG (now Aventis) Frankfurt in 1989 as a medical writer, and was Manager, Medical Writing Phase I-IIa at Aventis Pharma (now Sanofi-Aventis) in Frankfurt. He is past president of EMWA and is former Editor-in-Chief of *The Write Stuff, The Journal of the European Medical Writers Association* and Senior Partner at Trilogy Writing & Consulting.

Dr Stephen de Looze holds an MA in biochemistry from the University of Oxford and a PhD in biochemistry from the University of Freiburg, where he was a fellow of the Alexander von Humboldt Foundation. He joined Hoechst AG in Frankfurt in 1985 to establish the Medical Writing department and held the post of Head of Medical Writing at Aventis Pharma (formerly Hoechst AG) until the end of 2001. He was Director of Medical Writing and Electronic Publishing at AccovionGmbH in Eschborn (Frankfurt) from 2002 to 2011. He has served EMWA on the Education Committee since 2000, and was elected Education Officer 2001-2003 and 2007-2011. He sat on international committees under the auspices of the European Federation of Pharmaceutical industries and Associations for ICH E3 Structure and Content of Clinical Study Reports and ICH M4 The Common Technical Document.

Alistair Reeves holds a BA in applied languages (German, French and Spanish) after studying in London, Tübingen and Amiens. After a period in medical market research, he joined the pharmaceutical industry in 1979 where he worked as a medical translator, followed by successive positions as a medical writer in regulatory affairs and as standards manager (specialising in the design of case report forms and standardisation). This was followed by a period in document management and publishing. In 2002 he founded Ascribe Medical Writing and Translation, based in Wiesbaden, Germany, and besides now focussing on editing and rewriting texts in English by non-native speakers, he gives numerous training events throughout Europe on the use of English in medical and pharmaceutical documentation.

EMWA is an organisation committed to increasing awareness of medical writing throughout Europe and to the training and development of medical writers. EMWA has its own accreditation programme, carried out through workshops held at the yearly conferences and meetings. For more details please visit the EMWA website at www.emwa.org.

Please note this course does not carry any official EMWA accreditation

Day One — 28 September 2011

09.30 **Introduction**
Dr Stephen de Looze

09.45 **Writing Clinical Study Reports**
- The writing process
- Organizing the data
- Applying the ICH E3 guideline
- Step-by-step instructions
- Quality control

Dr Stephen de Looze

11.15 **Coffee**

11.30 **Writing Clinical Study Reports** *(continued)*
Dr Stephen de Looze

13.00 **Lunch**

14.00 **Enhancing Writing Skills – I**
- Punctuation for clarity and style

Alistair Reeves

15.15 **Tea**

15.30 **Enhancing Writing Skills – I** *(continued)*
- Punctuation for clarity and style
- Abbreviations

Alistair Reeves

16.15 **Writing the Investigator's Brochure**
- ICH E6 guidance
- Organizing multiple author contributions
- Project management
- Consistency within and between topics

Dr Barry Drees

17.30 **End of Day One**

Day Two — 29 September 2011

09.00 **Enhancing Writing Skills – II**
Syntax, word order and being kind to your reader
Alistair Reeves

10.15 **Coffee**

10.30 **Enhancing Writing Skills – II** *(continued)*
- Syntax, word order and being kind to your reader
- Prepositions

Alistair Reeves

11.30 **Tables, Graphs and Flowcharts**
- Table types
- Elements of table design
- Graphs, plots, charts and diagrams
- Design and use of flowcharts

Dr Barry Drees and Dr Stephen de Looze

Day Two — continued

12.45 **Lunch**

14.00 **Tables, Graphs and Flowcharts** *(continued)*
Dr Barry Drees and Dr Stephen de Looze

15.45 **Tea**

16.00 **Writing Publications**
- Publications vs. clinical study reports
- Consort guidelines for reporting randomised controlled clinical trials
- Maximizing acceptance
- Understanding 'Instructions to Authors'

Dr Barry Drees

17.00 **End of Day Two**

Day Three — 30 September 2011

08.30 **Statistics for Medical Writers**
- Statistical basis of clinical studies
- Misuse of p-values
- Primary vs. secondary efficacy variables
- Developing confidence in confidence intervals

Dr Barry Drees

10.00 **Coffee**

10.15 **Statistics for Medical Writers** *(continued)*
Dr Barry Drees

11.00 **The Common Technical Document**
- Introduction to clinical submission dossiers
- Purpose and types of clinical summary documents
- Writing the clinical overview and the clinical summary
- Recent regulatory developments

Dr Stephen de Looze

12.15 **Lunch**

13.15 **The Common Technical Document** *(continued)*
Dr Stephen de Looze

14.00 **Enhancing Writing Skills III**
- Tips on synopsis and report writing, use of tense

Alistair Reeves

15.00 **Tea**

15.15 **Enhancing Writing Skills - III** *(continued)*
- Tips on presentation of results section, discussion, and abstract writing

Alistair Reeves

16.00 **General discussion and End of Course**

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

SUCCESSFUL MEDICAL WRITING
28-30 September 2011

MANAGEMENT FORUM

MANAGEMENT FORUM

Application to Register

28-30 September 2011, Conf. No. A9-3011

Please PRINT your details:

Title..... First name.....
(Dr, Mr, Mrs, etc)

Family name .....

Position .....

Department.....

Company .....

Company VAT No. .....

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

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Card Security No. ☐☐☐ / ☐ AMEX

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

☐ Cheque enclosed payable to Management Forum Limited

☐ Bank transfer on receipt of invoice **W**

To Register

+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.

Registration Information

Dates **28-30 September 2011**

Times **28 September 2011 Start 09.30 – Finish 17.30**
29 September 2011 Start 09.00 – Finish 17.00
30 September 2011 Start 08.30 – Finish 16.30

Registration & Coffee
28 September 2011 09.15

Venue
The Rembrandt Hotel, 11 Thurloe Place, London SW7 2RS.

Directions
Opposite V&A Museum.
Nearest Underground station: South Kensington.
Map available on Website under Hotels and Venues.

Accommodation
A limited number of bedrooms have been reserved at The Rembrandt Hotel, 11 Thurloe Place, London SW7 2RS, at a special rate of £137.50 (Superior) £154.17 (Executive) both including English breakfast, excluding VAT – subject to availability.
Hotel Tel: +44(0)20 7589 8100.
Hotel Fax: +44(0)20 7225 3476.
Email: reservations_rembrandt@sarova.co.uk
All bookings should be made directly with the hotel or online at www.sarova.com/rembrandt, quoting promo code 'manforum'.

Conference Fee
£1,600 + VAT. The fee includes course documentation as well as mid-session refreshments and lunch. Invoice and confirmation will be forwarded to you.

Conference No. A9-3011

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 registrations@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 Robert Sinclair
(email: robert@management-forum.co.uk)