GOOD ENGINEERING PRACTICE (GEP)

MANAGEMENT FORUM

The Compliance Toolkit - Improve Effectiveness - Reduce Costs

A Practical Course to discuss Cost Effective Methods to help you achieve Regulatory Compliance of your Engineering Systems and Equipment

This seminar will focus on the following:

- ISPE Good Engineering Practice Guide
- Applicable Regulations
- Risk Management
- Practical application of science and risk based approach to process and system equipment verification
- Making best use of supplier documentation
- Understanding of terminology and the 'busting' of some myths
- Practical approach to documentation and document approvals
- Change management and how to gain acceptance of this
- Auditing
- Maintenance management
- Opportunity to take part in group exercises to use tools in real life examples

Speakers:

Mark Foss Head of Engineering, Boehringer Ingelheim, UK

John Andrews Director, Andrews Consulting Enterprise Ltd., UK

Register on-line at www.management-forum.co.uk
or telephone +44 (0)1483 730071, fax 730008

CPD CERTIFIED
The CPD Certification Service

21 & 22 April 2010
The Rembrandt Hotel, London

INTRODUCTION

Good Engineering Practice (GEP) is defined as the minimum set of processes and documentation that meet end-user expectations and relevant regulations covering the construction, commissioning, operation, maintenance and de-commissioning of an asset. This seminar will provide an interactive overview of the new *ISPE Good Practice Guide: Good Engineering Practice (GEP)* and give examples of how the suggested methodologies and templates may be used to significantly reduce the cost and improve operation efficiency in both project and maintenance activities.

Practical tools used will include:

- Guidance, templates and examples from ISPE Good Practice Guide on GEP
- Examples of risk assessment techniques
- ASTM E2500 Verification of Pharmaceutical Manufacturing systems and Equipment

Opportunity to take part in group exercises to use tools in real life examples

At the end of this seminar, participants will be able to:

- Balance expenditure and activity in relation to cost and benefits
- State a clear definition of good engineering practice
- Understand how the risk based approach will improve effectiveness and reduce costs
- Have a common understanding of the concept and principles of GEP
- Explain how GEP concepts may be applied in the healthcare industry
- Balance expenditure and activity against the associated risks and benefits of a defined scope of work

IN-HOUSE TRAINING

If you would like to discuss running this or any of our existing courses on an in-house basis, please contact: ellen.walker@management-forum.co.uk

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.

WHO SHOULD ATTEND

Professionals in:

- Quality Assurance
- Operations Management
- Engineering Management

And those involved in:

- Engineering Projects, Operations and Management
- Quality Assurance and Auditing

Those checking:

- Validation Documentation
- All aspects of Validation, Qualification, Verification and any other regulated background

SPEAKERS

Mark Foss BSc, CEng, MIET, MInstMC, MISPE
Head of Engineering for Boehringer Ingelheim in the UK for the last 10 years. He has worked since 1977 in both the Nuclear and Pharmaceutical Industries and was previously Engineering Manager for GlaxoSmithKline for 12 years and for Roche Products for 4 years. He is a member of the Industry Board and European Steering Committee of the GAMP Forum (Good Automated Manufacturing Practice) and current Chairman of GAMP UK. He has chaired the GEP, Process Control and the Calibration Special Interest Groups. These groups have developed Industry Good Practice Guides including the GEP Good Practice Guide released in 2008. He has also been a speaker on the above and other topics at many ISPE and other industry conferences, seminars and symposia.

John Andrews owns and runs Andrews Consulting Enterprises Limited from Worthing in West Sussex. Between 2001 and 2003 John managed the Information Technology (IT) Consulting Group of KMI, a division of PAREXEL International LLC (KMI). Prior to KMI, John held positions as a Computer System Validation Manager and Supply Chain Systems Project Manager with GlaxoSmithKline, UK. He is currently specialising in the application of GAMP principles to the validation and use of Process Analytical Technologies (PAT).

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

Day One 21 April — PROGRAMME — Day Two 22 April

Day One 21 April

09.30 Introduction and Welcome
- Expectations of participants
- General administration
- What is **Good Engineering Practice**

10.15 Regulatory Background
- Quality by Design, ASTM E2500
- Key concepts
- Design space
- Verification vs. Qualification

11.00 Coffee

11.30 Risk Management
- Patient / Product focus
- Concepts

12.30 The ISPE GEP Guide
- Structure and benefits
- Cost management
- Organisation and control
- Engineering management process

13.00 Lunch

14.00 Documentation
- Practices
- How to gain QA acceptance
- GxP vs GEP

14.30 Workshop: Documentation
- Creating a URS
- Workshop
- Workshop review

15.30 Tea

15.45 Project Process
- GEP Foundation
- Example

16.45 General Discussion

17.00 End of Day One

Day One: 21 April 2010 - 17.00-18.00
Drinks Reception in the Hotel for Delegates and Speakers

Day Two 22 April

09.00 Introduction
- Review of Day One

09.15 Auditing
- Suppliers
- Postal audits
- Internal audit systems

10.00 Maintenance Management Systems
- Criteria for selection
- Electronic systems
- Consider ALL regulators

10.30 Coffee

11.00 Case Study 1:
- Introduction to process
- Team responsibilities
- Process DVD
- Understanding the process
- Workshop in teams
- Workshop review

13.00 Lunch

14.00 Using Supplier Documentation
- Supporting the process
- Leveraging
- Do it once - do it right!

14.30 Case Study 2:
- Understanding the process
- Workshop in teams
- Workshop review

15.30 Tea

15.45 Summary and Closing Remarks
- Review of expectations

16.00 General Discussion

16.30 End of Seminar

GOOD ENGINEERING PRACTICE (GEP)

APPLICATION TO REGISTER

21 & 22 April 2010, Conf. No. M4-6010

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

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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.

REGISTRATION INFORMATION

Dates **21 & 22 April 2010**

Times

	21 April 2010	**Start 09.30 – Finish 17.00**
	Drinks Reception	**Start 17.00 – Finish 18.00**
	22 April 2010	**Start 09.00 – Finish 16.30**

Registration & Coffee

21 April 2010	**09.00**

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

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, at a special rate of £133.92 (Superior) £152.18 (Executive) both including English breakfast, excluding VAT – subject to availability.
A special rate for Friday, Saturday and Sunday of £120.87 (Superior) including English breakfast, excluding VAT – subject to availability when booked as additional nights.
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
£1,260 + VAT. The fee includes course documentation as well as mid-session refreshments and Lunch and Drinks Reception on Day One. Invoice and confirmation will be forwarded to you.

Conference No. M4-6010

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 Judith Black
(email: judith.black@management-forum.co.uk)

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