

JUNE 2007

PHSS NEWSLETTER

THE PHARMACEUTICAL AND HEALTHCARE SCIENCES SOCIETY



IS ANYONE OUT THERE?

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Have you ever thought about what you get out of this Society? Did you read the February Newsletter?, do you prefer to read it 'on-line', or would you prefer to revert to a printed copy via the post? I asked for comments, but none were forthcoming. So I will try again with this edition.

We try to cover most areas represented by our members with training courses, seminars, discussion forums, workshops etc., enabling you, the member, to keep up to date with developments in the subjects which interest you. Firstly we need to know what topics to cover. You would expect this to be easy with a healthy number of members, not!, most of the ideas come from the Management Committee, so when an event is poorly attended we wrestle with all the issues to try and find out why. It is an unsatisfying way to

run our schedule of events, because the market place we compete in is getting tougher. We need to provide exactly what you want, when and where you want it. We can even come to you, yes, most of our training courses can be presented 'in-house' and tailored to your needs for a minimum of 10 people, less expense for the Company, no overnight accommodation or travel for personnel; just pick up the phone and ask. Tel: 01793 824254 or email: info@phss.demon.co.uk

Details of forthcoming events are within this Newsletter and on the PHSS website, please pop into your diary the date for the Annual Conference. For the first time in 26 years the duration of the Annual Conference is only one day, mainly because of the difficulty members experience in getting 'time out' for such events. The content will be of interest to the

majority of members, and on the evening of the 3rd, there will be an evening reception and tour of Becton Dickinson's new facility at the Oxford Science Park, kindly sponsored by Becton Dickinson. The Management Committee has genuine enthusiasm for the task ahead and any support you can give will be welcomed. There are several ways to participate and become an active member within **YOUR** Society—turn the page for further information. In order to serve members we really do need feedback, a simple email will suffice; we put the effort in, it's now up to you.

June

PHSS ANNUAL CONFERENCE, TABLE –TOP EXHIBITION, A.G.M. 4 OCTOBER 2007 AT THE OXFORD BELFRY, nr Thame Regular Programme Updates on PHSS website

www.phss.co.uk

THE NEW RULES AND GUIDANCE FOR PHARMACEUTICAL MANUFACTURERS AND DISTRIBUTORS

(popularly known as The Orange Guide)

- An essential guide for all who manufacture or distribute medicines in Europe compiled by the Medicines and Healthcare Products Regulatory Agency (MHRA).
- New 2007 edition published by the Pharmaceutical Press and available to purchase from the PHSS.
- Up-to-date information on European and UK guidance and legislation.
- For the first time, The Orange Guide will be available digitally as a CD-ROM

To place your order: Telephone +44 (0)1793 824254 Fax: +44 (0)1793 832551 email: info@phss.demon.co.uk [QR](#) via the PHSS website

Prices: (add 5% post & packing to your order)

ISBN 978 0 85369 719 0 Book 244 x 172 mm 400pp Member: £40 Non-Member: £55

ISBN 978 0 85369 720 6 CD-ROM single user Member: £40 (+ £7 VAT) Non-Member: £55 (+ £9.62 VAT)

ISBN 978 0 85369 721 3 Book & CD-ROM Package Member: £60 (+ £5.25 VAT) Non-Member: £75 (+ £6.56 VAT)

MEMBERSHIP RENEWAL 2007 Last call for renewing your membership for 2007. The 2007 membership Directory, in CD format, will be processed during July. If you want your name to be included and have not yet renewed, you will need to do so immediately. Maybe you have mislaid your invoice, if so please contact The **PHSS** office.

Help **YOUR** Society increase it's membership, enroll a colleague during June, July & August and receive a **£20 Amazon gift voucher**. The individual membership fee still represents excellent value at £85 +VAT

We would like to thank Boehringer Ingelheim for hosting the June training course on Risk Management of Contamination During Manufacturing Operations in Cleanrooms

Benefits of

Membership: The PHSS offers a wide range of professional resources to help you further your understanding of new industry and regulatory developments. Some of which are accessible to PHSS members only, including the **new web Discussion Forum**.

Receive discounted fees on all PHSS literature including the quarterly **Journal, Conferences, Training Courses and Scientific Meetings** plus members have the opportunity of playing an active role on:

*The Management Committee
Special Interest Groups
Editorial Board
Programme Committee*

Marketing Opportunities:

Advertise—in the PHSS Newsletter and Journal, the European Journal of Parenteral and Pharmaceutical Sciences, and the Publications Catalogue. All of which are widely distributed.

Sponsorship—Get noticed at PHSS conferences etc by sponsoring an event or even hosting a training course.

Exhibit—Some PHSS events have table-top exhibitions, the perfect place for you to exhibit new products.

Recruitment - We can help you fill that vacant position by placing your advertisement onto the website at an exceptionally competitive rate.

Networking—meet up with colleagues new and old at PHSS events and via the **website discussion forum**.

Have you made a note of your **NEW** member Password and User name

NEW PUBLICATION:**Technical Monograph No.13****THE CLEANING OF FREEZE DRYERS**

ISBN: 1-905271-13-1

This is the 7th of a series of monographs on freeze dryer related topics compiled by the **PHSS Freeze Dryer Special Interest Group**. The overall purpose of the group and these monographs is to provide guidance on aspects of freeze dryers that the group believes, are not covered elsewhere within the literature.

The aim of this monograph is to provide guidance on freeze dryer Clean in Place (CIP) systems. It is not intended that the sections of this monograph are all inclusive and absolute in scope.

CONTACT US

If you would like to place an item in the Newsletter.

Telephone +44 (0)1793 824254

Fax: +44 (0) 1793 832551

Email: info@phss.demon.co.uk

Management Committee Election

Nomination forms must be received in the PHSS office no later than 4pm on the 30 June 2007. If you or a colleague would like to become a member of the Management Committee make sure your nomination is sent into the PHSS office no later than the above date. The nominee must be a current member.

SPECIAL INTEREST GROUPS

Would you like to join in with any of the PHSS Special Interest Groups? New members are always welcome.

L.A.L.

Autoclave Sterilisation

Aseptic Process Filtration

G.M.P.

Dry Heat Sterilisation

RABS

Maybe you have a suggestion for a NEW Group to be formed!

Contact the PHSS office.

SPECIAL SUMMER OFFER ON SELECTED PHSS TECHNICAL MONOGRAPHS—Offer ends 13 July 2007

Technical Monograph No.2

Environmental Contamination Control Practice (2002) £20

Technical Monograph No.8

Integrity Testing of Freeze Dryer Inlet Filters (1995) £8

Technical Monograph No.10

Introduction to Pharmaceutical Freeze Drying (1998) £12

Technical Monograph No.12

Refrigeration in Freeze Dryers (2003) £15

Please add 5% post & packaging

THE EUROPEAN JOURNAL OF PARENTERAL AND PHARMACEUTICAL SCIENCES

Issued quarterly to All PHSS members.

The Editor-in-Chief, John Sharp, would welcome members and their colleagues to submit original scientific papers on Parenteral and non-Parenteral topics. All papers are subject to review and should be sent to the PHSS office for the attention of the Editor in Chief. Your paper could also be considered for the Annual George Sykes Memorial Award, prize, £1000. The Journal also offers the opportunity to advertise at competitive rates.

Contact: Allan Andrews, tele: +44 (0)1245 477008

2006/2007 Publications Catalogue available to all members by post or on line. www.phss.co.uk

Whilst on the web, don't forget to take a look at the Monthly Regulatory Update prepared by Steve Fairchild, (Steve Fairchild Consulting)

YOUNG SCIENTIST AWARD

The PHSS is inviting young authors to present a scientific paper on any aspect of their work. The subject matter should fall within pharmaceutical sciences and associated technologies, including medical devices and packaging. Authors (aged up to 30 years) intending to submit a paper should send an abstract (max 200 words) to the PHSS office by 16 July, the completed paper should be submitted by 1 September 2007. Prize **£500 plus one years' PHSS membership.**

FORTHCOMING EVENTS

The full calendar of events can be viewed on the PHSS website, new events are being constantly added. If you would like to add a topic please contact the PHSS office. We are here to listen to your requirements, this is your Society, the choice is yours. We are committed to providing a complete service to ALL members. **PLACES ARE AVAILABLE ON THE EVENTS SHOWN BELOW**

12 June 2007 1-Day Training Course—**PHARMACEUTICAL WATER,**

venue: The Stratford Manor Hotel, Stratford-upon-Avon, Warwickshire.

13 June 2007 1-Day training Course—**RISK MANAGEMENT OF CONTAMINATION DURING MANUFACTURING OPERATIONS IN CLEANROOMS** *venue: Boehringer Ingelheim, Bracknell, Berks.*

14 June 2007 1-Day Seminar and Table Top Exhibition—**SPORICIDAL GASSING TECHNOLOGY**

venue: The Oxford Belfry Hotel, Nr Thame, Oxfordshire.

17-21 Sept 2007 5-Day Residential Training Course—**FUNDAMENTALS OF GMP A PRACTICAL APPROACH.**

venue: The School of Pharmacy & Pharmacology, University of Bath.

4 Oct 2007 **ANNUAL CONFERENCE, TABLE TOP EXHIBITION AND A.G.M. CURRENT AND FUTURE PRACTICES IN ASEPTIC MANUFACTURING.** Becton Dickinson will be hosting an Evening Reception and Tour of their New Facilities at the Oxford Science Park.

venue: The Oxford Belfry, Nr Thame, Oxfordshire

- Topics to be presented:
- The Future of Aseptic Processing (to include Impact of ICH Q9)
- FDA Guidelines—Audit Preparation
- Risk Management of an Aseptic Process (Q9 Approach)
- George Sykes Memorial Award Presentation and Paper
- Aseptic Transfers to Manufacturing Process
- Separation of Aseptic Process from Operators—Isolators, RABS—Options and Case Studies
- Manual Disinfection vs Fumigation vs Sporicidal Gassing
- **PLUS Half-Day Workshop—Sterile API Manufacturing**

17-19 Oct 2007 PHSS/ISL- FD (USA)

Joint Lyophilization Conference and Table Top Exhibition will include Poster Sessions.

venue: The Carlton Hotel, Dublin Airport, Ireland.

To Reserve your place telephone, fax, email Or book and pay on-line via the PHSS website

www.phss.co.uk

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