

# PHSS NEWSLETTER

FEBRUARY 2007

THE PHARMACEUTICAL AND HEALTHCARE SCIENCES SOCIETY



## GOING GREEN

We invite you to read the first PHSS Newsletter to be placed onto the website. We are all aware of the need to cut down on the amount of resources used for the production of general items such as a simple Newsletter. Future issues will be available to read or download from the Members' Area.

Information on PHSS events will have a one off mailing followed up by email reminders; and to reduce distances travelled by delegates, more PHSS events will become Regional.

The Constitution has also

been placed onto the website, again cutting down on printing and mailing.

It is our intention to place more information onto the website and/or email members with regular updates. So that you don't miss out on vital information it is extremely important that the membership database holds up-to-date email addresses. We understand how 'bogged down' the "inbox" can get, but we are sure you will agree that this move will be more beneficial. If we do not have your email address you could be missing out on vital information.

Members who have not submitted their email addresses will be contacted during February, please assist by returning the necessary information—by email of course!

We welcome your views on this move to a "greener" outlook.

**Almost one year on—  
have you become familiar with the name change of the Society?  
From:  
THE PARENTERAL SOCIETY  
TO:  
THE PHARMACEUTICAL & HEALTHCARE SCIENCES SOCIETY (PHSS)**

### Inside this issue:

Information on the NEW "Orange Guide"	2
Membership Information & Renewal	2
ISO Standards	3
George Sykes memorial Award	3
Management Committee News	3
Presentations	3
Forthcoming Events	4

[www.phss.co.uk](http://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 will be published by the Pharmaceutical Press and will be available to purchase late February 2007.
- 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](mailto:info@phss.demon.co.uk) OR 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

Invoices for renewal of membership subscription fees 2007 were issued in December. It would be most helpful if members could renew as soon as possible, this would enable us to produce the membership directory by May.

**R3Nordic Reciprocal Membership**—members of the PHSS have the opportunity of taking up membership of R3Nordic at a reduced cost until the end of February 2007. A green form was issued with your renewal invoice if you have mislaid the form please contact the PHSS office and we will send another.

Remember you only have until the end of February to apply for Reciprocal membership. Fee £40

**We would like to thank Schering-Plough Animal Health, Uxbridge for hosting the recent training course on Computer Validation for the Non-Specialist.**

**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. 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.

**Annual Membership Fee: £85 + 17.5% VAT**

# The NEW orange Guide Place your order today

## ISO INTERNATIONAL STANDARDS

### Draft International Standard—ISO/DIS

**13408-1** Aseptic Processing of Health Care Products—Part 1: General requirements.

ISO/TC 198 Voting terminates on 22.05.2007

Comments to Margaret Dempsey, ISO no later than **16 April 2007**

### Final Draft International Standard—ISO/FDIS

**11135-1** Sterilization of Health Care Products - Ethylene Oxide. Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.

ISO/TC 198 Voting terminates on 11-03-2007

This document is out for parallel vote with CEN. Comments to Margaret Dempsey no later **20 February 2007**. For documents and replies log onto [www.iso.org](http://www.iso.org) Please do not send your comments to the **PHSS** office.

**The 2006 Membership Directory (in CD format) was issued to all members in December,**

**2006/2007 Publications Catalogue has been issued to all members and is also available on line.**

**[www.phss.co.uk](http://www.phss.co.uk)**

## GEORGE SYKES MEMORIAL AWARD 2007

An Award presented to the Author of the best Scientific Paper published in the European Journal of Parenteral and Pharmaceutical Sciences over a 12 month period, (4 issues). The Editorial Board cast their votes during August and the winner announced early September. The prize consists of a cheque for £1000, framed certificate and

the opportunity to present the winning paper at the Society's Annual Congress. If you have a paper you would like to be considered, all you have to do is submit it to the Managing Editor, Ros Manning, email: [cerisemed@googlemail.com](mailto:cerisemed@googlemail.com). Papers may be submitted in languages other than English, but if accepted, will be translated by the publisher, using a specialist translator, and published in English with only the author's summary published in the original language. Full instructions for authors will be given. Papers will be refereed by members of the editorial board and/or their nominees. Perhaps this is something you have wanted to do but keep putting off, what have you got to lose.

## MANAGEMENT COMMITTEE

The Officers of the PHSS Management Committee for the period November 2006—October 2007 are:

Chairman—Phil Greaves, Bovis Lend Lease

Vice-Chairman—Chris Budd, Eli Lilly & Co

Treasurer—Simon McEwen, McEwen Laboratories

Newsletter Editor—June Prout, PHSS

Editor-in-Chief, Journal of Parenteral and Pharmaceutical Sciences—John Sharp

**The Chairman presented a gift to Gordon J Farquharson in recognition of his 25 years as a Management Committee Member, (Treasurer, Vice-Chairman & Chairman), Gordon is also an Honorary Member of the PHSS.**



The 2006 AGM Reports are available to members upon request.

**WHILST ON THE WEBSITE, DON'T FORGET TO TAKE A LOOK AT THE MONTHLY REGULATORY UPDATE PREPARED BY STEVE FAIRCHILD, (STEVE FAIRCHILD CONSULTING),**

**PHIL PRECIOUS RECEIVES HIS Honorary Member Certificate. Phil was awarded Honorary Membership in November 2006**



**[www.phss.co.uk](http://www.phss.co.uk)**

## 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. Think carefully, for example, the Annual Congress in October will, for the first time be held on one day only (usually 2), so let's make it an eventful day. The Technical Programmes Committee will be meeting soon to plan the programme. Your suggestions on Topics would be greatly appreciated, and if you would like to give a presentation then send in your details, all ideas and suggestions will be considered.

**8 & 9 March 2007** The Crowne Plaza Hotel, Amsterdam 2day seminar and table-top exhibition

**FREEZE DRYING CHALLENGES IN RESEARCH AND MANUFACTURING: Plenary Sessions, Workshop, Case Study, Discussion Forum**  
Bookings required no later than 16 February

**15 March 2007** The Nottingham Belfry Hotel, 1-Day Training Course

**ISOLATORS AND RABS (Restricted Access Barrier Systems): Design for Contamination Control, Cleaning and High level Disinfection, Qualification and Compliance, Operation and Standard Operating Procedures.** Course Leader: Mr James Drinkwater, Process Director, Bioquell UK.

**27 March 2007** The Stratford Manor Hotel, Stratford, Upon-Avon TWD Half-Day Workshops Choose to attend one or both,  
*Morning and afternoon sessions*

**COMPUTER AIDED TRAINING—PHARMACEUTICAL APPLICATIONS:** The workshop will include background to the educational and technical issues that influence the design, production and use of Computer Aided Learning and Computer Based Training packages with particular reference to their use in the pharmaceutical industry.

AND

**STERILISATION: Temperature & Pressure Measurement & Calibration, Dry Heat Sterilisation, Steam Sterilisation Standards/Guidelines, Validation and Routine Control of Sterilisation by Irradiation, Sterilisation/Validation of Isolators and Lyophilizers**

**24 & 25 April 2007** The Royal Pharmaceutical Society Headquarters, London 2-day Training Course

**EFFECTIVE INVESTIGATIONS AND CORRECTIVE ACTIONS:** This course teaches tools and techniques that can be employed to get to the "root cause" of unexpected quality events, and to resolve them in a manner such that they stay resolved in a GMP compliant manner. The course will examine actual situations as case studies, with students guided in effective investigation resolution, and required to perform effective investigations, and determine proper solutions to effect proper corrective action. Course Leader: Mr Michael H Anisfeld, President of GlobePharm.

ALL OF THE ABOVE EVENTS ARE ACCREDITED FOR CONTINUOUS PROFESSIONAL DEVELOPMENT WITH THE COLLEGE OF PHARMACY PRACTICE

**PLACES AVAILABLE ON ALL OF THE ABOVE**

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

[www.phss.co.uk](http://www.phss.co.uk)

THE PHARMACEUTICAL AND HEALTHCARE SCIENCES SOCIETY  
6A KINGSDOWN ORCHARD, HYDE ROAD, SWINDON, SN2 7RR, WILTSHIRE, U.K.  
Telephone +44 (0) 1793 824254 Fax +44 (0) 1793 832551  
Email: [info@phss.demon.co.uk](mailto:info@phss.demon.co.uk)