

Connecting Pharmaceutical Knowledge

Newsletter No. 67

Summer 2016

www.ISPE.org

In This Issue

Chairs Annual Review COVER

In Warm Memory of Erica Evans-Terlecki PAGE 2

> Editorial PAGE 2

2016 Annual Conference and Awards Dinner PAGE 3

> Forthcoming Regional Events PAGE 4

Newsletter Sponsor

ardmac cleanroom construction PAGE 4

🥤 @ISPEorg

Chair's Annual Review

The ISPE UK Affiliate Annual Event in Liverpool in November was a great success. The dinner was sold out and a sizeable sum of money raised for charity partly through the talents of on cue Dennis Taylor and the NW committee. CFS Events, our events organiser also contributed greatly.

We are continuing to dig in our heels regarding ISPE HQ's proposed removal of our ability to deliver UK based training. They have in response done some International training in Manchester but this is more expensive than our previous methods. We continue to lobby for the return of ISPE licensed training. This next year will see a restart in some form, which we hope our UK affiliate will see as a positive move.

There is a new venture on June 15th with a one day, low cost event being held in Birmingham on regulatory and guidance updates. This event places a particular focus on members that are young in the industry. As a society, our aim is to promote Pharmaceutical knowledge and whilst compared to a couple of decades ago, this knowledge has become established, there are still changes and advances. The speakers are very current and we believe that this will help people to feel up to date and more confident.

ISPE have attended 6 events during the year promoting the UK affiliate and 3 of these were organised by the MHRA. As a non- profit making society, promoting best practice, we are able to assist in sharing learning in a collaborative manner. In the UK, we have a regulator that is keen to advance pharmaceutical product quality, safety and efficacy by encouragement to better states of operation, distribution and innovation. (They can also wield the stick.) We are grateful for this. It is constructive and it is a UK competitive advantage.

The ISPE UK Affiliate mainly reflects the activities of technical people in UK Pharma. We are aware of significant structural changes since the financial crisis of 2008 and as a community we need to now move back to overall growth in UK Pharma. There are around 800 UK based ISPE members and this number is stable. We can grow together.

The next ISPE UK Affiliate conference and exhibition is in Leeds on Thursday 10 November. There is 10% more capacity than last year's venue, allowing the ISPE to cater for the continued growth of interest and success of this event. The meeting will also be marking the 25th anniversary of the formation of the ISPE UK GAMP community of practise. We hope you can join us and support your regional programmes and committees.

Dr Peter Dodd ISPE UK Affiliate Chair

Newsletter No. 67

ISPE UK Affiliate Update

In Warm Memory of Erica Evans-Terlecki

Sadly, Erica passed away in April. Erica was a driving force behind the early years of the UK Affiliate of ISPE and here is a tribute to a most interesting lady.

She was born in 1936 in London and had a privileged education at Cheltenham Ladies College and then on to a European finishing school. Languages and drive were key to her next step. She saw an advertisement for young ladies to join Bletchley Park which she did before the age of 21. She met her husband Renat Terlecki, a veteran of the Polish Free Air Force during the war but unfortunately, he died after only 2 years of marriage.

Most of her career seems to be secret, working for the UK Government and the United Nations. She was a forceful lady with bundles of determination. From here she joined CI Electronics and as a believer of their products usefulness to the Pharmaceutical industry decided to open up this market for Cl. During this time, she joined the fledgling ISPE UK Affiliate and soon became the organiser of the Annual Event and the routines of the ISPE newsletter. She served the UK Affiliate Board for a couple of decades and reluctantly only had to withdrawal due to fading health, first cancer which she survived once and then vascular dementia. She died at the age of 80 having received the ISPE Member of the Year and Fellow of the Year awards from the UK Affiliate and a Special Recognition Award from ISPE International. See photo. ISPE UK is very grateful for all her energy for the society. On behalf of the ISPE, thank you Erica.

Dr Peter Dodd, ISPE UK Affiliate Chair

The Award of ISPE Fellow was made to Erica Evans-Terlecki for services to the UK Affiliate over a number of years by UK Affiliate Chair Albert Evans.



Guidance & Regulations Conference

LATEST DEVELOPMENTS TO ISPE GUIDELINES AND INDUSTRY REGULATIONS



Wednesday 15th June Venue:



National Conference Centre At The National Motorcycle Museum

Topics to be covered:

- cGMP the latest regulatory updates
- Sustainability Handbook
- Oral Solid Dosage Forms 3rd Edition
 Baseline Guide
- Controlled Temperature Chamber (CTC) Mapping Good Practice Guide
- Operational Excellence
- GAMP Data Integrity
- Single Use Technologies Good Practice Guide

ISPE Members: £60

Places are limited so register soon to avoid disappointment at www.ispe.org

Editorial



So you may have noticed that the newsletter looks a little different this time. The ISPE has rebranded and this has now filtered down to the UK affiliate too. It has certainly made things look modern and reflects the ISPE's ethos to be at the forefront of pharmaceutical manufacturing knowledge.

Front page, our chair, Peter, has provided an excellent summary of the AGM notes. The theme I take from his notes are that the ISPE are listening to our UK affiliate and adapting to encourage growth of the organisation.

I hope this newsletter has been informative, as always, please get in touch if you have any comment or interest in further promotion of the ISPE.

Philippa philippa.king-smith@ardmac.com

@PipArdmac

Newsletter No. 67

Thursday 10 November The Queen's Hotel, Leeds



2016 ISPE UK Affiliate Annual Conference, Table Top Exhibition and Awards Dinner

In Partnership with the GAMP[®] COP UK Forum **(2)** ISPE. Gamp and 25th Anniversary Celebrations 2016

Annual Conference

Topic: Technologies for the 21st Century

A series of papers, including a show case for new technologies and techniques will cover a wide breadth of Pharmaceutical Engineering topics with a focus on application. The conference will pose the questions:

- What experience is there in such technologies?
- How did the regulatory authorities view these advances to our industry?

UK Pharma has changed significantly and needs to continue to grow for the benefit of UK plc. This demands the use of new technologies that can streamline and improve the product quality offering to patients and reward stakeholders. Papers on the growing UK Biopharmaceutical processes, new techniques for both process and facilities, sustainability and regulatory innovation are being progressed. Getting new technologies accepted by regulators is intended to be exemplified by people who have obtained the tee shirt.

Farly bird Conference Attendance Costs:

ISPF Members: £140 inc VAT Non- ISPE Members: £240 inc VAT IChemF Members: £160 inc VAT Pharmig Members: £160 inc VAT Students: £75 inc VAT

Awards Dinner

Tickets are still available for the Annual Awards Dinner but look set to sell out quickly, as we join forces with the GAMP⁺ COP UK Forum and hold their 25th anniversary celebrations as part of the Awards Dinner, in the beautiful Queen's Hotel Ballroom.

Annual Awards Dinner incl GAMP COP 25th **Anniversary Celebration Prices:**

Table of 10 persons: £930.00 inc VAT Individual Dinner Places: £95.00 inc VAT

Book early to avoid disappointment!

Sponsors

We still have sponsorship packages available. Please contact Robyn for more details. We would like to thank our sponsors for their support. Current sponsors:



www.cfsevents.co.uk/ispe



Southern Region

15 June 2016 Latest Developments to Guidelines and Regulations -Daytime conference Venue: National Motorcycle Museum, Birmingham

Contact Shawn Whitfield at: E: shawn.whitfield@btgplc.com

Central Region

Potential 2016 Events & Visits

- Manufacturing Medicines -
- Industrial Partnerships
- Introduction to Pharma Series

Contact Shaun Baker at: E: sbaker@idexcorp.com

Forthcoming Events

North West Region

22 June 2016 AZ Macclesfield Site Visit Steriles Facilitiy

7 September 2016 Quality, Risk Management Evening Event Venue: Elanco, Speke

Contact Rob Walker at: E: robwalker.chester@ btinternet.com

North East Region

10 November 2016 2016 ISPE UK Affiliate Annual Conference, Table Top Exhibition and Awards Dinner Venue: Queens Hotel, Leeds

7 July 2016 Site Visit to CPI's National Biologics Manufacturing Centre, Darlington

IChemE - 3rd High Value Technology Transfer Conference in Durham Supported by ISPE UK NE Region

Contact Peter Dodd at: E: peterwdodd@ntlworld.com



QUALITY, INNOVATION & COMPLIANCE

SUPERIOR CLEANROOM FINISHES

- Design completion
- Integration and co-ordination of MEP services
- Strict adherence to DQ, IQ, OQ and construction procedures
- Management of construction process
- Installation of cleanroom architectural products
- A safe, compliant, and 'on time' validated facility



NEARLY 40 YEARS IN CLEANROOM CONSTRUCTION DELIVERING THE HIGHEST STANDARD IN TECHNICAL AND VALUE ENGINEERED SOLUTIONS

info@ardmac.com