An exciting Autumn ahead

ANGELA STOKES, TOPRA PRESIDENT

As we say goodbye to summer and welcome autumn, there are a number of exciting events and training opportunities from TOPRA you should mark in your calendar.

Many of us are back at work after the summer holidays, the children are back at school and we are now approaching the end of another year. For me, it has been an exciting one as your President, but before I hand over the reins to my successor, there are still exciting times ahead.

Were you nominated for the TOPRA Awards? The shortlist is now out (see p3). We celebrate the winners and the shortlisted nominees on 1 November at the Awards Ceremony in London. This prestigious event is extra special this year because TOPRA is turning 40 and there will be a celebration of this at the ceremony.

I have been a member of TOPRA (initially BIRA) for almost 30 of those 40 years but I still remember the first course I attended. It was the course we all know as “the Introductory Course”. It has provided delegates with a firm foundation in regulatory affairs and, in my view, is the most comprehensive of its kind, presented by speakers and facilitators from industry and agencies, all respected authorities in their field. This year, the four-day Autumn Introductory Course is being held in Prague on 6–9 November. It will cover all aspects of the product development process and provide an overview of EU legislation and regulatory procedures, plus explore the central role regulatory affairs plays in modern healthcare companies and the development cycle of new drugs. Do you know someone new to the profession who would benefit from an opportunity to attend this course? Spread the word!

TOPRA is also offering two events focused on different aspects of the product lifecycle. The first, being held on 31 October, considers that regulatory and health technology assessment submissions must ensure that no special population is left behind. Regulators and patients need reassurance that clinical data and product information are relevant in any situation. This meeting will explore the regulatory and practical clinical issues associated with paediatric populations, the elderly and obese patients.

Also, from 24–26 October is a course focused on the lifecycle of medical devices. This can be enrolled as a standalone course or as part of the TOPRA MSc. Both of these courses will be held at the TOPRA offices in London.

Do you have an interest in nutrition and food supplements? TOPRA is offering a webinar on 16 October that will provide an understanding of the dossier requirements for the nutrition and health claims scientific assessment undertaken by the European Food Safety Authority (EFSA). This is a growing area of our profession and I, for one, will be registering to learn more about this exciting sector.

Elsewhere, there is a one-day workshop on 11 October in London from regulators and industry experts who will provide an insight on European SmPCs, package leaflet and label preparation and implementation.

Lastly, how is your continuing professional development (CPD) record coming along? Remember to log on to TOPRA’s MY CPD to record your training.
NEW TOPRA FELLOWS

Daniella Drago (left) and Majella Ryan have been made Fellows of TOPRA. Dr Drago is an Associate Professor and Director of the Regulatory Affairs Programmes at George Washington University, United States. She has been extensively involved in developing global regulatory strategies and had substantial exposure to regulatory agencies worldwide. Dr Drago is also a member of the Advisory Council of TOPRA. Ms Ryan has been working as a regulatory affairs professional for over 20 years. She has worked in a number of multi-national pharmaceutical companies before setting up her own consultancy business in 2002. Ms Ryan helped set up and was chair of TOPRA In Ireland from 2010 to 2011.

TOPRA colleague joins AGRE Board of Directors

Samantha Alsbury, TOPRA’s Head of Professional Development, has been elected to the Board of Directors of the Association for Graduate Regulatory Educators (AGRE).

AGRE is an organisation that brings together leaders of programmes offering graduate training in regulatory affairs and regulatory science. Its aims include sharing best practices in regulatory education; promoting the continued development of regulatory education as an academic discipline; and providing a forum for discussion of issues of mutual importance for educating stakeholders involved with commercialising products or services in the biomedical product and healthcare industries. It also supports the development of an organisational critical mass that is well positioned to influence public policies which affect regulatory education.

On being elected to the board, Dr Alsbury said: “I am delighted to serve on the AGRE Board of Directors and am looking forward to working with the other board members, which includes Daniela Drago, a member of the TOPRA Advisory Council, to raise awareness of the value of qualifications in regulatory affairs and to sharing best practice.” Dr Alsbury will serve on the Board for a two-year term.

Members-only opportunities

Part of TOPRA’s membership benefits includes being able to network with professionals locally and to attend focused sessions virtually (eg, via webinars). Below is an upcoming event in October:

- **TOPRA In France meeting, 4 October** This free webinar will help you understand how to be successful when interacting with EU regulators and health technology assessment bodies.

More information about TOPRA In groups and webinars available online.

TOPRA is delighted to announce that Voisin Life Sciences Consulting (VCLS) is supporting the INNOVATION category of this year’s Awards for Regulatory Excellence. The Awards and dinner ceremony will be held on 1 November at One Moorgate Place, London. Do not miss your chance to celebrate excellence within the profession and to find out who will win from one of the nine categories on the night.

For more information about the Awards click [here](#).

INNOVATION SPONSOR
## AWARDS FOR REGULATORY EXCELLENCE 2018

1 November, One Moorgate Place, London

### THE SHORTLISTS

*After a record-breaking number of entries, we are delighted to announce the shortlisted nominees*

**JOIN US TO CELEBRATE THE BEST IN REGULATORY AFFAIRS**

### COMMUNICATION

- **Global Regulatory Affairs Community (GRAC)** – PRA Health Sciences, UK
- **Marie Deneux** – VCLS – Voisin Consulting Life Sciences, France
- **Marjorie Zettler** – Cardinal Health, USA
- **Nancy Smerkanich** – University of Southern California, USA

### CONTRIBUTION

- **Andrew Marr** – Marr Consultancy, UK
- **Caroline Le Doré** – Sanofi, France
- **Julie Warner** – Alan Boyd Consultants, UK
- **Maurizio Suppo** – Qarad, Belgium
- **Mike McConnell** – DLRC, UK

### EDUCATION

- **Nathalie Schultz and team** – F Hoffmann-La Roche Ltd, Switzerland
- **Peté Embley** – VCLS – Voisin Consulting Life Sciences, UK
- **Sanofi GRA ODYSSEY** – Sanofi, France
- **Sherael Webley** – University of Hertfordshire, UK

### FUTURES

- **Diamond BioPharm** – UK
- **Emilia Heimann** – Immunicum AB, Sweden
- **Natasha Nesterova-Smith** – Alan Boyd Consultants, UK

### HORIZON

- **Francois Hebraud** – F Hoffmann-La Roche Ltd, Switzerland
- **Jenny R Cochran** – Cardinal Health Regulatory Sciences, USA
- **Magda Bujar** – CIRS, UK
- **Vatsala Patel** – Regulis, UK

### INNOVATION

- **eIFU Service** – Qarad, Belgium
- **Stuart McCully** – Syneos Health, UK
- **Viagra Connect Team** – Pfizer, UK

### INSPIRATION

- **Bao Le** – Sanofi, USA
- **Raquel Mura** – Sanofi, France
- **Sylvia Lobo** – Pfizer, UK

### SUPPORT

- **Acorn Regulatory** – Ireland
- **Alan Boyd Consultants** – UK
- **Diamond BioPharm** – UK
- **Regulis** – UK
- **Global Regulatory Consulting, Syneos Health** – UK

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**CHAMPIONS**
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TOPRA at ICDRA

TOPRA Executive Director Lynda Wight at the 48th International Conference of Drug Regulatory Authorities (ICDRA), held in Dublin, Ireland, from 3–7 September 2018. The event brought together regulatory authorities from World Health Organization member states to strengthen collaboration and develop international consensus on regulatory priorities.

Have your say: TOPRA annual membership survey 2018

Once again we invite all members to complete our annual survey.

In October, members will receive an email notification to take part in our annual membership survey.

We carry out this research to understand what members want from TOPRA. The responses will also help shape our action plans for the coming year. This is your chance to share your ideas and feedback on all the benefits we provide for you.

Actions from last year’s survey can be seen in our April 2018 InTouch article “You spoke, we listened”.

NEW TOPRA Members

TOPRA welcomes the following new and returning members.

- Miss Alessandra Agostini, PhD student in Life Sciences, UK
- Ms Fang Ba, Student, Iowa, US
- Ms Mirela Oana Tudor Badea, Senior Regulatory Consultant, Syneos Health, Spain
- Mr Philipp Bammer, Senior Regulatory Consultant, Syneos Health, Spain
- Mr Rishi Dewan, Global Regulatory Affairs Officer, STRATEC Biomedical UK Ltd, UK
- STRATEC Biomedical UK Ltd, UK
- Ms Mirela Oana Tudor Badea, Senior Regulatory Consultant, Syneos Health, Spain
- Mr Rishi Dewan, Global Regulatory Affairs Officer, STRATEC Biomedical UK Ltd, UK
- STRATEC Biomedical UK Ltd, UK
- Ms Viet Anh Do*, Manager – Regulatory Affairs, Celgene International SARL, Switzerland
- Dr Clare Briggs*, Regulatory Consultant, Seven Seas Ltd, UK
- Mr Remy Chateau, Regulatory Affairs Apprentice, France
- Dr Philipp Davenport, Higher Device Specialist, Medicines and Healthcare products Regulatory Agency, UK
- Miss Adele Alia Chapman, Global Regulatory Associate, Reckitt Benckiser, UK
- Mr Remy Chateau, Regulatory Affairs Apprentice, France
- Dr Phillipp Davenport, Higher Device Specialist, Medicines and Healthcare products Regulatory Agency, UK
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