



November 2014

# InTouch

THE TOPRA NEWSLETTER – KEEPING MEMBERS IN TOUCH

## In this issue...

It's amazing what a difference another year makes: you need look no further than our TOPRA President who now looks decidedly stern with that upper lip growth – thank goodness it was all for a good cause!

As ever, TOPRA continues to go from strength to strength celebrating 25 years of the MSc in Regulatory Affairs and 20 years for the Autumn Introductory Course.

I remember my participation in this course in Prague in November 2008 with great fondness. It was a fantastic experience and I sincerely believe this course is of tremendous value for anyone who is serious about their regulatory career. I wonder where we will be in another 20 years?

*Greer Deal*  
Director, Global Regulatory Services  
Co-Editor, InTouch

## A milestone month

JONATHAN TRETOWAN, TOPRA PRESIDENT

*November has been an exciting month for TOPRA, with both the Autumn Introductory Course and the MSc in Regulatory Affairs celebrating their 20th and 25th anniversaries respectively*

By the time you are reading this I will have lost the 'Movember' growth (much to the relief of my family and friends). See below for the result I managed to achieve along with a link for anyone who would like to support this excellent cause.

December means that I am now in the final month of my TOPRA Presidency, which for me highlights just how quickly a year can fly by. We are also just days away from celebrating excellence throughout our profession at the Awards for Regulatory Excellence 2014. I look forward to catching up with many friends and colleagues at this fantastic event!

The Annual European Medicines Agency (EMA) Review of the Year and Outlook for 2015 meeting in November was very successful (see page 3). It was wonderful to see so many colleagues at the event representing the EMA, national authorities, industry and consultants. We were treated to an excellent two-day programme that concluded with

an afternoon town hall session, the content of which was led by questions raised by delegates attending the event.

We were delighted to celebrate the 25th anniversary of the MSc in Regulatory Affairs on 20 November at the EMA. It was a privilege to be joined by so many people who have been involved with the MSc over the years (see page 2).

Speaking with students and course leaders involved, both past and present, it was clear that this course has a remarkable lasting impact on our profession. Everyone who has been and continues to be involved in the MSc should be proud of their contribution to this world class, gold standard qualification.

I was pleased to hear that the inaugural meeting of the Young Regulatory Professionals Group Working Party was well attended with lots of ideas generated to take the group forward. It will be exciting to see how this evolves and I know they will be looking for mentors – please do keep on the lookout to see what



expertise is needed and offer your support if possible.

On this note, I encourage everyone to get involved in your professional membership organisation in any way possible. The value that members are able to receive from TOPRA correlates to the investment made in your membership. Volunteers are always welcome, and if you are interested in investing some of your time and expertise please contact the TOPRA office team who will be delighted to discuss this with you.

Finally, I would like to say a huge thank you to all the volunteers who have committed their time and expertise in 2014. These great people, dedicated to their profession, ensure we have the drive and energy that makes TOPRA the strong forward-looking professional organisation that we are today.



## Three shears for **Movember**

*TOPRA President Jonathan Trethowan joined the 'Movember' movement for the 30 days of November, growing a moustache in aid of men's health*

The Movember Foundation is dedicated to raising awareness and funds for programmes working to improve the lives of men affected by prostate cancer, testicular cancer and mental health issues.

If you would like to donate please visit Jonathan's donation page at <http://mobro.co/jonathantrethowan>

# 25 years of the TOPRA MSc



*A celebration was held at the new EMA offices on 20 November to mark the 25th anniversary of the initiation of the TOPRA Postgraduate qualification in regulatory affairs*

We were delighted to welcome to the event many past students who were able to meet up with old friends and look at the displays of material and photographs of graduates from the past 25 years.

TOPRA President Jonathan Trethowan outlined how volunteers who originally set up the Introductory Course decided that a formal qualification was the next logical step, even though that was a very innovative thought at the time! He paid tribute to them and to the

volunteers who, since its inception, have worked as module leaders and speakers and ensured that the course has continued to the highest of standards.

Speaking for the University of Hertfordshire which now validates the course, Professor John Senior, the Pro Vice-Chancellor (Research and International), expressed their pleasure at the association with TOPRA and hoped that it would develop further in the future.



- 1 TOPRA President Jonathan Trethowan opened the celebration with a tribute to the volunteers whose contributions have been invaluable in the development of the MSc.
- 2 TOPRA was thrilled to welcome back the original Post Graduate Faculty: John Poland, Valerie Isitt, Anne Wigmore, Gillian Lennard, Joan Brooks, Anne Openshaw and Graham Higson.
- 3 More than 50 past students and volunteers gathered to celebrate this important milestone.
- 4 Professor John Senior of the University of Hertfordshire raised a toast.
- 5 Guests were able to view the photo displays highlighting the history and development of the course over 25 years.

# A CHANCE TO REFLECT

*TOPRA held its now customary year-end review of the activities of the EMA and a look towards 2015 in the Agency's impressive new offices*



The 9th annual review of the activities of the European Medicines Agency (EMA) provided the chance to reflect and plan for the challenges ahead

Attendees were welcomed by Andreas Pott, Deputy Executive Director of the EMA. A number of issues were discussed including the EU regulatory ecosystem in a global context, where Sabine Haubenreisser who is based at the US FDA provided a whirlwind trip around the current global interactions.

Following this the latest update on Adaptive Licensing was heard – now to be known as Adaptive Pathways to Patients, a patient-centred approach to development. Presentations were also given on benefit–risk methodologies, clinical trials, transparency and rounded off by two fascinating interactive sessions about the EMA and how it operates with its European agency partners.

*Full session reports will be available in an upcoming issue of Regulatory Rapporteur.*

## CELEBRATING 20 YEARS

*This November saw the ever-popular Autumn Introductory Course celebrate its 20th year with a fantastic array of speakers from industry and regulatory agencies*

A diverse and vivacious set of delegates participated in a highly interactive programme that covered the spectrum of drug development from a regulatory perspective.

This year's course, held at the Leonardo Royal Hotel in Berlin, coincided with the 25th anniversary of the fall of the Berlin Wall. One of the extracurricular highlights of the course was an informative and poignant trip to the DDR museum for a tour and dinner.

*Katie Pye, Speaker and WP member*



50 delegates attended this year's Autumn Introductory Course, marking its 20th anniversary

## NEW TOPRA MEMBERS

*TOPRA welcomes the following new members who joined recently*

**Dr Emmanuel Metz**, Head of Regulatory Affairs, SCC Scientific Consulting Company GmbH, Bad Kreuznach, Germany\*

**Dr Istvan Csere**, General Manager, Tiflovet Consulting, Budapest, Hungary\*

**Dr Stella Wooder**, Managing Consultant, Team Consulting, Ickleton, UK

**Mrs Sanyukta Kher**, Associate RA Director, Apotex Research, Ontario, Canada\*

**Mr Mathios Michelinakis**, Quality Assurance & Regulatory Affairs Director, Orthosurgical SA, Piraeus, Greece\*

**Dr Elinor McCartney**, President, Pen & Tec Consulting SL, Barcelona, Spain

**Dr Bruno Speder**, Head Clinical Regulatory Affairs, SGS Life Science Service, Berrchem, Belgium\*

**Mr Peter Klembala**, Regulatory Affairs Consultant, KlemTrade, Bratislava, Slovakia

**Miss Belinda Good**, UK (Student)

**Miss Maria Skotchko**, UK (Student)

**Ms Esme Kester**, Regulatory Operations Assistant, Q Dossier, Waalwijk, Netherlands

**Dr Irina Dumistracel Famar**, Head of Technology Transfer Dept, L'Aigle, France\*

**Mrs Hannah Dalia Nielsen**, Regulatory Affairs Specialist, Pfizer Consumer Healthcare, Soborg, Denmark\*

**Dr Michele Dubini**, Regulatory Affairs Manager, IBSA Institut Biochimique SA, Pambio-Noranco, Switzerland\*

**Mrs Sue Johnson**, Manager Labelling Strategy, Shire, Basingstoke, UK\*

**Mr Rishil Patel**, Regulatory Affairs & Quality Officer, Strandhaven, Ilford, UK

**Miss Vaishali Vyas**, Regulatory Affairs Officer, Medreich, London, UK\*

**Ms Jodi Croskerry**, Senior Manager, Genpact Pharamalink, European Talent Acquisition, Maidenhead, UK\*

**Dr Hans Rensland**, Director Regulatory Affairs, Rensland Pharma Consulting, Schriesheim, Germany\*

**Mr Marco Steiner**, Group Manager RA, Geistlich, Wolhusen, Switzerland\*

**Mr Paul Norton**, Regulatory Affairs Manager, Teva UK, Harlow, UK\*

**Mrs Catherine Christensen**, Novo Nordisk, Regulatory Affairs Specialist, UK\*

**Dr Elspeth Gray**, Senior Pharmaceutical Assessor, MHRA, UK

**Mrs Morag Bratby**, Senior RA Manager, GW Pharmaceuticals, Sittingbourne, UK

**Dr Parastoo Karoon**, Scientific Assessor, MHRA, UK\*

**Dr Arianna Bolla**, Market Access Manager, Milan, Italy

**Ms Caroline Freeman**, Principal Consultant, Quintiles, Reading, UK\*

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