Welcome to our new home

SARAH ROBERTS, TOPRA PRESIDENT

TOPRA’s big news this month is the announcement of the office move to Harbour Exchange, South Quay – a relocation which has been a long time in the making!

The TOPRA Board has been discussing the various options for our new home for at least two years. During that time a number of different premises in a variety of locations have been considered.

Each option had many pros and cons which needed to be weighed up to benefit both the needs of the organisation and its members, as well as the current and future economic environment (see page 2).

Harbour Exchange offers many advantages in terms of location (it is closer to the EMA with great access to Canary Wharf and South Quay stations), but also has flexible meeting rooms so that TOPRA can continue to run some of its educational offerings ‘in-house’ and of course continue to host regular Working Party meetings.

Perhaps most importantly, the new building offers us long-term security as we have negotiated a very competitive 10-year lease.

A big thank you to the TOPRA office team for ensuring a very quick and efficient move, with a special mention to Loretta Brown (Facilities Manager at TOPRA) for her outstanding efforts in making sure that the new office was fitted out to a great standard and ready for the move.

In the January and February 2015 issues of InTouch we showcased some testimonials from our graduates of the MSc in Regulatory Affairs, now validated by the University of Hertfordshire.

Some of the comments made in the testimonials struck a chord for me, and it is great to see such commitment to our profession.

Creating a solid foundation of regulatory knowledge, focusing on career progression and improving transferrable skills such as strategic thinking are all important factors in building a successful career.

The MSc course welcomes new participants and more information can be found on the TOPRA website or by contacting kay@topra.org.

Finally, you may have seen our recent notifications that nominations are now open for the Awards for Regulatory Excellence 2015. To view the category criteria in full and to request nomination forms please visit www.regulatoryaffairsawards.org.

This is a prestigious annual event, but it is of course reliant on receiving high quality nominations for each of the categories. If you would like to discuss which category would best suit your nominee, or to find out more information about completing the nomination form, please contact the TOPRA team at awards@topra.org who will be happy to help!
The TOPRA office moved on 13 April, and our new address is:

**TOPRA**
6th Floor
3 Harbour Exchange
South Quay
London E14 9GE

**Better facilities, better location**
There are substantial advantages to the new offices which help secure TOPRA’s long-term future. We have a 10 year lease, meaning TOPRA has a stable home in our preferred location.

With a Boardroom and separate meeting room we will be able to host more TOPRA courses and meetings in-house. TOPRA members will also be able to make use of these facilities for their own meetings at preferential rates.

The move takes us closer to EMA headquarters, and is just next to South Quay DLR station and an easy walk from the Jubilee Line at Canary Wharf.

We hope to see you at the new office soon!

Please note that our telephone numbers and email addresses remain the same.

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**ARE WE MEETING THE CHALLENGE?**

Delegates from seven EU member states and the US gathered together last month to discuss the impact of EU paediatric regulation on drug development and regulatory strategy

Paolo Tomasi, Head of Paediatric Medicines at the European Medicines Agency (EMA) began proceedings by presenting an overview of the EU regulatory landscape in this area since the new regulation was introduced in 2007.

This was followed by a summary of how industry has adapted to these changes, outlined by Anthony Compton of Pfizer (Director, Worldwide Safety and Regulatory, Global Innovative Pharma Business). Pamela Dicks (Manager, Scottish Children’s Research Network) also discussed how patient groups have worked with the new regulation.

The session was later split into three separate workshops (pictured above) to widen the debate, focusing on the following paediatric topics:

- **Workshop 1:** Practical challenges with Paediatric Investigation Plans (PIPs), led by Anthony Compton
- **Workshop 2:** Global development challenges, led by Jill Challis (NDA) and Dirk Mentzer (Chair of the Paediatric Committee)
- **Workshop 3:** Paediatric networks and their place in challenges associated with the conduct of studies in paediatrics, led by Pamela Dicks with support from Irmgard Eichler (Co-Chair of Enpr-EMA (European Network of Paediatric Research at the EMA)).

The day was rounded off with a panel session aided by Jordi Linares-Garcia, Head of Department of Product Development Scientific Support at the EMA. A full report of the lively discussion which followed will appear in *Regulatory Rapporteur* in the coming months.

TOPRA also announced the launch of an online course on EU paediatrics legislation, including topics such as developing a PIP. Module 1 is available now: [www.topra.org/online_paediatrics](http://www.topra.org/online_paediatrics).

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As a TOPRA member you have access to a wealth of networking and discussion opportunities to share your expertise and in turn benefit your professional development.

You might be interested in joining one of the ever-growing number of TOPRA In groups facilitating meetings in individual countries. Alternatively, if you have a specific area of interest – from biotechnology through to clinical trials – then joining one of the TOPRA Special Interest Networks (SPINs) may be for you.

With the recent launch of the new member engagement service, you can now manage your groups under the ‘My communities’ tab on the TOPRA website. This will enable you to share in discussion that is relevant to your professional interests, and will ensure that you get the most out of your TOPRA membership. Join a TOPRA Community today or contact membership@topra.org for more information.

### How do TOPRA Communities work?

#### TOPRA In groups

Our TOPRA In groups support regulatory professionals living and working in a particular country or region, providing a relevant and focused forum for discussion and networking.

- Austria
- Italy
- Spain
- France
- North America
- Ireland
- Scotland
- Sweden
- Switzerland

#### Special Interest Networks (SPINs)

TOPRA SPIN groups promote contact between regulatory professionals working in the same specialist sector, encouraging the exchange of views and ideas.

- Biotechnology
- CMC
- eRA
- Young Regulatory Professionals
- Medical Technologies
- Veterinary
- Pharmacovigilance
- Regulatory Intelligence
- Japan
- Clinical Trials

### TOPRA In UPDATE

**TOPRA In Italy**

*Dr Antonio Orsi, Chair of TOPRA In Italy and Director, Salupont Consulting Ltd*

TOPRA In Italy was formed in 2012, intended to provide Italian members with the opportunity to come together and discuss different perspectives in regulatory affairs, make new contacts and help with daily regulatory work in the healthcare sector.

I have been the Chair of this group since its inception and I am delighted with the progress it has made; thank you to its active Working Party for their help! We have already organised two successful events in 2015, the first to discuss ‘Falsified Medicines in Italy and Europe’ and the second on ‘Clinical Stem Cell Research: a review of recent regulatory updates and Italian activities’. We are now preparing for further interesting meetings, including a session on ‘Adaptive Pathways’ (21 April) and the ‘Escher Project’ (19 May).

Do not hesitate to contact me (aorsi@salupontconsulting.com) if you have any questions about TOPRA In Italy or would like to join the group – I look forward to welcoming you at our next meeting!
Career opportunity at TOPRA

TOPRA is looking to appoint a senior regulatory professional to join the team as Director of Policy in our new offices in the Canary Wharf area of London.

What is the role? This new role will be responsible for taking forward strategies to develop increasing professionalism for those working in regulatory roles, and to ensure that TOPRA has the structures, tools and resources to support members in achieving professional recognition.

The Director of Policy will have oversight of the evolution of membership and education activities within the organisation, and also an important role in building and maintaining our key external relationships.

Who do we want? You will be an experienced regulatory practitioner, perhaps with a policy or regulatory intelligence background. You will have an appreciation of how TOPRA works, an understanding of the importance of professional development and a commitment to furthering regulatory excellence.

Your track record will demonstrate an ability to manage change and achieve consensus with excellent oral and written communication skills. An interest in developing a career in the association sector is crucial.

Interested? If you would like to learn more please contact Lynda Wight (lynda@topra.org) to request a full position description or to talk about the role in confidence.

Closing date: Tuesday 12 May

NEW TOPRA MEMBERS

TOPRA welcomes the following new members who joined recently.

Mr Vladimir Obradevic, Regulatory Officer, Pfizer, Belgrade, Serbia and Montenegro*

Mrs Julie Raybould, Search & Selection Consultant, TM Recruit, Berkhamsted, UK

Dr Katarina Alheim, RA Manager, Nordicinfo Care, Nacka Strand, Sweden*

Dr Aisling Frizzell, RA Specialist, Merck Sharp and Dohme, Hoddesdon, UK*

Mr Etienne Daher, Joseph Fourier University, Grenoble, France (Student)

Mrs Kirsten Van Garsse, France (Student)

Dr Aisling Frizzell, Dr Katarina Alheim, Mr Vladimir Obradovic, Ms Michelle Ortiz, Miss Ligita Montvilaite, Miss Rabiea Abdullah, Mrs Kirsten Van Garsse, Mr Ian Love, Mr Tristan Maguet, Miss Eesha Vyas, Ms Elizabeth Rimmer, Mr Philip Ross, Dr Stuart Beattie, Miss Eshha Vyas, Mr Tristan Maguet, Mr Ian Love, Mrs Margarita Rodriguez Espinosa, Mrs Samantha Marshall, Ms Pauline Martinez, Ms Kathleen Harris, Miss Aparajitha Ganapathi, Miss Melissa Griffith, Ms Judit Dunbar, Miss Fatima Naseer, Dr Silvia Stingele, Dr Ilide Depraetere, Miss Rabula-Elena Enuta, Mrs Sue Scott, Ms Elena Hermina, Ms Jacqueline Awigena-Cook, Ms Sandrine Couturier, Ms Charlotte Vergara, Mrs Anne-Marie Turner, Ms Sandra Arif, Mrs Martina Kretz, Ms Sandra Arif, Mr Jonathan Archer, Mr Martin Kretz, Dr Graeme Deuchar, Mr Martin Kretz, Mr Jonathan Archer, Mrs Happy Bhat, Mr Jonathan Archer.

*Registered Member