

# intouch

KEEPING YOU

THE TOPRA NEWSLETTER – KEEPING MEMBERS IN TOUCH

JULY/AUGUST 2012

## In this issue

It's great to see the Olympic theme incorporated into this edition of *InTouch*. Athletes spend years learning their sport, training and honing their skills. Each challenge overcome and every lesson learnt is used to continually improve their performance.

The same is true for the regulatory professional as we can see in this issue. See how our Masters students and TOPRA In groups are thriving. We also have 'medal winners' with our new Fellows and new appointees to the TOPRA Advisory Council. If this isn't inspiring enough, what about the Aspire Manx Minkes, led by RA consultant Jill Bunyan, who will be swimming the English Channel?

Finally, TOPRA has its own version of the Olympics: yes, the TOPRA Awards Ceremony on 28 November. Come along and join in the celebrations, be inspired and, above all, be proud of being a regulatory professional.

*Greer Deal, Co-editor, InTouch*

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## Olympic ideals and regulatory practice

*A message from David Jefferys, TOPRA President*



**This summer all eyes will be on the TOPRA offices. Well, that's not quite true. Rather, all eyes will be on the London Olympic Park which is approximately two miles from our HQ.**

I recently visited the Olympic Park and the facilities are very impressive. All is set for a truly magnificent Olympic and Paralympic celebration.

If members of TOPRA are visiting London for the Olympics it could be a great chance to call in at the office, perhaps have a cup of coffee and meet with the staff. Remember, TOPRA is your organisation and we want you to feel very much a part of what goes on in our office and to see the team at work.

This is also a great opportunity to view the offices as a potential site for a company meeting or a base during an EMA discussion, as the boardroom is available for hire when not in use.

Despite all the critics, the Olympics still generate great enthusiasm. At their best they bring forth great stories of human endeavour and achievement. They bring together people from across the world in competition but also in fellowship and in the pursuit of excellence. I am sure over the summer we will marvel at events on both track and field, we will share some of the successes and some of the pain of failure. All aspects of life are caught up in the Olympic story. London will provide a perfect backdrop for these Olympics with many iconic venues and vistas.

Increasingly, sportsmen are being employed as motivators and recruited into major roles in industry and other activities.

There are many parallels between sport and activities in regulatory science. We also have our endurance events, our high intensity activities. We experience headwinds, are required to take alternative courses and to challenge the time clock as regular features of our working lives.

### Challenges

Words such as hurdle, sprint and finishing line are all too common parlance for us in the regulatory profession. Indeed the introduction of the new EU pharmacovigilance legislation has been referred to as a marathon and not a sprint and this was a theme echoed in the advertising for the recent Spring Introductory course, which took place in May.

Understanding psychology is important in sport and increasingly is important in regulatory decision-making.

I hope you all enjoy the summer break and in particular the Olympic and Paralympic Games. As we look ahead to the Autumn, there is an exciting programme organised by

TOPRA. We begin with the Benefit-Risk discussion meeting on 13 September, which will be the first of TOPRA's new 'Roundtable' events: an occasional series looking at current issues in regulatory science in an interactive environment. If you want to be part of the discussion on how regulatory science and Regulatory Affairs might evolve then these meetings are for you.

This will be followed by our Annual Symposium in Dublin and then we have the TOPRA Awards celebration and the highly successful annual joint meeting with the EMA. There are several other events in the TOPRA calendar during the Autumn.

Please join us to support these functions. They will be great opportunities for learning and also for networking and meeting colleagues. If you have any ideas for future meetings or activities that TOPRA should engage in please let myself, Lynda Wight or other members of the Board know.

## TOPRA Board ELECTIONS

**A reminder to all Members and Fellows that nominations are now open for the TOPRA Board for the 2013 session. Board members elected in October will take up their seat from January to December 2013. You have until 3 August to get your nomination in – see <https://www.topra.org/boardnom2012> for more information.**



John Greenwood and Kamal Sehdev, course director



## Congratulations to our MedTech Masters students

TOPRA is delighted to announce that three students were awarded their degrees in Medical Technology Regulatory Affairs (MTRA) MSc at Cranfield University's Graduation Ceremony on 14 June 2012.

Congratulations to John Greenham, Sean O'Dowd and Tina Mistry who have successfully completed their degrees and are already reaping the benefits of their hard work and achievements.

On Graduation Day we caught up with, John, Global Regulatory Affairs Manager from Systagenix Wound Management, who won the MTRA 'Best student' prize to hear what he had to say about his MSc experience... 'After 20+ years industry experience in Quality/Regulatory Management within the medical devices industry, the MSc represented a welcome opportunity to study and obtain a formal qualification in this specialist discipline. It also served to broaden my knowledge and understanding in this diverse field, and in aspects that I'm not routinely exposed to in the day-to-day role within my specific industry sector.'

For more information about our MSc in Medical Technology Regulatory Affairs with Cranfield University, please visit the TOPRA website or contact Kay Wood at [kay@topra.org](mailto:kay@topra.org).

## The Judges are Judging

**Nominations have now closed and it is up to the judging panel to evaluate the many entries we have received for this year's Awards.**

While we wait for the shortlist to be announced in mid-September why not make a date in your diary to attend the prestigious Awards Ceremony on 28 November at the Radisson Blu Hotel, Portman Square.

### Announcement

Attendees to the Awards Ceremony will be invited to the Inaugural TOPRA lecture given by Professor Sir Michael Rawlins. The topic is entitled 'Is the regulatory profession fit for the future? Why understanding regulatory procedures is no longer enough'.

In times of economic pressure, escalating development costs, increasing demands for transparency, legislative evolution and scientific revolution, regulatory professionals need to be 'future proofed' to stay successful. What will be the key skills for a regulatory scientist in the future?

We are delighted that Professor Sir Michael Rawlins will give this inaugural lecture, drawing on his experience in clinical medicine, as a regulator and in the evolving discipline of health technology assessment.

### Your company can align with the ethos of the awards through sponsorship

For those who care about regulatory excellence this is an ideal opportunity to promote your company in a commercially appropriate and highly visible new way!

**For further information about the 2012 TOPRA Awards, please contact Mark Wilkins, by email [mark.wilkins@ashridgecommunications.com](mailto:mark.wilkins@ashridgecommunications.com) or telephone: +44 (0)1753 714999.**



## Regulatory Affairs MSc update

Module 1 of the TOPRA MSc course Strategic Planning in Regulatory Affairs was held at the Arcotel Kaiserwasser, Vienna, Austria on 12-14 June.

The course was well attended with 41 delegates from across the world, including Singapore, Israel, Russia, the UK, Ireland, Switzerland, Spain, Germany, France, Slovenia, Czech Republic, Belgium and The Netherlands. They came from companies including Bayer, Takeda, Merck, Roche Products, Gilead, Meril, Wockhardt and Sanofi.

We welcomed two new students to the MSc from Boehringer Ingelheim and Novartis Consumer Health based in Germany and Belgium, reflecting the European appeal of the course. We were also joined by 18 additional delegates who are not currently studying towards the MSc in Regulatory Affairs.

Christine Degeling, the Module Leader, and her team produced an exciting programme.

#### Speakers included:

- Ingeborg Gerngross from the Austrian Authority presenting on the US strategic considerations
- Hirotaka Tsugumi from AstraZeneca Japan covering Japanese strategic considerations and Rick Lilley from UCB covering the interaction with regulatory agencies from an industry perspective.

**Our next MSc Module 2 – Regulatory Strategy for a New Active Substance: Preclinical Development – will take place at DeVere Latimer House, Chesham, UK from 25-27 September 2012. Please go to [www.topra.org/events](http://www.topra.org/events) for further information and a booking form.**



## TOPRA Staff

### WHO'S WHO

A series in which *InTouch* profiles members of TOPRA's office team

**Kay Wood – Postgraduate Administrator**

Kay joined TOPRA in July 2006 as maternity cover for the Membership and Advertising Secretary. She then took on the role of Office Co-ordinator.

When the Academic Registrar left in October 2007, Kay took over the position as Postgraduate Administrator. She currently looks after around 100 students who are studying for their Masters in Regulatory Affairs.

Kay is responsible for organising the MSc modules, finding venues, negotiating contracts and organising the logistics for the modules.

She is also the Secretary to External and Internal Exam Boards, Course Management Committee meetings, Module Leaders meetings, Staff/Student

liaison meetings, and the Joint Board of Studies. She assists the Course Director in the update of the yearly Annual College and Course Review, Student Handbook and other course documentation. Kay co-ordinates the Quinquennial review and arranges the annual graduation ceremony.

Among her other key tasks, Kay manages the library resources in the office, updates monthly stats and the database as well as other ad hoc duties for the Director of Education, Course Director and Dissertation Supervisor. In addition to administering the MSc, Kay helps organise the TOPRA Regulatory Affairs Awards. Email [kay@topra.org](mailto:kay@topra.org) if you have any MSc-related queries.

## New TOPRA Fellows

It is pleasing to note that following the recent modifications of the Fellowship nomination system to allow applications to be made by those wishing to become Fellows, there has been an influx of applications for consideration. Of these, the following have been approved by the Fellowship Appointment Panel and ratified by the Board, based on the information submitted and we are delighted to announce their appointments to Fellowship of TOPRA:

- David Snodin
- Angela Stokes
- Peter Blakeney
- Yves Tillet
- Christina Mayer Nicolai
- Paul Jeffreys

If you would like to consider applying for Fellowship or nominating a colleague please see [https://www.topra.org/sites/default/files/assets/pdf/TOPRA\\_Fellowship\\_proposal\\_clean.pdf](https://www.topra.org/sites/default/files/assets/pdf/TOPRA_Fellowship_proposal_clean.pdf) for an application form and guidance.

## NETWORKING MEETINGS IN EUROPE

TOPRA held two large TOPRA In...Networking events in Europe last month, one in Switzerland hosted at the Vifor Pharma offices in Zurich on 12 June and another event tied into an MSc Module in Vienna, Austria on 13 June.

In Zurich more than 35 participants were present at the third TOPRA In Switzerland event. The presentations ranged from regulatory issues for non-biological complex drugs to global requirements for local clinical trials as well as two non-regulatory topics to provide advice about soft skills for regulatory professionals.

It was a great opportunity to network with people from many different Swiss regions and various company backgrounds.

In Vienna at the TOPRA In Austria's fourth event, members built upon the existing MSc Module that was taking place and invited more than 15 of their members to join the students, to experience the last two sessions on 'Orphan Drug Development – Strategic Considerations' and 'Regulatory Strategy for the Emerging Markets – Far East, Africa, Middle East, Latin America.' This was then followed up by a rigorous question and answer session involving students and Austrian TOPRA In members, followed by a networking wine reception.

These two successful meetings had slightly different

speakers and agendas that reflected the needs and interests of members in their own countries and were free events open to all healthcare Regulatory Affairs professionals.

Both were aimed at providing an opportunity to hear the latest about TOPRA as well as the latest news on Pharmaceutical and Medical Devices in their respective countries, while also providing a perfect opportunity to network with colleagues in Switzerland and Austria in a relaxed and sociable setting.

Future meetings of these groups are planned for later in the year and if anyone is interested in joining their national TOPRA In group please email your details to [meetings@topra.org](mailto:meetings@topra.org) or call +44 (0) 207 538 9502.

*Neil Fisher (right) with delegates at the TOPRA In Switzerland meeting.*



Portcullis House

The main aim is to focus on those issues where science and politics meet, informing Members of both Houses of Parliament by indicating the relevance of scientific and technological developments to matters of public interest and to the development of policy.

Greer is delighted that GRS is the first dedicated Regulatory Affairs Consultancy to be a member of this Committee and that the importance of Regulatory Affairs professionals is being recognised at Government level.

'As many of you know, I'm passionate about raising the profile of Regulatory Affairs professionals as, only too often, they are the unsung heroes of the life sciences industry. I believe that our company's membership to this Committee is the perfect opportunity to emphasise the essential and often critical role of the regulatory professional. I'm looking forward to GRS being a very active member!'

'We attended our first meeting on Tuesday 12 June at Portcullis House, Westminster, where there was discussion and debate about whether or not the EU regulations are adequate for animal research.

*Greer Deal, Director, Global Regulatory Services (GRS)*

## REGULATORY AFFAIRS recognised in UK Parliament

**Co-Editor of *InTouch*, Greer Deal was asked to join the UK's Parliamentary & Scientific Committee at the end of last year. Her company has now been formally accepted as a member of the UK's Parliamentary & Scientific Committee.**

This parliamentary group focuses on scientific and technological issues, providing a long-term liaison between Parliamentarians and scientific bodies, science-based industry and the academic world.



## On the EMTRAIN

**EMTRAIN** (European Medicines Research Training network) is part of the Innovative Medicines Initiative (IMI).

Its aim is to establish a pan-European platform for education and training covering the whole lifecycle of medicines from basic research through clinical development to pharmacovigilance. There are a number of projects within EMTRAIN and TOPRA is involved with a few of them, most notably the provision of MSc education in regulatory affairs and the provision of Continuing Professional Development opportunities. One aspect has been the production of 'on-course', which is an online catalogue of biomedical courses offered by academic institutions and professional bodies. The TOPRA MSc courses feature on this database but the full range covers all aspects of medicines development and has both full time and part time courses included – 3,353 in total and rising! Visit <http://www.on-course.eu/> for more information.

## TOPRA Advisory Council

TOPRA is privileged to have a number of very eminent personalities from the international regulatory world as members of its Advisory Council, which gives advice to the Board on what TOPRA should be doing for its members and the regulatory community at large.

Several very long-serving members have recently stood down with our thanks for all they have done for us since they joined – some in 2004! These include Professor Tamas Paal, Noel Wathion, Graham Higson and Jytte Lyngvig. Their input and support has been greatly appreciated.

We have recruited some new members to the Council and these include: Mel Walker (GSK), Rui Santos Ivo (University of Lisbon), Martina Cvelbar (Slovenian Agency), Axel Breitstadt (MSD) and Nicola Bedlington (European Patients' Forum).

They will bring some new perspectives to the Council which are relevant for the changes we are seeing in the regulatory environment. The new Council had its first meeting with the Board on 5 July and we look forward to working together in the coming years.



## Channelling their efforts for **Aspire**

In September 2012 the Aspire Manx Minkes aim to be the first Isle of Man based team to swim the English Channel. The attempt will raise money for Aspire, which helps people with spinal cord injury. Wetsuits are not permitted and the team started their cold water training in April in temperatures of only 7-8°C!

The Minkes are headed up by Regulatory Affairs consultant Dr Jill Bunyan, who many will know is an enthusiastic open water swimmer, as well as a qualified swimming teacher, coach and judge.

For corporate sponsorship opportunities, please contact Jill on [jillbunyan@manx.net](mailto:jillbunyan@manx.net). Donations can also be made via <http://www.justgiving.com/teams/aspiremanxminkes>



Back row: Silla Parnell, Brandon Ellis, Heather Mattocks, Jo Barkwith  
Front: Christine Howell, Jill Bunyan

Pic credit: By kind permission of Isle of Man Newspapers.

### InTouch Editors:

Jenine Willis, Greer Deal and Virginia Guellal

### How to contact InTouch

InTouch welcomes contributions from TOPRA members.

If you would like to contribute to the newsletter, or find out about deadlines, please contact Jenine Willis ([jenine@topra.org](mailto:jenine@topra.org)).

Please address any articles and correspondence to: [intouch@topra.org](mailto:intouch@topra.org) or submit your contribution via [www.topra.org/intouch](http://www.topra.org/intouch)

Views expressed in InTouch are those of the contributors and not necessarily those of the editors or TOPRA. While every effort is made to ensure information is accurate, conditions may change and readers are advised to consult current official texts and/or to seek appropriate professional advice before taking any regulatory action.

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InTouch is free to TOPRA members. Annual membership of TOPRA is €220. TOPRA members can read or download InTouch online at [www.topra.org](http://www.topra.org)

## Taking part in social media

TOPRA embraces social media as an important tool for organisational and member engagement. TOPRA also encourages its members and volunteers to use social media in a personal capacity in order to reach out and share information and views with other members and regulatory communities – both old and new.

TOPRA is at its best when represented by our volunteers and staff, but anything we publish online will reflect on all of us. We have produced some guidelines for members wanting to participate in LinkedIn, Facebook, Twitter, our eGroups and any other social networking forums on a professional basis.

For a copy of the guidelines contact [will@topra.org](mailto:will@topra.org).

## TOPRA LinkedIn

TOPRA LinkedIn member Juliana Brankova is a Regulatory Affairs Manager at Baxter BioScience, in Vienna Austria. She has worked at Baxter since 1997, and joined the European Regulatory Affairs team in Vienna in 2007.

Juliana is a medical doctor and holds an MBA degree in General Management from City University Seattle. She specialises in European RA for Biologicals (drug development, licensing and marketing in the EU).

Why did she join LinkedIn? 'To build relationships online and grow my network with people of similar interests, by generating new connections with people I didn't know before,' she says.

'I'm very happy being accepted as a member in the TOPRA group on LinkedIn and I'm looking forward to being engaged in interesting group dialogues and networking with elite professionals,' she adds.



## NEW TOPRA MEMBERS

TOPRA welcomes the following new members who joined recently.

**Miss Kathryn Bishop**, Actavis, Barnstaple, UK\*

**Miss Karima Debar**, London, UK (Student)

**Ms Anne Deblock**, Basel, Switzerland (Student)

**Dr Madlyn Denyer**, Billingshurst, UK\*

**Dr Dolores Edmont**, L2D Consulting 34, Les Matelles, France

**Mrs Cheryl English**, Herne Bay, UK\*

**Ms Sylvie Gelebart**, UCB Pharma, Brussels, Belgium\*

**Ms Jolanta Golec**, Middleton, Ireland (Student)

**Ms Irene Gow**, Core Clinical Research and Consultancy, Ireland\*

**Ms Martina Hoeth**, Baxter Innovations, Vienna, Austria\*

**Dr Shinobu Iwai**, CellSeed, Shinjyuku-ku, Japan

**Dr Tamara Lezhava**, Arlington, US

**Mr Manos Mavromatis**, Shire, Switzerland\*

**Dr Christian Monnerjahn**, Salutas Pharma, Barleben, Germany

**Miss Frida Olsson**, Pierre Fabre, Winchester, UK

**Mr Kamlesh Patel**, Greenford, UK\*

**Mrs Avani Patel**, London, UK\*

**Mrs Anna Ponten-Engelhardt**, AstraZeneca, Sodertalje, Sweden\*

**Mr Julien Raynaud**, Kloten, Switzerland (Student)

**Mr Arjun Singh, Mi3**, Blackburn, UK\*

\*Registered Member



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