The meeting was followed by the first Advisory Council discussion of 2015, with leading figures from the regulatory world giving their frank feedback on our activities and input into TOPRA’s future direction.

Perhaps it was being in these new surroundings that lent a sense of ‘new beginnings’ and excited optimism for the future of our organisation. This edition of InTouch conveys a similar message, as it includes reports of events designed for those who are at the start of their regulatory careers.

The Spring Introductory Course was once again a success (see page 3) and attracted participants from as far away as Saudi Arabia – TOPRA’s name and reputation is certainly spreading, it seems!

Last month we ran a careers webinar (see page 3) and it was a great opportunity for newer recruits to develop a plan for their future. It is also encouraging to see the growth in the number of our student members.

With more undergraduate courses embedding a regulatory affairs component into their curriculum, our profession is increasingly becoming a positive career choice for new graduates. We will have to ensure we can continue to offer the resources and tools they and their employers will need to help them on the road to success.

The graduation of some of our MSc students (see page 4) represents the culmination of the hard work they have put in over the past few years, equipping them with a highly valued qualification that will set them apart and start them off on the next stage of their careers.

Of course, TOPRA is not just for the ‘new recruits’ and we are fortunate to have many very experienced professionals in our membership. Not only do they give back to the profession by helping with our teaching and other activities, they also value TOPRA as an independent forum for debate and a means to keep their own regulatory intelligence up-to-date by taking part in events tailored for them. The TOPRA Roundtable on social media and the upcoming Fellows’ Dinner (see page 2) are good examples of the way in which TOPRA provides networking opportunities for our members while allowing us as individuals to make our opinions known.

It is important to recognise those who are at the start of their careers as well as those who have already made a huge contribution, and the Awards for Regulatory Excellence provide the ideal opportunity for this. I would urge you all to think about the colleagues you work with and consider showing them how much you value them by nominating them for an Award.

Finally, talking of ‘new beginnings’, our TOPRA President Sarah Roberts has not authored this month’s editorial as she is on maternity leave. We look forward to news of the new arrival and wish her all the best for the future!
A group of senior professionals gathered at the Royal Overseas League in London to discuss the growing role of social media in regulatory affairs.

Roundtables are an occasional series of meetings for senior regulatory professionals held under Chatham House Rules. The sessions examine upcoming issues and assess their impact on the work of regulatory specialists, attempting to draw conclusions on the best way forward for the profession.

This month’s Roundtable was chaired by Professor Sir Alasdair Breckenridge, who raised the question of how the increased use of social media by patients could be utilised by industry and regulators.

Mick Foy, leader of the IMI WEB-RADR (Recognising Adverse Drug Reactions) brought the audience up-to-date with the project’s progress. WEB-RADR is currently developing a mobile app for patients and healthcare professionals to report suspected adverse drug reactions to national EU regulators. The creation of a policy framework for this purpose would cover the use of technology in ADR reporting, medication errors and quality defect monitoring.

Sunayana Shah from the Association of the British Pharmaceutical Industry (ABPI), reviewed some recent key reports on what is already being done by the top ten companies in this area, and challenged the audience to think about accuracy, privacy and ethical issues. The discussion which followed was a lively one – with delegates from agencies including the European Medicines Agency (EMA), large and small companies and consultancies – all making a contribution.

Future Roundtables are planned on a range of topics including vaccine regulation and the use of Article 58. If you would like to be involved please contact christopher@topra.org.

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TAKING REGULATORY BACK TO FUNDAMENTALS

Last month the 37th Spring Introductory Course took place in the beautiful surroundings of Wotton House, Surrey.

Bringing together delegates from eight different countries, including the US and Saudi Arabia, attendees spent a week learning about the broad spectrum of regulatory functions at this annual residential course.

We were fortunate to have an outstanding array of speakers from both industry and agencies including the Federal Institute for Drugs and Medical Devices (BfArM), the Health Products Regulatory Authority (HPRA), the Medicines and Healthcare products Regulatory Agency (MHRA) and the Medicines Evaluation Board (MEB).

The participants worked hard throughout the week, taking part in a number of interactive case study workshops in addition to the formal lectures.

There were also plenty of opportunities for networking and fun, including a quiz night and dinner dance where delegates were able to relax and enjoy spending time with their colleagues and new friends.

CAREERS WEBINAR, 28 APRIL

KICKSTART YOUR CAREER

TOPRA recently hosted a Webinar focusing on ‘A Career in Regulatory Affairs: Your First Steps’

The session was opened by Emma McNeely, Regulatory Professional Development Manager at TOPRA and former industry regulatory professional. Emma introduced delegates to what a career in regulatory affairs involves, as well as the many varied roles which can be undertaken.

Susan Botfield, a careers coach specialising in the pharmaceutical industry, then went on to describe some practical steps to help secure your first regulatory role. Three of our members also presented their own case study of their entry routes into the profession.

The archived webinar is available free to all members – please visit www.topra.org/webinars for more information.

STUDENT POSTER COMPETITION

Are you a student currently studying at a European university? If so, TOPRA invites you to submit a scientific poster for presentation at the 12th Annual Symposium in Berlin.

Posters should succinctly describe a piece of planned or completed research to the general audience of professionals from the regulatory healthcare arena.

Although primarily concerning healthcare regulatory affairs, this is a cross-disciplinary conference, and therefore any topic which would be of interest to the human or veterinary healthcare regulatory community covering pharmaceuticals, biotechnology or medical devices can be submitted.

Those who have posters accepted will also be eligible for a free delegate pass to the TOPRA Annual Symposium, subject to availability (awarded on a first-come-first-served basis and excluding travel and accommodation).

To find out the key dates for submitting your poster please visit www.toprasymposium.org/posters.
CONGRATULATIONS TO OUR GRADUATES!

Two of our students studying for the MSc in Regulatory Affairs at the University of Wales recently attended their Graduation Ceremony, held on Thursday 30 April at the Millennium Centre in Cardiff.

Andrew Sabuneti from Novartis, Switzerland (L) and Elke Hofer-Litzbauer from Baxter, Austria (R) achieved this Award while working full-time at their respective companies. We offer them congratulations on their success!

NEW TOPRA MEMBERS

TOPRA welcomes the following new members who joined recently:

Dr Francisco Inesta, Postdoctoral Scientist, University of Dundee, UK
Dr Markus Petermeier, Manager Dossier Leadership, Merck Serono, Darmstadt, Germany*
Ms Maya Savailiene, Consultant Regulatory Affairs, 2SM Pharma Regulatory Services, Goa, India*
Mr Sam Howells, Regulatory Affairs Advisor, Bayer, Newbury, UK
Ms Danielle Rieks, Regulatory Affairs Officer, Beaphar, Raalte, Netherlands
Ms Malin Waage, Director Regulatory Affairs, Scandinavian Development Services, Danderyd, Sweden*
Ms Maria McCarr, Regulatory Affairs Officer, EirGen Pharma, Waterford, Ireland
Mrs Jenny Bennett, Senior Regulatory Affairs Associate, Reckitt Benckiser Brands, Hull, UK*
Mr Thomas Christesen, Director Regulatory Affairs, Reckitt Benckiser Brands, Hull, UK*
Mr Jonathan Jones, Associate Director Regulatory Affairs, Pharmalink, Maidenhead, UK*
Ms Danielle Tobin, Consultant, EMRS, West Hougham, UK*
Miss Alixdu Hessain, Regulatory Affairs Officer, Diamond BioPharm, Harlow, UK
Mrs Neelam More, Regulatory and Medical Affairs Executive, Gedeon, London, UK*
Ms Kerry Tsang, Regulatory Affairs Officer, EirGen Pharma, Waterford, Ireland
Mrs Jenny Bennett, Senior Regulatory Affairs Associate, Reckitt Benckiser Brands, Hull, UK*
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Mr Thomas Christesen, Director Regulatory Affairs, Reckitt Benckiser Brands, Hull, UK*
Miss Grace Marsden, Regulatory Affairs Specialist, GW Pharmaceuticals, Cambridge, UK
Dr Nicola McKeivie, Associate Director Regulatory Affairs, Circassia, Reading, UK*
Mr Moche Irah, Director Global Vaccine Regulatory Affairs, Phibro Animal Health, West Industrial Zone, Israel*
Ms Danielle Tobin, Consultant, EMRS, West Hougham, UK*
Miss Alia Hussain, Regulatory Affairs Officer, Diamond BioPharm, Harlow, UK
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TOPRA InTouch Newsletter – May 2015

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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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ENABLING AND PROMOTING EXCELLENCE IN THE HEALTHCARE REGULATORY PROFESSION

*Registered Member