I was delighted to spend an inspiring evening celebrating excellence throughout our profession with so many colleagues at the annual Awards for Regulatory Excellence. This year’s ceremony attracted nominations from across the globe and presented our eminent judging panel with the challenging task of identifying the ultimate winners from the numerous high quality entries received.

As a judge myself for the past four years, I can assure you that the standard of entries this year was as high as ever; a testament to the respect that our Awards now command across the global regulatory profession. Clearly the Awards Ceremony would not be possible without the hard work and dedication of many people and I would like to personally thank the following for their valuable contributions, ongoing commitment and passion to make this night a success.

Firstly, thank you to the Awards Working Party chaired by Craig McCarthy; our Awards champions who throughout the year promote and encourage colleagues and friends to enter.

Secondly, thank you to everyone who invested their time to make a nomination, as well as the nominees themselves. Thank you to the judges and sponsors for the event; in particular to Samarind who have been category sponsors for the fourth year running (having won Innovation themselves at the inaugural Awards in 2010).

Finally to everyone who attended and ensured that it was a night to remember – it was fantastic to witness and share in the winners’ celebrations.

I hope that you enjoy this special Awards edition of InTouch; best wishes for Christmas and a happy and healthy 2015.

For more information about the Awards go to www.regulatoryaffairsawards.org
This year’s Awards for Regulatory Excellence were hosted by Greg Perry, Executive Director of the Medicines Patent Pool, in a glittering ceremony held at the Royal College of Surgeons on 9 December.

As in all previous years, the Awards attracted nominations from big and small companies; from agencies and universities; and from work in the drug and devices sectors – genuinely representing the breadth of regulatory activity.

TOPRA’s Executive Director, Lynda Wight, said that ‘these Awards make me very proud of our regulatory profession and the extraordinary people who work in it – and of course of TOPRA, which through the Awards is celebrating excellence across the whole spectrum of regulatory activity’.

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### HORIZON

The HORIZON Award recognises those starting out on their regulatory careers who have shown outstanding skill and potential.

This year the Award went to Costantino Congiatu, a Senior Regulatory Affairs Specialist at PPD, a global CRO, in recognition of his proactive approach to problem-solving, his positive attitude and assimilation of knowledge in a short time. His ability to be both strategic and practical has earned him excellent feedback from all his clients.

### INSPIRATION

INSPIRATION is aimed at senior regulatory professionals who have inspired others with their regulatory knowledge and mentorship. Regulatory Consultant Gillian Gregory was the proud recipient of this Award, having launched the careers of many of the excellent regulatory professionals who form the bedrock of today’s profession. For more than 30 years she has inspired and motivated young graduates entering the field to become confident and respected regulatory professionals.

### INNOVATION

The INNOVATION Award went to Benny Ons, Director Regulatory Affairs Europe at Beckton Dickinson and Company in Belgium. This honour was presented by Samarind’s Miranda Pothiawala, a previous winner and strong supporter of this category.

Benny is a member of the European Diagnostics Manufacturers Association Executive Committee and Chairman of the EDMA Regulatory Committee. He has also been Vice-Chair of the Global Harmonization Task Force Study Group. Last year he was appointed an advisor to the Asian Harmonization Working Party.

### FUTURES

FUTURES acknowledges the role of regulatory scientists in realising the potential of cutting edge technologies.

The first recipient of this new Award was Alison Wilson of CellData Services, who specialises in the regulatory affairs of gene and cell therapies and tissue engineered medicinal products, and is an authority in this difficult regulatory and technological area. She has used her educational, entrepreneurial and communication skills to lecture and publish several regulatory scientific papers, and to establish a specialist consulting service for leading edge products.
The EDUCATION Award honours those who have helped shape and have made a significant contribution to the world of regulatory education and training. The winner this year was Gabriele Dallmann, the Founder of EUCRAF. Gabriele was one of the first to introduce a specialised education programme in biopharmaceutical-related regulatory affairs in Germany. She has established EUCRAF as a centre of excellence in providing professional networking and educational programs in the regulatory affairs community. Gabriele is a visiting lecturer on biopharmaceuticals at the Faculty of Pharmacy of Freiburg University, and is also the Founder and Director of two other companies, Pharmatching GmbH and Biopharma Excellence GmbH.

The SUPPORT category recognises the crucial role that those in the support sector play in the effectiveness of the regulatory process, and the importance of the quality of the work they do. Ranging from advice and consultancy, provision of extra resources, to specialist services – these companies provide vital support for all regulatory activity. The Award was presented to Voisin Consulting Life Sciences (VCLS), based in Paris, France. The team were recognised for their work on an orphan drug-device combination product for a paediatric indication. They were praised for their outstanding scientific and regulatory knowledge, their proactive approach and constant commitment to quality.

The penultimate Award of the evening was the second new category: CONTRIBUTION, rewarding experienced regulatory professionals who do an excellent job. Given the dedicated work of regulatory professionals it was not a surprise that this category received the most nominations this year. The Award was given to Sue Harris from the MHRA, who is no stranger to these Awards having been shortlisted previously in other categories. Sue has made a significant contribution to public health, the profession of regulatory affairs and to TOPRA. In her work at the MHRA she has trained and mentored hundreds of new recruits and is an inspirational manager. She represents the agency at the highest level in Europe and worldwide.

As the highlight of the Ceremony, this Award celebrates the career of an individual who has committed themselves to furthering the cause of regulatory affairs, drug development and regulatory science.

The Award was presented to Dr Murray Lumpkin, who has played a significant role on the global healthcare stage throughout his career. Currently a senior fellow of the Gates Foundation, he is helping to support the development of global regulatory systems by providing assistance to foreign regulatory training programs, contributing to a regional regulatory hub located within the Pan-American Health Organization and developing new pharmacovigilance systems in Africa and Asia.

Murray started his long career with the US FDA in 1989 as Director of the Division of Anti-Infective Drug Products in the Center for Drug Evaluation and Research. Five years later he became Deputy Center Director for CDER where his main responsibilities included oversight and management of the Offices of Drug Evaluation and their new drug review divisions. He was one of the initial members of FDA’s representation to the International Conference on Harmonization; and he was FDA’s representative for 9 years to the World Health Organization’s CIOMS working groups on drug safety issues.
Congratulations to our graduates

This year TOPRA celebrated the 25th anniversary of the MSc in Regulatory Affairs, reinforcing its esteem in regulatory training.

The Awards evening began with a formal recognition of this year’s graduates, who received their qualifications from Professor Sir Alasdair Breckenridge CBE. Congratulations to them all!

Above (L to R): Aaron Cousins achieved an MSc in Medical Technology RA; Elke Hofer-Litzlbauer and Katrina Ashcroft each received their MSc RA presented by Professor Sir Alasdair Breckenridge

A big thank you to 2014’s Awards Sponsors!

TOPRA is grateful to our sponsors for their support in rewarding excellence in regulatory affairs, without whom the celebration could not take place. This year our sponsors were Samarind, who we were delighted to welcome back as sponsors of the Innovation Award for another year; along with Roche and PPD who’s support we were thrilled to gain as Champions of the Awards.

Samarind’s Software Director Miranda Pothiawala commented, ‘We’re delighted to continue our support for this significant and prestigious award for another year. Encouraging innovation is an intrinsic part of Samarind’s ethos, and so it’s quite natural that we should encourage others to believe in, and fully develop their ideas. We look forward to continuing our valuable association with TOPRA and to presenting the award to the winners, at what is now one of the key events in the regulatory calendar.’

We would like to say a big thank you to all our sponsors for supporting what was a truly memorable evening of celebration.