

November 2015

TOPRA
AWARDS

InTouch

THE TOPRA NEWSLETTER – KEEPING MEMBERS IN TOUCH



AWARDS EDITION

The sixth TOPRA Awards for Regulatory Excellence took place on 18 November at the Royal College of Obstetricians and Gynaecologists in Regent's Park, London.

Now a regular feature in the regulatory calendar, this year's programme attracted a record number of nominations celebrating work in the drug and devices sectors, and genuinely representing the amazing breadth of regulatory activity today.

We are delighted to share with you the individual and team successes for 2015 in this special Awards edition of *InTouch*.

Rewarding our regulatory stars!

LYNDA WIGHT, TOPRA EXECUTIVE DIRECTOR

November saw the glittering ceremony to announce the winners of the 2015 Awards for Regulatory Excellence – we offer our congratulations to all shortlisted nominees and winners of these prestigious Awards!

In this special edition of *InTouch* you will be able to find out the details of our winners, but suffice to say it was humbling to hear so many stories of exceptional achievement, ground-breaking regulatory strategies and outstanding teamwork.

This year we announced winners in eight categories: Horizon, Inspiration, Innovation, Futures, Education, Support, Contribution and Lifetime Achievement. As always, it

was great to see our nominees recognised at all stages of their regulatory careers.

Our Lifetime Achievement winner, Dr June Raine, was a very popular choice by the judges (see page 3). In her acceptance speech she paid tribute to the role that TOPRA plays in the regulatory community and the shared values we have in common.

It was also a privilege to welcome our MSc graduates to collect their certificates from

TOPRA President-Elect Thomas Kühler.

It is clear that TOPRA's post-graduate courses have set the standards for regulatory education. They were ground-breaking in their conception and remain innovative in their delivery. We congratulate all our graduates for their hard work!

A great time was had by all at the ceremony – as the photographs prove – and we are already planning the 2016 event. Who will *you* nominate?



Share your photos of the evening with us by emailing them to awards@topra.org. Thank you!

ENABLING AND PROMOTING EXCELLENCE IN THE HEALTHCARE REGULATORY PROFESSION



TOPRA was delighted to welcome back Greg Perry, Executive Director of the Medicines Patent Pool, as the host for this year's Awards for Regulatory Excellence.

Opening the Ceremony, Greg said, "We should congratulate everyone who has been nominated for what they have achieved. As a first-time judge this year I'd also like to particularly applaud everyone who has made the shortlist. The quality of candidates was outstanding and you are *all* winners for getting this far."



Awards Working Party Chair Craig McCarthy presented Kirsty Cotton with her Award

HORIZON



The HORIZON Award is open to an individual with fewer than five years' experience, who has shown outstanding ability and promise.

This year the Award went to **Kirsty Cotton**, a Senior Regulatory Affairs Executive at TRAC Services. In just over two years Kirsty has become an excellent regulatory professional, competently managing multiple client commitments. Her 'can do' attitude and professional approach make her an asset to TRAC and the profession.

She is already a project lead for a key client, responsible for delivering a significant CMC project as well as managing the Patient Information Leaflet 'readability testing' service.



Judge Alastair Kent presented our tied winners with their Awards: Marta Parmar of Roche and Judge Chris Griffett on behalf of Florence Houn

INSPIRATION



INSPIRATION is aimed at senior regulatory professionals who have inspired others with their knowledge, or who have mentored those around them.

This year there were joint winners for the Inspiration Award: **Leyla Lister** and **Marta Parmar** of Roche, and **Florence Houn** of Celgene.

Marta and Leyla led a global cross-functional project to accelerate regulatory submission and approval timelines within emerging markets. They brought together different functions to deliver strategic and operational changes to their organisation. They were always positive, motivated and enthusiastic – truly leading by example!

Florence consistently questions the status quo and challenges her teams with new perspectives. She has used her leadership and mentoring skills to help colleagues right across the industry and has developed trusted relationships with health authorities while continuing to commit time and energy to important professional groups.



Michelle, Anna and Kate received their Awards from Miranda Pothiwala, representing Samarind as sponsor of this category

INNOVATION

samarindRMS
regulatory management software



The INNOVATION Award went to **Michelle Riddalls, Anna Nightingale and Kate Stockman** of Pfizer. **Samarind's Miranda Pothiwala** presented our winners with their Award, herself a previous winner and strong supporter of this category.

Seldom are there 'first-ers' in the world of regulatory affairs, but that's exactly what this team accomplished with Nexium Control in the UK! Their innovative strategy helped set a new regulatory precedent, improved access to an effective medicine, and widened consumer choice for those suffering from frequent heartburn.



Maureen Graham with Nicholas Edwards, Chairman of Kinapse and sponsor of this Award

FUTURES

kinapse



FUTURES acknowledges the role of regulatory scientists in realising the potential of cutting edge technology. The Futures Award was sponsored by Kinapse and presented by their Chairman **Nicholas Edwards** to **Maureen Graham**, Managing Director of Diamond BioPharm.

Maureen and her team at Diamond made a significant contribution to the successful marketing authorisation for Europe's first gene therapy product. The Glybera approval procedure has resulted in much discussion and may have helped with the proposal for future innovative regulatory pathways.



Professor Sam Salek presented the Award to Steve Slater on behalf of the Roche team



Valérie Codrons accepted her Award from Judge Glenn Carpenter



Angela Stokes received her Award from Judge Vincent Lawton

EDUCATION



The EDUCATION Award honours those who have helped shape and have made a significant contribution to the world of regulatory education and training.

The winners this year were **Detlef Hold, Nathalie Schultze and Elke Sims** of the Roche Global Regulatory Pipeline Programme. Accepting the Award on their behalf was Steve Slater, Senior Global Regulatory Leader at Roche.

The programme is an innovative way to accelerate and enhance the readiness of future global regulatory leaders and increase their level of competency. It aims to identify candidates through targeted, individualised, accelerated and intensive learning.

SUPPORT



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.

The Award was presented to **Valérie Codrons and the Quintiles RA Team**, based in Belgium. The team provided high-quality regulatory science, strategy and operational support for a very challenging indication area (which is a significant public health problem globally).

Their integrated support – working closely with the sponsor – has resulted in a pioneering approval. They demonstrated great teamwork and a creative regulatory approach.

CONTRIBUTION



The penultimate Award of the evening was CONTRIBUTION, rewarding experienced regulatory professionals who do an excellent job to provide the very best in regulatory professionalism.

The Award was given to **Angela Stokes** from Chiltern International. Angela is a highly-motivated regulatory professional with a strong scientific background in chemistry, pharmacology and toxicology.

She has more than 20 years of experience, gained both in contract research organisations and pharmaceutical companies. She is an excellent communicator at all levels and influential in regulatory affairs training and mentoring.

LIFETIME ACHIEVEMENT



This special Award celebrates the career of an individual who has committed themselves to furthering the cause of regulatory affairs, drug development and regulatory science.

The Lifetime Achievement Award was presented to **Dr June Raine**, who has strengthened public health protection for the benefit of all citizens in the European Union and beyond.

Having trained in general medicine at Oxford University, her interest in drug safety paved her way to a life-long career in medicines regulation spanning several critical and pivotal roles in assessment, management and strategic development within the UK national authority and European regulatory network.

As part of an EU collaboration June was instrumental in ensuring all EU citizens had wider access to medicines through co-chairing the EU Commission's project on 'Promoting good governance for non-prescription drugs.' She designed and led the first Better Regulation initiative in UK medicines regulation, subsequently endorsed by the European Commission.

June is a member of a senior management team which has transformed the MHRA into an international success, based on a strategic model that has since been adopted by regulatory authorities worldwide. She has made outstanding contributions towards the delivery of the world-class European Union pharmacovigilance system that we see today.

Her application of her cross-disciplinary knowledge and experience in medicine, pharmacy, regulation of medicines and public health protection through pharmacovigilance and risk-management of medicines has truly shaped the practice of regulatory affairs.



Dr June Raine receiving her Award from Dr Ian Hudson, Chief Executive of the MHRA

Congratulations to our graduates for 2015

The Awards celebration began with a formal recognition of the students who have achieved a TOPRA postgraduate qualification in the past year.

TOPRA has established an excellent reputation in regulatory education. Last year the MSc Regulatory Affairs passed its 25 year milestone, and this year sees the 10th anniversary of the formation of the Medical Technology course with our partners at Cranfield University.



Above (L to R): TOPRA Past-President Jonathan Trethowan, Tamsyn Frost, Christian Monnerjahn, Francesca Buttigieg, Jimmy Pang, Astrid Satler and TOPRA President-Elect Thomas Kühler

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A big thank you to our Sponsors!

TOPRA would like to say a huge thank you to our Awards sponsors for showing their support for the regulatory profession and for TOPRA's commitment to it. Without them the celebration could not take place!

Samarind has continued their generous support for the Innovation category this year. We are truly grateful to them for their commitment and encouragement for this category since our very first Awards event in 2010. Thank you also to Kinapse, who joined us as category sponsors of the Futures Award for 2015.

This year we were fortunate to welcome four companies as Champions of the Awards Programme. Roche and PPD have supported us in the past, continuing to show that they value the regulatory profession and care for good practice.

We also thank our new Champions for 2015: TRAC Services and Product Life Group, for joining this elite group and helping to make this evening possible.

