PRESS RELEASE

Sir Michael Rawlins delivers the first TOPRA Annual Lecture

28 November, 2012, London, UK

The inaugural TOPRA Annual Lecture took place ahead of this year's TOPRA Awards for Excellence in Regulatory Affairs at London's Radisson Blu Portman Square on 28 November.

Speaking to packed audience of healthcare regulatory affairs professionals from industry, consultancy, agency and patients’ groups, Sir Michael Rawlins, the chairman of NICE (National Institute for Health and Clinical Excellence), addressed the question 'Is the regulatory profession fit for the future?' to which he answered he didn’t know, but that that the profession would need to adapt to the rapidly changing regulatory environment and respond to healthcare innovation.

The audience had no need to be disappointed by Sir Michael's opening response to the question as he clearly set out the challenges which the pharmaceutical industry will face over the next decade. He then put the challenges into the historical context of the debate within science between the deductive approach, which tests a theory, and the inductive approach, which tests a pattern identified by observation. This set the groundwork for his message that regulators and industry have to re-evaluate how they test and use clinical data to support decisions on marketing authorisations and benefit-risk decisions.

Sir Michael argued for a major reappraisal of the hierarchy of evidence and the need for flexibility to use observational data, historical control studies and to introduce real-world studies. He also stressed the opportunities offered by the use of Bayesian statistics and the need for pilot projects to take forward adaptive licensing.

He concluded by stressing the need and the opportunity for the regulatory science
profession to seize and lead the debate – a challenge that the audience seemed willing to take on.

Thanking Sir Michael for his insightful lecture, Dr David Jefferys, Past President of TOPRA, said the lecture was ‘a timely wake up call for all engaged in medicines regulation that the profession would take forward’.

NOTES FOR EDITORS

The Organisation for Professionals in Regulatory Affairs (TOPRA)

TOPRA is the global organisation for Regulatory Affairs professionals and for those who have an interest in Regulatory Affairs in the healthcare sector. Current membership is drawn from around 50 countries and members worldwide are actively involved in delivering the services needed by busy regulatory specialists. Members are drawn from industry, the regulatory agencies and the consultancy community and work in all sectors including medical technologies, biotech, borderline products and pharmaceuticals.

The TOPRA Annual Lecture

The TOPRA Annual Lecture offers Regulatory Professionals an opportunity to hear a world-class authority reflect on the current environment for the regulatory profession and give their predictions for the future. Although the lecturers will present a personal perspective, they will offer an important ‘horizon scan’ to give attendees an insight into the challenges faced by the profession.

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