



THE ORGANISATION
FOR PROFESSIONALS IN
REGULATORY AFFAIRS

ANNUAL SYMPOSIUM 2010

[Better Access to Medicines in a Changing Regulatory Environment](#)

Monday 4th to Wednesday 6th October 2010

Hilton Hotel, Park Lane, London, UK

Organised in conjunction with

Medicines and Healthcare products Regulatory Agency (MHRA), UK



Working Party

- Alan Hunter – Consultant (Chair)
- Suzanne Lawrence - MHRA, UK
- June Raine – MHRA
- Ian Hudson – MHRA
- Hans Georg-Eichler – EMA
- Tony Humphreys – EMA
- Nuno Simoes – Infarmed, Portugal
- Margareth Jorvid – LSM Group, Sweden
- David Jefferys – Eisai
- Brenton E James – EU Consultant
- Caroline Baillif - Amgen
- Craig McCarthy – Campharm, France
- Helene Thybo - LEO Pharma A/S, Denmark
- Zubair Husain – Pfizer Ltd
- Beatrix Friedeberg – AstraZeneca
- Maria Arce Tomas – Norgine

From Special Interest (SPIN) groups:

Veterinary - Ray Harding, Cyton Biosciences

Med Devices – Neil Adams, BSI group

eRA – Philip Hall, Abbott Laboratories

CMC - Stuart Finnie, AstraZeneca

Biotechnology - Meg Leahey, Pfizer, Ireland

TOPRA N America – Carlos Langezaal, Eisai Inc, USA

| Monday 4th October 2010 | |
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| 09:30 | Registration and Exhibition |
| 10.30 | Welcome to 2010 Symposium |
| | Lynda Wight, <i>Executive Director, TOPRA</i> Alan Hunter, <i>Chair of Symposium working party</i> Kent Woods, <i>Chief Executive, Medicines and Healthcare products Regulatory Agency, (MHRA)</i> |
| SESSION 1: Improving Access - the Interface of Health Technology Assessment and the Regulatory Process | |
| Leader: Beatrix Friedeberg, AstraZeneca, UK | |
| <i>This session will provide an overview of current regulatory and HTA-related requirements and how these may best be addressed in drug development to ensure patients can access new medicines within their national health care systems. With the EMA and the European network for health technology assessment (EUNetHTA) having announced closer cooperation, and some Member States now piloting joint regulatory and HTA scientific advice, this is a highly relevant topic for today's regulatory professional.</i> | |
| Chairperson: Hans-Georg Eichler, Senior Medical Officer, EMA and Co-chair: Beatrix Friedeberg, Director Regulatory Policy and Intelligence, AstraZeneca | |
| 11.00 | Introduction |
| 11:10 | Access to new medicines – a view from the European Commission (EC) |
| | Jérôme Boehm - <i>Policy Officer - Health systems, Health and Consumers Directorate General, European Commission</i> |
| | <ul style="list-style-type: none"> • EC vision on the future of HTA cooperation in Europe • What does it mean for all stakeholders involved: industry, regulators and payers? |
| 11:30 | Collaboration between regulators and payers - could it facilitate drug development? |
| | Hans-Georg Eichler – <i>Senior Medical Officer, European Medicines Agency (EMA)</i> |
| | <ul style="list-style-type: none"> • How do the information needs of regulators and payers differ? • Where could regulators and payers collaborate? • What effect would this collaboration have on drug development? |
| 11:50 | Industry viewpoint - examples from the field of oncology |
| | Alan Barge - <i>VP and Head of Oncology and Infection, Drug Development, AstraZeneca, UK</i> |
| | <ul style="list-style-type: none"> • Understanding the changing scientific environment • Targeted drug development • Opportunities through market segmentation • Reward for innovation - what is the best approach? |
| 12:05 | Industry viewpoint - the UK environment |
| | Clare McGrath - <i>Senior Director HTA Policy, Europe/ROWD, Pfizer, UK,</i> |
| | <ul style="list-style-type: none"> • Understand the changing environment • Experience of joint scientific advice (with thoughts on MHRA/EMA/NICE) • Understand where there are challenges and where there may be opportunities. |
| 12:20 | Questions with this session's speakers plus invited panellist: |
| | Ian Hudson, <i>Director of Licensing, MHRA, UK</i> |
| | The speakers will take questions from the floor – this is your opportunity to explore the topic more fully. |
| 12.45 | Lunch |

Monday 4th October 2010

SESSION 2: Improving Access – using Scientific Advice and Early Access Schemes

Leader: Margareth Jorvid, LSM Group, Sweden and TOPRA Board Director

This session will cover Scientific Advice at European level at EMA but also from a National Agency and Industry perspective. It will discuss recent experiences of pilot Joint Scientific Advice including Health Technology Assessment (HTA) and how this might develop in the future. Is Parallel Scientific Advice between US and EU still alive?

Chairperson: Margareth Jorvid, LSM group, Sweden and TOPRA Board Director

14:00 **Introduction**

14:10 **Does Scientific Advice in Europe make a difference?**

Bruno Flamion - *Chair, Scientific Advice Working Party, EMA and University of Namur, Belgium*

- Scientific Advice in Europe
- Recent developments
- Future changes

14:30 **Scientific Advice from a National Agency perspective**

Bengt Ljungberg - *Head of Section Pharmacotherapy, MPA, Sweden*

- National Scientific Advice – how does it work?
- A report on a pilot of joint scientific advice including HTA
- Is HTA there to stay?

14:50 **Industry Experience of joint HTA and Regulatory Authority Scientific Advice**

Isabella Sanderfelt - *Head of Regulatory Affairs, Pfizer, Sweden*

- Differences in preparation
- How did it work?
- Future development – good or bad?

15:10 **Panel discussion with this session's speakers and invited panellist:**

Janice Soreth, *US FDA Liaison at EMA*

- Update on Parallel Scientific Advice (US/EU).
- Is EU approaching the US way of regular scientific advice during development?
- Is HTA here to stay?

The speakers will take questions from the floor – this is your opportunity to explore the topic more fully.

15.40 **Break**

Focus on the Medicines and Healthcare products Regulatory Agency (MHRA)

The role and priorities of the national competent authority now and in the future

In this session the MHRA will review and discuss the role that a national agency can play within the European health care system and they will touch upon some of the current and future challenges facing us such as access to medicines, risk management and how best to communicate in the healthcare arena.

16.10 **Contributors will include:**

Professor Kent Woods - *Chief Executive, MHRA*

Ian Hudson - *Director of Licensing, MHRA*

June Raine - *Director of Vigilance and Risk Management of Medicines, MHRA*

Simon Gregor - *Director of Communications, MHRA*

THE TOPRA ANNUAL REVIEW

17:20 **The TOPRA Review of the Year**

to
18:15 Paolo Biffignandi– *TOPRA President 2009/2010*
Including announcement of the 2010/11 Board

18:15 **Drinks Reception**– Delegates are cordially invited to a drinks reception in the exhibition hall.

to
19:30 After this you are free to explore London.

Tuesday 5th October 2010
Main Symposium

SESSION 3: Improving Access - through Clinical Trials Harmonisation

Leader: Caroline Baillif, Amgen, UK

The Clinical Trials Directive (CTD) was meant to streamline the approval of clinical trials across Europe but the reality has not lived up to this ideal. Several challenges remain that were highlighted in the outcome of the assessment of the functioning of the CTD by its main users. This session will explore how the European Commission has been reviewing the operation of the CTD and its current plan to address the issues raised, how the CTFG have responded to the need for improved harmonisation across the EU, and the position of the EMA and industry on the topic.

Chairperson: Sue Forda – Vice President, International Regulatory Affairs, Eli Lilly and Company, UK

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| 08:30 | Introduction |
| 08:35 | An Update from the European Commission |
| | Stefan Fuehring – <i>Unit SANCO C8- Pharmaceuticals European Commission – Health and Consumer's DG</i> |
| | <ul style="list-style-type: none"> • Assessment of the state of harmonisation • Action of Commission to improve the situation <ul style="list-style-type: none"> - Short/medium term: further strengthening cooperation between Commission, Authorities and Ethics Committees; guidelines - Medium/long term: Guidelines, Review of the Clinical Trials Directive • Main issues looked at in the Review |
| 08:55 | The HMA viewpoint |
| | Professor Kent Woods – <i>Chief Executive, Medicines and Healthcare products Regulatory Agency (MHRA), UK</i> |
| | <ul style="list-style-type: none"> • The role of National Competent Authorities • Cooperative action between member states on implementing the Clinical Trials Directive • The Voluntary Harmonization Procedure |
| 09:10 | Activities and latest developments at the European Medicines Agency in support of clinical trials |
| | Fergus Sweeney – <i>Head of Compliance and Inspection, EMA</i> |
| | <ul style="list-style-type: none"> • EMA activities and their interaction with the clinical trial process • Eudra databases and clinical trials (EudraCT and EudraVigilance Clinical Trials Module) • GCP and the Globalisation of clinical trials |
| 09:25 | An industry perspective on the CTD and what needs to be changed |
| | Mats Ericson – <i>Director Regulatory Affairs – Policy, Amgen, France</i> |
| | <ul style="list-style-type: none"> • EFPIA response to the Commission CTD consultation: • Clinical trial authorisations (including discussion on Centralised Procedure for CT) • CA and EC remits, ADR reporting, 3rd country trials |
| 09:40 | Panel discussion with this session's speakers |
| | The speakers will take questions from the floor – this is your opportunity to explore topics more fully. |
| 10:00 | Break |

| Tuesday 5th October 2010 | |
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| SESSION 4: Globalisation of Pharmaceutical Regulation – what do Agencies Discuss behind Closed Doors? | |
| Leader: Carlos Langezaal, North America Representative TOPRA Board and Chair of North America Leadership Team | |
| <i>In this session, the US FDA, EMA, EU National Health Authorities and the Japanese Health Authority procedures for sharing information will be presented. A panel discussion with session speakers and invited guest(s) will offer the opportunity to explore the topic more fully.</i> | |
| Chairperson : Carlos Langezaal – Director Regulatory Affairs, Eisai Inc.,USA | |
| 10:40 | Introduction |
| 10:50 | US FDA mechanisms for sharing information between regulators |
| | Janice Soreth - <i>US FDA Liaison at EMA</i> |
| 11:15 | EMA mechanisms for sharing information between health authorities |
| | Hilde Boone - <i>European Medicines Agency Liaison Official at the US FDA</i> |
| 11:40 | Setting up the Office of International Programs within the Japanese PMDA and the PMDA mechanisms for sharing information between health authorities |
| | Yoshikazu Hayashi - <i>International Liaison Officer responsible for EU relations, PMDA, Japan -</i> |
| 12:05 | Panel discussion with this session's speakers |
| | Questions from the floor to the speakers – this is your opportunity to explore these issues more fully. |
| 12:15 | Lunch |

| Tuesday 5th October 2010 | |
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| SESSION 5: From Risk Management to Benefit/Risk Management | |
| Leader: Craig McCarthy, Campharm, France | |
| <i>This session will cover the challenges in the changing regulatory environment as we move from an emphasis on risk management to benefit-risk management and the need for regulatory affairs professionals to update their knowledge and take a leadership role in this important changing regulatory area.</i> | |
| Chairperson: June Raine - Director of Vigilance and Risk Management of Medicines, MHRA, UK | |
| 13.10 | Introduction to the challenges in the changing regulatory environment in the coming years following the introduction of the EU strengthened pharmacovigilance legislation and the increasing importance of benefit-risk management and communication in this changing area of regulatory affairs. |
| | June Raine - <i>Director of Vigilance and Risk Management of Medicines, MHRA, UK</i> |
| 13.30 | Planning for the strengthened EU pharmacovigilance regulatory system, focussing on an industry approach to effectively organising project teams |
| | Craig Hartford - <i>VP, Safety Surveillance and Risk Management , Worldwide Safety Strategy , Pfizer Medical</i> |
| | <ul style="list-style-type: none"> • How to effect signal detection/risk management activities • Governing approval of Benefit-Risk decisions: Roles/Responsibilities • Managing global product Benefit-Risk assessment |
| 13:50 | Modelling to support Benefit/Risk assessment – Will it enhance our capability and improve transparency? |
| | Lawrence Phillips, Benefit-Risk Project, IMI-PROTECT project, Human Unit, European Medicines Agency (EMA) |
| | <ul style="list-style-type: none"> • What do we mean by 'benefit' and 'risk'? The new EMA terminology • What we, and others, have learned from applying different models to several drugs and one vaccine • How can this learning be applied in industry and regulation, and to what effect? |
| 14:10 | Benefit-Risk communication strategies |
| | Rafe Suvarna – <i>Unit Manager, Vigilance and Risk Management of Medicines, MHRA, UK</i> |
| 14:30 | Panel discussion with this session's speakers |
| | The speakers will take questions from the floor – this is your opportunity to ask those questions on pharmacovigilance and the growing importance of benefit/risk management and communication in regulatory affairs |
| 14:40 | Break |

Tuesday 5th October 2010

SESSION 6: The Intellectual Property Minefield - do SPCs, Data Exclusivity Provisions and Patents Affect Access?

Leader: Helene Thybo, Leo Pharma, Denmark

This session will look at the various aspects of intellectual property rights that are of importance to regulatory strategies both during drug development but also when looking for developments to already approved products. The speakers will provide a better understanding of the concepts but also discuss some of the latest developments and trends..

Chairperson: Helene Thybo, Corporate Regulatory Intelligence Specialist, Regulatory Affairs and Safety, Leo Pharma, Denmark

15:00 **Introduction**

15:10 **Patents and related issues**

Tony Rollins - *Managing Counsel, European Patents, Merck & Co Inc. UK*

- Overview of Patents and Supplementary Patent Certificates
- “Zero term” issues
- SPC extensions in accordance with the Paediatric Regulation

15:30 **Regulatory aspects (8+2+1)**

James Ritchie - *GlaxoSmithKline, UK*

- Overview of EU Data and Marketing Exclusivity
- Strategies to optimise protection
- Experience to date

15:50 **Intellectual property and patient rights**

Aginus Kalis – *Executive Director, College ter Beoordeling van Geneesmiddelen, Medicines Evaluation Board, the Netherlands*

- The basic principles
- The tension between transparency and IP rights
- Is there a need for a harmonised approach?

16:10 **Panel discussion with this session’s speakers**

The speakers will take questions from the floor – this is your opportunity to explore the topics more fully.

16:30 **Close of session**

18:30 **Drinks Reception, Gala Dinner and the first TOPRA Regulatory Affairs AWARDS ceremony**

| Wednesday 6th October 2010 | |
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| SESSION 7: Improving Access – how can all Stakeholders make a Contribution? | |
| Leader: Nuno Simoes, Infarmed, Portugal | |
| <i>This session will look at the important contribution of all stakeholders, specifically patients, healthcare professionals, academia, pharmaceutical industry, EU institutions and regulatory agencies, in achieving better health outcomes and improved access. The session will discuss the input of such stakeholders to the regulatory decision-making process. The experiences of interaction between stakeholders and working parties at national and EU level in strengthening transparency and public trust in the EU regulatory process will be discussed.</i> | |
| 08.30 | Introduction |
| How patients, doctors and academia can contribute to improving the regulatory process | |
| Chairperson: Nuno Simoes, Advisor to the executive board of INFARMED (Portuguese National Authority of Medicines and Health Products), Portugal | |
| 08:50 | Mary Baker, MBE - <i>President of the European Federation of Neurological Associations- (EFNA)</i> |
| 09:10 | Michael Wilks - <i>past President of the Standing Committee of European Doctors</i> |
| 09:30 | Professor Rosalind Smyth - <i>Head of School of Reproductive & Developmental Medicine, University of Liverpool Institute of Child Health, Alder Hey Children's NHS Foundation Trust, UK</i> |
| 09:50 | Questions |
| 10.00 | Break |
| The contribution of the industry | |
| Chairperson: Professor Stuart Walker, Founder, CMR International Institute for Regulatory Science | |
| 10:30 | Andrea Rappagliosi - <i>Vice President European Government Affairs & Head of Brussels Office, GlaxoSmithKline, Belgium</i> |
| 10:50 | Stuart Dollow – <i>Chief Development Officer, Norgine, UK</i> |
| 11:10 | Neil Armstrong - <i>C.E.O. - MeddiQuest Limited, UK</i> |
| 11:30 | Questions |
| 12.00 | Lunch |
| The institutional perspective | |
| Chairperson: Professor Trevor Jones CBE, Director Allergan Inc | |
| <i>This session will look at how the credibility and transparency of the European Medicines Regulatory System (ERMS) is supported by all stakeholders and will consider the HMA Strategy paper, the EMA Road map, the Parliamentary perspective, the pharma package and draw on the US FDA experience of collaboration with stakeholders</i> | |
| 13:00 | Heads of Medicines Agency (HMA) |
| | Kristin Raudsepp - <i>Director General, State Agency of Medicines, Estonia</i> <ul style="list-style-type: none"> The contribution of national agencies and highlights on the HMA Strategy Paper (2011-2015) |
| 13:20 | European Medicines Agency (EMA) |
| | Noël Wathion - <i>Head of Unit Patient Health Protection, EMA</i> <ul style="list-style-type: none"> Highlights on the EMA Road Map (2011-2015) |
| 13:40 | European Parliament |
| | Marisa Matias - <i>MEP, Portugal</i> <ul style="list-style-type: none"> The European Parliament perspective |
| 14:00 | Access to medicines and risk-sharing agreements in the Italian experience |
| | Professor Rasi - <i>Chief Executive, Agenzia Italiana del Farmaco, Italy</i> <ul style="list-style-type: none"> The Italian viewpoint |
| 14:20 | U.S. Food and Drug Administration (FDA) |
| | Murray Lumpkin - <i>Deputy Commissioner for International Programs, Office of the Commissioner, U.S. Food and Drug Administration (FDA), USA</i> <ul style="list-style-type: none"> The FDA experience of collaborating with stakeholders |
| 14:40 | Panel discussion with today's session speakers |
| 15:10 | Closing Remarks for the 2010 Symposium Professor Kent Woods- <i>Chief Executive, MHRA, UK</i> |
| 15:20 | Zubair Hussain – <i>TOPRA President 2010/2011, Pfizer, UK</i> |
| | The 2011 symposium – welcome from Professor Rasi, <i>Chief Executive, Agenzia Italiana del Farmaco, Italy</i> |
| 15:30 | Close of symposium |

| Parallel Sessions During the Symposium | |
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| Monday 4th October | |
| Electronic Submissions - Are you Ready? Are we Ready? | |
| Leader: Philip Hall, Chair of TOPRA eRA SPIN (Special Interest) Group, Abbott Laboratories, UK | |
| Electronic working in Regulatory Affairs. | |
| Chairpersons: | |
| Alison Davis - Director, Information Management Division, MHRA, UK | |
| and | |
| Philip Hall - Chair of TOPRA eRA SPIN, Abbott Laboratories, UK | |
| 13.30 | Introduction Philip Hall - Chair of TOPRA eRA SPIN, Abbott Laboratories, UK |
| 13.40 | Official Status on Acceptance of Electronic Submissions |
| | Human - Miguel Bley - Head of European Affairs, Afssaps, France Veterinary - speaker TBA |
| 14.00 | Agency experiences of receipt of electronic submissions (human, vet) |
| | Karin Grondahl – MPA, Sweden and Steve Dean – Chief Executive, Veterinary Medicines Directorate, UK |
| 14.20 | EMA experience of receipt of eCTDs for Centralised Procedure |
| | Hans-Georg Wagner - Head of Information and Communications Technology, EMA |
| 14.45 | Industry view |
| | 1. Nees - how easy to produce, company benefits? |
| | 2. eCTD - how easy to produce, company benefits? |
| | 3. Main Differences, Advantages |
| | Alastair Nixon – Director, Submission Publishing, GlaxoSmithKline, UK |
| 15.05 | Agency Presentation |
| | Gateway to Common Electronic Repository - |
| | When will it be ready? How will it work? |
| | EMA Gateway? |
| | Rob de Haan - Deputy Director, Medicines Evaluation Board, The Netherlands |
| 15.20 | Open forum to discuss the need for mandating electronic submissions What formats? |
| | When? Harmonize requirements |
| | Alison Davis - Director, Information Management Division, MHRA, UK |
| 15.50 | Break and close of this session |

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| Tuesday 5th October | |
| The New Variation Regulation: Regulatory Agency and Industry Practical Experiences Nine Months On | |
| Leader: Stuart Finnie, Chair of TOPRA CMC SPIN Group, AstraZeneca, UK | |
| <i>This session will review practical aspects of the implementation of the new variations legislation and guidance. Short presentations will be followed by an interactive question and answer session</i> | |
| Chairperson: | |
| Stuart Finnie, AstraZeneca, UK, chair of TOPRA CMC SPIN group | |
| 08:30 | Introduction |
| 08:35 | The new variation regulation – industry experiences nine months on |
| | Chris Dafforn - <i>Regulatory Affairs Director, CMC Regulatory Compliance, Global Quality Operations, AstraZeneca, UK</i> |
| 08:55 | The new variation regulation - Agency experiences nine months on |
| | The MHRA Perspective |
| | Krystyna Fielden - <i>Manager, PLAT 2 (Product Lifecycle Assessment Team), MHRA, UK</i> |
| | The EMA Perspective |
| | Sonia Ribeiro – <i>Regulatory Affairs Adviser, EMA</i> |
| 09:30 | Interactive session: Discussion and Q&A with a panel from regulatory agencies and industry |
| | Case Studies – Discussion of anonymised rejection letters |
| | Question and answer session |
| 10.00 | Break and close of this session |

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| Tuesday 5th October | |
| Current Challenges with Biosimilar Monoclonal Antibodies | |
| Leader: Meg Leahey, Pfizer, Ireland | |
| <i>As technology advances and regulations evolve, the era of Biosimilar Mabs has arrived to our industry. Due to the complexities of these products, there are many challenges that span across non-clinical, clinical and quality aspects. This session will explore and discuss these challenges in a tripartite approach with speakers from EMEA and MHRA.</i> | |
| Chairperson: | |
| Cecil Nick – <i>Vice president (biotechnology), Parexel, UK</i> | |
| 13.10 | Introduction and Overview of Biosimilar Monoclonal Antibodies |
| | Cecil Nick – <i>Vice president (biotechnology), Parexel, UK</i> |
| 13.15 | Perspectives and Challenges in the global Regulation of Biosimilars |
| | Falk Ehmann – <i>Scientific Secretariat of the 'Similar Biological (Biosimilar) Medicinal Products Working Party' (BMWP), Safety and Efficacy Sector, European Medicines Agency</i> |
| | <ul style="list-style-type: none"> Guidelines |
| 13.35 | Quality Considerations and Challenges |
| | Anne Cook - <i>Senior Quality Assessor, MHRA, UK</i> |
| | <ul style="list-style-type: none"> How effective are physico-chemical methods in detecting meaningful differences in structure and microheterogeneity? To what extent are differences in microheterogeneity acceptable? Can biosimilarity be achieved using different expression systems? Future Challenges? |
| 13.55 | Clinical Considerations and Challenges |
| | Marie Bielsky - <i>Senior Medical Assessor, MHRA, UK</i> |
| | <ul style="list-style-type: none"> To what extent does non clinical testing add informative value? Can comprehensive orthogonal biological testing be used to minimise supporting clinical data? What is the importance and feasibility of PK/PD studies? To what extent can surrogate end points replace accepted clinical end points Extrapolation of clinical data from one or some indications or populations to all others approved for the reference product? Future Challenges? |
| 14.15 | Panel discussion which will include this sessions speakers plus an invited Industry representative. |
| 14.40 | Close of session |

| Tuesday 5th October | |
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| Advanced Therapies | |
| Leader: Meg Leahey, Chair of TOPRA Biotechnology SPIN, Pfizer, Ireland | |
| <i>Advanced Therapy Medicinal Products (ATMPs) are ground breaking medicines based on gene therapy, somatic cell therapy or tissue engineering. This session will provide the regulatory professional with knowledge and awareness of these cutting edge products</i> | |
| Chairperson: | |
| Alison Wilson - <i>Principal Consultant, Cell Data Services, UK</i> | |
| 15.00 | Introduction |
| | Alison Wilson - <i>Principal Consultant, Celldata Services, UK</i> |
| | <ul style="list-style-type: none"> • Brief introduction to ATMPs • Legislative background |
| 15.05 | Overview of advanced therapy medicinal products |
| | Sergio Fraccia - <i>Regulatory Affairs Manager, Molmed, Italy</i> |
| | <ul style="list-style-type: none"> • Overview of ATMP Regulation • Key issues and concerns for industry • Guidelines in preparation – what does industry need? |
| 15.25 | A Regulatory Agency perspective |
| | Gopalan Narayanan - <i>Expert Medical Assessor, MHRA, UK and UK CAT member at EMA</i> |
| | <ul style="list-style-type: none"> • Role of the CAT in ATMP procedures – classification, certification and MAA assessment • Issues and themes arising in Scientific Advice procedures • Clinical development – is there a possibility of shifting the balance towards post-marketing commitments? |
| 15.50 | The future of Advanced Therapies |
| | Speaker TBA |
| | <ul style="list-style-type: none"> • Today's cutting edge technologies • The next 5 -10 years – what is really possible? • How regulators can facilitate the development of safe and effective new therapies |
| 16.15 | Panel discussion |
| Finish at 16.30 | |

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| SME Day | |
| Monday 4th October | |
| Regulatory Challenges and Support for SME companies | |
| Leader: Margareth Jorvid, LSM group, Sweden and TOPRA Board Director | |
| <i>This special one day meeting for Small and Medium sized Enterprises (SME) starts with a session in the morning devoted to SMEs where you will hear from the EMA SME office and the experiences of a UK SME followed by a panel session. Following this first SME session, you will be able to take part in the first day of the main TOPRA Annual Symposium which opens later on the Monday morning</i> | |
| Chairperson: Margareth Jorvid, LSM group, Sweden and TOPRA Board Director | |
| Registration from 8.30 | |
| 09.00 | The SME Office at EMA |
| | Melanie Carr - <i>Head of SME Office, EMA</i> |
| | <ul style="list-style-type: none"> • Activities of the Agency's SME Office • Support given to SMEs • Experience of EMA Scientific Advice process and Centralised Procedure |
| 09:30 | UK SME experiences |
| | Helen Shaw - <i>Proveca, UK</i> |
| | <ul style="list-style-type: none"> • SME challenges • Practical experience of scientific advice • Experience of the approval procedure |
| 10:00 | Panel Discussion with this session's speakers |
| | The speakers will take questions from the floor – this is your opportunity to explore this topic more fully |
| 10:15 | Close of this session and join Day 1 of main symposium |