



THE ORGANISATION  
FOR PROFESSIONALS IN  
REGULATORY AFFAIRS

# **ANNUAL SYMPOSIUM 2009**

## **European Regulatory Affairs in a Global Environment**

**Wednesday 7<sup>th</sup> October to Friday 9<sup>th</sup> October 2009**

**Clarion Hotel, – Ringvägen, Stockholm, Sweden**

**Organised in conjunction with  
Swedish Medical Products Agency (MPA)**

**Working Party**

Margareth Jorvid – LSM Group, Sweden (chair)

Lena Björk - MPA, Sweden

Ursula Forner - (communication director), MPA  
Sweden

Henrik Holst - (Veterinary), MPA, Sweden

Lennart Philipson - (Medical Devices), MPA,  
Sweden

Tony Humphreys - EMEA

Patrizia Nestby – PAREXEL Consulting, UK

Brenton E James – EU Consultant, UK

Caroline Baillif - AMGEN, UK

Beatrice Oberlé-Rolle - NobelBiocare, Switzerland

Vera Franzén – SentoClone AB, Sweden

Åsa Holmgren - Orexo AB, Sweden

Paolo Biffignandi - VI.REL Pharma S.a.s, Italy, EU  
Vigilance Ltd, UK

Helene Thybo - LEO Pharma A/S, Denmark

From SPIN groups:

Vet - Ray Harding, Cyton Biosciences, UK

Med Devices – Neil Adams, BSI group, UK

eRA - Peter James, Dao-eRA Ltd, UK

CMC - Aine Kane, Pfizer Ltd, UK

TOPRA N Amer – Susanne Dorn, Halozyme  
Therapeutics, USA

AAPS - Sharon Pichon, AAPS, USA

Footnotes:

AAPS = American Association of Pharmaceutical Scientists

<b>Wednesday 7<sup>th</sup> October 2009</b>	
11:30	<b>Registration, Lunch and Exhibition</b>
12:30	<b>Welcome from Lynda Wight, Executive Director, TOPRA</b>
12:35	<b>Welcome from Christina Åkerman, Director General, MPA, Sweden</b>
12:40	<b>Welcome to Sweden and introduction to the theme for the 2009 symposium by Margareth Jorvid, Chair of Symposium Working Party, Senior Partner, LSM Group, Sweden</b>
<b>SESSION 1: Best practice on the use of Centralised Procedure for Marketing Authorisation in the European Union</b>	
<p><i>This session will provide critical and practical success factors for obtaining marketing authorisation in the European Union; the emphasis will be on innovative medicinal products going through the Centralised Procedure. The number of applications being rejected has generally been considerably high. Well-acknowledged speakers from industry and regulatory authorities will share their practical hands-on experiences, illustrated by case studies and examples, on how to use the Centralised Procedure in the most optimal way, to ensure that the medicinal product is being approved in the shortest time possible and with an optimal Summary of Product Characteristics. A practical comparison will also be drawn between the EMEA procedure and the marketing license procedure as applied by the Food and Drug Administration (FDA) in the United States of America. For symposium delegates, this session will be a master class in the use of Marketing Authorisation procedures. Rather than focusing on the issues associated with the procedures themselves, practical recommendations on how to best deal with these issues will be offered.</i></p>	
<p><b>Chairpersons:</b></p> <p style="padding-left: 40px;">Tomas Salmonson – <i>Medical Products Agency (MPA), Sweden, and Vice Chair of Committee for Medicinal Products for Human Use (CHMP)</i></p> <p style="padding-left: 40px;">Patrizia Nestby – <i>Senior Consultant, PAREXEL Consulting, United Kingdom</i></p>	
12:50	<b>Introduction by Patrizia Nestby</b>
12:55	<b>Practical experience and best practice – the CHMP Rapporteur’s view</b>
	<i>Steffen Thirstrup – Chief Medical Officer, Danish Medicines Agency, Denmark, and Member of CHMP</i>
	<ul style="list-style-type: none"> <li>• The CHMP review process at a glance</li> <li>• Applicants interaction with the Rapporteurs: what to do and don’t do</li> <li>• Applicants interaction with other interested parties during the review: what to do and don’t do</li> </ul>
13:15	<b>Success and risk factors in the Centralised Procedure; former regulator viewpoint</b>
	<i>Markku Toivonen - Scientific Director, NDA Advisory Board, NDA Regulatory Science Ltd</i>
	<ul style="list-style-type: none"> <li>• Interactions during medicinal product development</li> </ul>

	<ul style="list-style-type: none"> <li>• Scientific Advice – adherence and non-adherence</li> <li>• Interaction with EMEA, Rapporteur/Co-rapporteur and CHMP</li> <li>• Major Objection response strategies</li> <li>• Oral Explanation – preparation and conduct</li> <li>• Re-examination – Case study</li> </ul>
13:35	<b>A global perspective on marketing authorisation procedures - EMEA/FDA differences and how these affect innovation</b>
	Carrol Marcus – <i>Vice President, PAREXEL Consulting, United Kingdom</i>
	<ul style="list-style-type: none"> <li>• Analysis of outcomes of EMEA and FDA regulatory system for marketing approval</li> <li>• Discussion on similarities and differences between EU and FDA and how these affect innovation</li> <li>• Considerations of overall regulatory strategy</li> </ul>
	<b>Panel discussion with this sessions speakers - led by Tomas Salmonson</b>
13:55	The speakers will take questions from the floor – this is your opportunity to explore topics more fully on issues of interest to you.
14:25	Tea and Coffee

## Wednesday 7<sup>th</sup> October 2009

### SESSION 2: Advanced Therapy Medicinal Products /CAT

*This session will review the experience of the implementation of the Regulation on advanced therapy medicinal products which applies from December 30, 2008. Representatives of the European Medicines Agency (EMA), the Committee for Advanced Therapies (CAT) and industry will share their experience with the delegates.*

**Chairpersons:**

Vera Franzén –, *Regulatory Affairs Director, SentoClone AB, Sweden*

Lennart Åkerblom – *Head of section, Medical Products Agency (MPA), Sweden and member of CAT*

14:55	<b>Introduction by the Chair</b>
15:00	<b>Implementation of ATMP Regulation and establishment of CAT</b>
	Patrick Celis - <i>Scientific Administrator, CAT secretariat, Post-Authorisation Unit, EMA</i>
	<ul style="list-style-type: none"> <li>• Implementation activities at EMA in 2008 and 2009</li> <li>• Establishment of CAT: membership, new tasks</li> <li>• Experience of first half-year operation of the CAT</li> </ul>
15:20	<b>The CAT and challenges with Advanced Therapies</b>
	Christian Schneider - <i>Head, Division EU-Cooperation/Microbiology, Paul-Ehrlich-Institut, member of the CHMP and Chair of the CAT, Germany</i>
	<ul style="list-style-type: none"> <li>• ATMPs are different</li> <li>• Challenges with ATMPs</li> <li>• The CAT and the CHMP</li> </ul>
15:40	<b>Industry implications</b>
	Wilfried Dalemans – <i>Vice President, Regulatory Affairs and Corporate Quality, TiGenix, Belgium</i>

	<ul style="list-style-type: none"> <li>• Differences between developing a classical drug product, a biological, and an ATMP</li> <li>• Process validation challenges for autologous products</li> <li>• Relevant non-clinical studies</li> <li>• Clinical studies expectations and challenges</li> </ul>
	<b>Panel Discussion</b> Speakers plus invited panellist Wing Cheng, <i>MPA, Sweden</i>
16:00	The speakers will take questions from the floor – this is your opportunity to explore topics more fully on issues of interest to you.
16:30	Short comfort break

<b>Medical Products Agency - Sweden</b>	
16.45 – 17.30	<b>An introduction to the activities of the Swedish Medical Products Agency (MPA)</b>
	First 12-months at the MPA – reviewed by Christina Åkerman, Director General, MPA, Sweden

<b>TOPRA ANNUAL MEETING</b>	
17:30 to 18:15	<b>The TOPRA Review of the Year:</b> Alan Hunter – <i>TOPRA President 2008/2009</i>
18:15 to 19:30	<b>Drinks Reception</b> – Delegates are cordially invited to a drinks reception in the exhibition hall. After this you are free to explore the delights of Stockholm

ON THIS SECOND DAY, 8<sup>TH</sup> OCTOBER, TWO PARALLEL SYMPOSIA WILL RUN: 4th VETERINARY MEDICINES SYMPOSIUM AND 4th MEDICAL DEVICES SYMPOSIUM – see separate programmes for these

<b>Thursday 8<sup>th</sup> October 2009 Main Symposium</b>	
<b>SESSION 3: Drug-Device Combination Products</b> <i>THIS SESSION IS HELD JOINTLY BETWEEN THE MAIN SYMPOSIUM AND MEDICAL DEVICES SYMPOSIUM</i>	
<i>Combination products are an increasing regulatory challenge to industry and regulators. Drugs and device are regulated differently and depending on classification of a combination product the process for market access will be different. This session will help the delegate to understand different terminology used, different procedures and how to successfully manage the combination product to market. Differences between Europe and US will also be discussed.</i>	
<b>Chairpersons</b>	Margareth Jorvid – Senior Partner, <i>LSM group, Sweden</i>  Ann O'Connor – Director, <i>Human Products Authorisation and Registration, Irish Medicines Board (IMB), Ireland</i>
08:30	<b>Introduction by the chairs</b>
08.35	<b>Combination products in Europe</b>
	Ann O'Connor – Director, <i>Human Products Authorisation and Registration, Irish Medicines Board (IMB), Ireland</i>
	<ul style="list-style-type: none"> <li>• Drug or Device</li> <li>• Ancillary action</li> <li>• Consultation procedure / dossier requirements</li> <li>• Competent Authority perspective</li> </ul>
08:55	<b>Notified Body</b>
	Gert Bos - <i>Head of clinical and regulatory affairs, BSI, UK</i>
	<ul style="list-style-type: none"> <li>• Notified Body role</li> <li>• Consultation procedure</li> <li>• Working with different Competent Authorities</li> </ul>
09:15	<b>Combination products in US</b>
	Margareth Jorvid – Senior Partner, <i>LSM group, Sweden</i>
	<ul style="list-style-type: none"> <li>• Office of Combination Products (OCP)</li> <li>• Request for Designation (RFD) and Primary Mode of Action (PMOA)</li> <li>• Lead center review</li> <li>• GMP/QSR</li> </ul>
09:35	<b>Panel Discussion</b> with this sessions speakers plus invited panellists:  Lennart Philipson, <i>Scientific Director Medical Devices, MPA, Sweden</i> and Janice Soreth, <i>Deputy Director, Europe/US FDA and Liaison to EMEA</i>
	The speakers will take questions from the floor – this is your opportunity to explore topics more fully on issues of interest to you.
10:00	<b>Coffee and Tea</b>



**Thursday 8<sup>th</sup> October 2009**

**SESSION 4: Pharmacovigilance: Data Entry or Data Value: a Hamlet monologue?**

*This session will aim to discuss some of the regulatory paradigms of pharmacovigilance (Phv), compared to its real value for public health. The increased burden to collect, report, and enter data into national databases and Eudra Vigilance poses the question of the real value of these efforts.*

*Is compliance with regulations enough to protect public health? What can be done to ensure a safer use of medicines by all parties involved? How other learned actors on the Phv stage can play a role together with regulators and industry? What about the cost/benefit analysis of Phv and its real feedback for the citizens?*

*And, is the industry getting a better knowledge of the risk associated with their products or are they just making some academic risk management exercises?*

**Chairpersons:**

Paolo Biffignandi – *CEO, VI.REL Pharma S.a.s, Italy, EU Vigilance Ltd, UK and TOPRA President 2009/2010*

Ingemar Persson – *Co-opted member of CHMP and Senior Assessor, unit of Pharmacovigilance, Medical Products Agency, Sweden*

10:45	<b>Introduction by the Chair</b>
10:50	<b>European Pharmacovigilance system</b> Jan Petracek – <i>Risk Management Team, EMEA</i>
11:10	<b>How Industry feels about Pharmacovigilance</b> Sarah Daniels - <i>Senior Partner, TranScrip Partners LLP, UK</i>
	<ul style="list-style-type: none"> <li>• Current challenges with Pharmacovigilance regulation</li> <li>• A brief look at the regulatory response to recent Drug Safety issues that potentially impact public health e.g. Vioxx, Tegenero etc</li> <li>• What this means for the Pharmaceutical Industry eg in terms of increasing regulations, increased scrutiny, cost of drug development etc</li> <li>• Does this translate into improved public health?</li> </ul>
11:30	<b>Pharmacovigilance - daily practise in pharmacy in Europe for the best of the patient</b> Thony Björk - <i>President PGEU (Pharmaceutical Group of the European Union), Vice President, Apoteket AB, International affairs, Sweden</i>
	<ul style="list-style-type: none"> <li>• PV data in pharmacy, how to collect and use?</li> <li>• What can be improved for the best of the patient?</li> <li>• Legal framework for pharmacists</li> </ul>
11:45	<b>The Role of Physicians and the Feedback to Patients</b> Vincenzo Costigliola - <i>President European Medical Association, Belgium</i>
	<ul style="list-style-type: none"> <li>• Role and importance of doctors in post-marketing activities</li> <li>• Re-thinking of the existing system</li> <li>• The importance of teaching pharmacovigilance</li> </ul>

12:00	<b>Panel Discussion- with this sessions speakers plus invited panellist:</b> Truus Janse-de Hoog, <i>Chair of CMD(h), MEB, Netherlands.</i>
	Questions from the floor to the speakers – this is your opportunity to explore more fully issues of interest to you
12:30	<b>Lunch</b>

<b>Thursday 8<sup>th</sup> October 2009</b>	
<b>SESSION 5: Paediatrics</b>	
<p><i>Paediatric Regulation, operational for more than 2 years, this session will look into the overall experiences gained having the paediatric regulation in place for over 2 yrs. Special consideration will be given to the compliance check experiences both from regulators and the industry perspective. In addition the objective and the organisation of the implemented structure of the EU network will be covered over two year experience with the EU pediatric regulation - a success story (?)</i></p>	
<p><b>Chairpersons:</b></p> <p style="padding-left: 40px;">Daniel Brasseur – <i>Chair of PDCO and Belgian Federal Agency for Medicines and Health Products</i></p> <p style="padding-left: 40px;">Beatrice Oberlé-Rolle – <i>Head of Regulatory Affairs, NobelBiocare, Switzerland</i></p>	
14:00	<b>Introduction by chairs</b>
14:10	<b>Global collaboration</b>
	Agnes Saint Raymond – <i>Head of Sector, EMEA</i>
	<ul style="list-style-type: none"> <li>• How can global regulatory acceptance on paediatric plans be ensured?</li> <li>• Frequency of interaction with FDA (others?), discussion topics decision</li> <li>• Involvement of PDCO members within global setup</li> <li>• What are the biggest deficiencies in global applications?</li> </ul>
14:30	<b>Industry Experience - SME</b>
	Annelie Skagerlind – <i>Director Regulatory Affairs, Medivir, Sweden</i>
	<ul style="list-style-type: none"> <li>• 2yr pediatric regulation - can SMEs cope with the requirements</li> <li>• Can any specific issues for SMEs be identified</li> <li>• Interaction with EMEA and getting up to date information on policies</li> <li>• Has the regulation fulfilled its objective?</li> </ul>
14:50	<b>Industry Experience - big Pharma</b>
	Kerstin Franzén- <i>Sr Director Worldwide Regulatory Policy &amp; Intelligence, Pfizer, Sweden</i>
	<ul style="list-style-type: none"> <li>• Experience with compliance checks, is reward achievable?</li> <li>• PIP Opinions/Decisions and national local EC acceptance</li> <li>• Global paediatric development - how is the reality?</li> <li>• Articles 45 and 46</li> </ul>
15:10	<b>Panel Discussion with this sessions speakers plus invited panellist,</b> Truus Janse-de Hoog, <i>Chair of CMD(h), MEB, Netherlands</i>
	The speakers will take questions from the floor – this is your opportunity to explore topics more fully on issues of interest to you.
15:30	<b>Afternoon Tea</b>

## Thursday 8<sup>th</sup> October 2009

### SESSION 6: Pharmaceutical Clinical Trials in the Global Environment

*This session will look at the challenges posed by the conduct of global clinical trials, notably in relation to setting up the right regulatory organisation in support of such activity. The place of Europe within this challenging global environment will be assessed. Initiatives from EMEA in reaching a common understanding and framework for ethical and scientific standards, achieving a strong regulatory and ethical framework in all countries where clinical trials are conducted, assistance through sharing of expertise and capacity building, increase the number of third country GCP inspections and the need to improve the international collaboration on GCP inspections will be reviewed.*

*Finally a presentation of the actions from the HMA to ensure the European Union remains competitive in the conduct of clinical trials will be given including a status report on the voluntary harmonisation procedure and an overview of the latest activities from the CTFG.*

#### Chairpersons:

Hartmut Krafft - *Referatsleiter Klinische Prüfungen*  
*Head, Section Clinical Trials, Paul Ehrlich Institut, Germany and chair CTFG*

Caroline Baillif – *Senior Manager Regulatory Affairs, AMGEN, UK*

16:00	<b>Introduction by the chairs</b>
16:05	<b>Global clinical trial – review of organisational set-up and regulatory challenges</b>
	<i>Caroline Baillif - Senior Manager Regulatory Affairs, Amgen Ltd, UK</i>
	<ul style="list-style-type: none"> <li>• How are regulatory organizations structured to support the conduct of global clinical trials including emergent countries?</li> <li>• What are the challenges from a regulatory perspective that arise from the conduct of such global clinical trials (Regulatory Affairs documentation, importation, quality, etc)?</li> <li>• How can regulatory systems be optimized for that purpose and ensure success?</li> <li>• How can the EU package be used in these regions?</li> </ul>
16:25	<b>International GCP Inspections- EMEA Perspective</b>
	<i>Ana Rodriguez - Scientific Administrator - Inspection Sector - EMEA</i>
	<ul style="list-style-type: none"> <li>• Regulatory Framework in EU</li> <li>• EU GCP inspections: GCP inspection in EU versus third country inspections</li> <li>• The international context:               <ul style="list-style-type: none"> <li>- Review of activities of the Ad Hoc Working Group on third country clinical trials: EMEA strategy and Wok Plan</li> <li>- Review of EMEA GCP collaboration initiatives (WHO, 3rd countries)</li> </ul> </li> </ul>
16:45	<b>Review of the recent initiatives within the EU model for Clinical Trials</b>
	<i>Hartmut Krafft - Referatsleiter Klinische Prüfungen</i> <i>Head, Section Clinical Trials, Paul Ehrlich Institut, Germany and chair CTFG</i>
	<ul style="list-style-type: none"> <li>• The “Voluntary harmonization procedure” for clinical trial approvals: concept, progress of this activity</li> <li>• Preliminary learning from this activity</li> <li>• Other activities of the CTFG</li> <li>• Concluding comments on European model vs globalisation</li> </ul>
17:05	<b>Panel Discussion with this sessions speakers plus invited panellists:</b> <i>Ingrid Wallenbeck, Medical Products Agency (MPA), Sweden</i> and <i>Janice Soreth, Deputy Director, Europe/US FDA and Liaison to EMEA</i>

	The speakers will take questions from the floor – this is your opportunity to explore topics more fully on issues of interest to you.
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17:30	<b>Close of session</b>
From 19.00	<b>Bus transport to City Hall</b>
19:30	<b>Gala Dinner at the City Hall</b>

## Parallel to Session 2 to 7

### Parallel break out sessions covering:

**Electronic Regulatory Affairs:** TOPRA eRA group

**Regulatory Careers**

**North America:** TORPA NA group

**CMC:** TOPRA CMC group

### Friday 9<sup>th</sup> Oct

#### Electronic Regulatory Affairs: Are we ready for 1 January 2010?

*Electronic working in Regulatory Affairs is much more than just the eCTD but in this session we shall be focusing on the challenges of implementing the eCTD in accordance with our commitment to the Heads of Medicines Agencies of the European Economic Area meeting in Reykjavik, Iceland February 2005 where they agreed a target of the end of December 2009 for implementation of the eCTD across Europe.*

*We shall look at the eCTD experiences of the FDA and the EMEA to date, global best practices and the readiness status of both the agencies and industry in meeting the 1st January 2010 target. We shall also start to look to the future beyond the eCTD and the vision of global e-Working.*

#### Chairpersons:

Peter James – *Dao-eRA Ltd, UK and secretary of TOPRA eRA SPIN group*

08:30	<p><b>Electronic Submissions to FDA: Advantages and Challenges From a Quality Viewpoint</b></p> <p>Norman Schmuff - <i>Branch Chief, Office of New Drug Quality Assessment (ONDQA), CDER, FDA, USA</i></p> <ul style="list-style-type: none"> <li>• FDA's experience with eCTD and SPL: how and how many</li> <li>• Life cycle (lifecycle?) and granularity</li> <li>• Issues confronting the ICH CTD-Q/eCTD Implementation Working Group</li> <li>• Suggested Best Practices for FDA eSubmissions</li> </ul>
08:55	<p><b>Where do the EU agencies stand on “e” working – are they ready for 1 January 2010?</b></p> <p>Hans-Georg Wagner – <i>Head of Communications and Networking, EMEA</i></p> <ul style="list-style-type: none"> <li>• Current status on the use of the eCTD and NeeS in Europe.</li> <li>• Are the NCAs ready to comply with the 2005 HMA Reykjavik target of the end of 2009 to accept eCTDs instead of paper applications?</li> <li>• Future Vision and trends : e-Working beyond the eCTD.</li> </ul>
09:20	<p><b>Structuring eCTD Applications - Multiple Strengths, Dosage Forms</b></p> <p>Alastair Nixon – <i>Director, Submission Publishing, GSK, UK</i></p> <ul style="list-style-type: none"> <li>• The EU guidance for eCTD - how it impacts the structure of eCTD applications in the different regulatory procedures</li> <li>• Advantages and disadvantages of building eCTDs covering multiple strengths or dosage forms</li> <li>• Using eCTD XML to best advantage to display to the assessor what is</li> </ul>

	new or changed
09:40	<b>Panel Discussion</b>
	The speakers will take questions from the floor – this is your opportunity to explore topics more fully on issues of interest to you
Finish at 10.00 for tea and coffee	

<b>Thursday 8<sup>th</sup> Oct</b>	
<b>North America: Hot topics at the US Food and Drug Administration (FDA)</b>	
<i>This session will provide an update from the FDA in the USA on the following hot topics:</i>	
<ul style="list-style-type: none"> <li>• <i>The New Commissioner Margaret Hamburg and other new key staff</i></li> <li>• <i>The European and US regulatory personnel exchange programme</i></li> <li>• <i>Biosimilars – unlike the EU, the FDA does not currently have legislation for generic biological products and so what future legislation might be proposed in this important area</i></li> <li>• <i>Comparative effectiveness – placebo controlled studies are the bench mark of a US application but how should new medicines be compared to other treatments. The latest thoughts on this will be provided</i></li> </ul>	
<b>Chairpersons:</b>	
Susanne Dorn – <i>Executive Director Regulatory Affairs</i> Halozyme Therapeutics, USA	
08:30	<b>An update from the FDA</b>
	Murray Lumpkin – <i>Deputy Commissioner (International and Special Programs) of the United States Food and Drug Administration (FDA), USA</i>
09:00	<b>Industry perspective on USA</b>
	Don Kennard - <i>Vice President of Regulatory Affairs and Quality - Halozyme Therapeutics, USA</i>
09:30	<b>"Fireplace" discussion including this sessions speakers</b>
	The speakers will take questions from the floor – this is your opportunity to explore topics more fully on issues of interest to you
Finish at 10.00 for tea and coffee	

<b>Wednesday 7<sup>th</sup> Oct</b>	
<b>CMC: Variations</b>	
<i>The Revised EU Variation Regulation, preparing for implementation. This session will provide an overview of the revisions to the Variations Regulation and guidelines due for implementation on 01 Jan 2010 and how industry views the new revised Variation Regulation and guidelines.</i>	
<b>Chairpersons:</b>	
Áine Kane – <i>Pfizer Ltd, UK and chair of TOPRA CMC SPIN group</i>	
15:00	<b>Revision of the Variation Regulation: Overview and Implementation</b>

	<b>preparation</b>
	Hilde Boone – <i>Scientific Administrator, EMEA</i>
	<ul style="list-style-type: none"> <li>• Overview of the key aspects of the Regulation</li> <li>• Regulatory perspective</li> <li>• Preparation and status of the implementing guidelines</li> </ul>
15:30	<b>Preparing for Implementation, an Industry Perspective</b>
	Zena Smith – <i>Regulatory CMC Manager, Pfizer, UK</i>
	<ul style="list-style-type: none"> <li>• Industry drivers for change to the variations regulations</li> <li>• Reflection on the progress from the new regulations and draft guidance.</li> <li>• Future vision and opportunities, including the Post Approval Management Plan</li> </ul>
16:00	<b>Panel Discussion including all this sessions speakers</b>
	The speakers will take questions from the floor – this is your opportunity to explore topics more fully on issues of interest to you
Finish at 16:30 for short break	

<b>Wednesday 7<sup>th</sup> Oct</b>	
<b>Regulatory Careers</b>	
<p><i>In its infancy the role of a registration officer was primarily that of documentation and collation: completion of forms, compiling the work of others into standard formats, numbering, copying and binding! During the past two decades certain areas have been absorbed into the duties of the registration officer, some of which (for example pharmacovigilance) have since become specialities in their own right as a consequence of increasingly complex regulation. At the same time, the emphasis of the strategic and planning components in their role has led to the establishment of the 'regulatory affairs' professional, increasingly important to commercial success and the protection of patient safety.</i></p> <p><i>In 2009/10 the world of European regulatory affairs is seeing many changes, and as a consequence the remit of the RA professional is expanding – or is it? What are the new areas that RA professionals should be abreast of? Will new professions take over from RA or will RA develop 'specialisms' within it to cope? Is this good or bad news for regulatory professionals? What should regulatory Directors be doing with their teams to deal with this evolution? Will these changes require new competencies? How can professional bodies help and offer training? Are the changing roles in industry being reflected in the way national agencies and EMEA are organising?</i></p> <p><i>Come and join this workshop session which will examine ways in which the RA role has changed and may change in the future.</i></p>	
<b>Chairpersons:</b>	
Lynda Wight – <i>Executive Director, TOPRA</i>	
15.00	<b>Interactive Session with invited panellists Agnes Saint Raymond, EMEA and David Jefferys, Eisai .</b>
	A chance for all delegates to participate in an interactive session
Finish at 16.30 with short break	

**Friday 9<sup>th</sup> October 2009**

**SESSION 7: Globalisation**

*This session will look at the Drug Development World outside the EU and its visionary opportunities and challenges*

- *What drives globalisation in companies? Market size, cost chasing, patient access and more?*
- *Regulatory globalisation. Increasing co-operation and number of memoranda of understanding - counterbalanced by concern about too much data from "unfamiliar" regions. Time to re-visit ICHE5 on Ethnic Factors in the Acceptability of Foreign Clinical Data?*
- *Agency outreach - opportunity for increased mutual recognition e.g. of inspections?*
- *Regional regulatory collaborations outside of the USA and EU. Could for example the pan-Asian collaboration shift the "Japanese Drug Lag" into a "Western drug Lag"?*

**Chairpersons :**

Åsa Holmgren – *Vice President Regulatory Affairs, Orexo, Sweden*

Murray Lumpkin – *Deputy Commissioner for International Programs – United States Food and Drug Administration (FDA), USA*

08.30	<b>Introduction by the Chair</b>
08:35	<b>USA</b>
	Murray Lumpkin – <i>Deputy Commissioner for International Programs - United States Food and Drug Administration (FDA), USA</i>
	<ul style="list-style-type: none"> <li>• Update on new FDA posts in foreign countries</li> <li>• Other international collaboration activities with foreign counterpart regulatory agencies, including GMP and GCP initiatives</li> </ul>
08:55	<b>Japan</b>
	Masatomi Akana - <i>Director Global Regulatory Eisai</i>
	<ul style="list-style-type: none"> <li>• Recent initiatives to promote early clinical trials in Japan.</li> <li>• Programmes to reduce the "drug lag" in Japan</li> <li>• How to incorporate Japan into an integrated "global" development programme</li> </ul>
09:05	<b>Asia Pacific -Regional Collaboration</b>
	David Jefferys - <i>Senior Vice President Global Regulatory, Eisai</i>
	<ul style="list-style-type: none"> <li>• How to incorporate Asia Pacific countries into the global development programme</li> <li>• Developing products for the Asia Pacific Market , extending these to the USA/EU.</li> <li>• Regionalisation versus Globalisation - the current issues</li> </ul>
09:15	<b>Industry</b>
	Christer Safholm - <i>VP pre-clinical safety assessment, AstraZeneca, Sweden</i>
	<ul style="list-style-type: none"> <li>• Industry view on Global Drug Development – what drives it and what prohibits it?</li> <li>• Industry’s increasing activities in China described as an example</li> </ul>
09:35	<b>Panel Discussion with today’s session speakers and invited guests -</b>
	The speakers will take questions from the floor – this is your opportunity to explore topics more fully on issues of interest to you.
10:00	<b>Coffee and Tea</b>

**Friday 9<sup>th</sup> October 2009**

**SESSION 8: European Union – latest news**

*This session will describe the status of the European Commissions Pharmaceutical Package, the Road Map's of the European Medicines Agency (EMA) and implementation of the Heads of Medicines Agency (HMA) Strategy paper.*

**Chairpersons**

Thomas Lönngren - *Executive Director, European Medicines Agency (EMA)*

Brenton James – *Consultant in Strategic Regulatory Affairs in Europe*

10.45	<b>Introduction by the Chair – Brenton James</b>
10:50	<b>The Pharmaceutical Package – latest information</b>
	Irene Sacristan Sanchez – <i>deputy head unit F2 Pharmaceuticals, European Commission</i>
	<ul style="list-style-type: none"> <li>• The Communication</li> <li>• The 5 legislative proposals               <ul style="list-style-type: none"> <li>- Counterfeits</li> <li>- Information to patients</li> <li>- Pharmacovigilance</li> </ul> </li> </ul>
11:15	<b>The European Medicines Agency – an update</b>
	Thomas Lönngren - <i>Executive Director, European Medicines Agency (EMA)</i>
	<ul style="list-style-type: none"> <li>• Road Map to 2010 – the successes</li> <li>• Road Map to 2015 – an overview</li> <li>• The new European Medicines Agency organisation</li> </ul>
11:40	<b>Heads of Medicines Agencies – an update</b>
	Jean Marimbert - <i>Directeur Général Agence Française de Sécurité Sanitaire des Produits de Santé (Afssaps), France</i>
	<ul style="list-style-type: none"> <li>• Implementation of the Heads of Medicines Agencies Strategy paper – the latest</li> </ul>
12:05	<b>Panel discussion:</b> Today's session speakers plus invited guests: Olof Tyden, Eureda, Sweden and Ture Sjoblom, Astra Zeneca, Sweden who will provide their observations before the session is opened to the floor for questions
12:40	<b>Closing Remarks</b> Lena Björk - <i>Director Medicinal Products, Medical Products Agency, Sweden</i>
12:50	<b>Thanks and TOPRA Closing Remarks</b> Paolo Biffignandi – <i>TOPRA President 2009/2010, CEO, VI.REL Pharma S.a.s, Italy, EU Vigilance Ltd, UK</i>