



The 6th TOPRA Annual Symposium 2009



TOPRA – The Organisation for Professionals in Regulatory Affairs

Reference: SYM/09



European Regulatory Affairs in a Global Environment

Organised in conjunction with the Swedish Medical Products Agency

The largest purely Regulatory Affairs event of the year - now in its 6th year.

Previous Symposia have been in Paris, Berlin, Amsterdam, Copenhagen and Budapest. In recent years there has been a close working relationship with local regulatory agencies and this year we welcome the input of the Medical Products Agency, Sweden. This is the key regulatory event of the year to meet fellow regulatory agency and industry colleagues.

Why attend the TOPRA Symposia?

- Hear the latest regulatory intelligence on key issues in Regulatory Affairs from our international speaker panel.
- Collect new ideas to help you and your business meet the challenges and maximise the opportunities offered by the current regulatory environment.
- Maintain and develop your network of industry and agency contacts.

Parallel Symposia



**Medical
Devices**



**Veterinary
Medicines**



**SME
Day**

See also www.topra.org/medicaldevsym2009, www.topra.org/vetsym2009 and www.topra.org/smeday for details for the Medical Devices and Veterinary Symposia on 8th October, as well as the SME Day on 7th October.

Three-day Symposium

Date:

Wednesday
7th October to
Friday
9th October 2009

Venue:

Clarion Hotel,
Ringvägen,
Stockholm,
Sweden.

Timings:

Symposium Registration:
11.30 – 12.30 Wednesday
7th October 2009

Start of Symposium:
12.30 Wednesday
7th October 2009

Close of Symposium:
13.00 Friday
9th October 2009

For more information or to register your interest, please contact TOPRA (see below).

email: meetings@topra.org tel: +44 (0) 20 7510 2560 fax: +44 (0) 20 7537 2003 web: www.topra.org/symposium2009



2 Speakers

Masatomi Akana, Director Global Regulatory, Eisai, UK

Lennart Åkerblom, Head of Section, MPA, Sweden and member of CAT

Caroline Baillif, Senior Manager RA, AMGEN, UK*

Paolo Biffignandi, CEO, VI.REL Pharma S.a.s, Italy*

Thony Björk, President PGEU (Pharmaceutical Group of the European Union), Vice President, Apoteket AB, International Affairs, Sweden

Hilde Boone, Scientific Administrator, EMEA

Gert Bos, Head of Clinical and Regulatory Affairs, BSI, UK

Daniel Brasseur, Chair of PDCO and Belgian Federal Agency for Medicines, Belgium

Patrick Celis, Scientific Administrator, EMEA

Vincenzo Costigliola, President, European Medical Association, Belgium

Sarah Daniels, Senior Partner, TranScrip Partners LLP, UK

Wilfried Dalemans, Vice President, Regulatory Affairs and Corporate Quality, Tigenix, Belgium

Kerstin Franzén, Sr Director Worldwide Regulatory Policy & Intelligence, Pfizer, Sweden

Vera Franzén, RA Director, SentoClone AB, Sweden*

Åsa Holmgren, Vice President RA, Orexo AB, Sweden*

Alan Hunter, TOPRA President 2008/2009

Brenton E James, EU RA Consultant, UK*

David Jefferys, Senior Vice President Global Regulatory, Eisai, UK

Margareth Jorvid, Senior Partner, LSM Group, Sweden**

Don Kennard, Vice President of Regulatory Affairs and Quality, Halozyme Therapeutics, USA

Hartmut Krafft, Head, Section Clinical Trials, Paul-Ehrlich-Institut, Germany and chair CTFG

Thomas Lönngren, Executive Director, EMEA

Murray Lumpkin, Principal Associate Commissioner, FDA, USA

Carrol Marcus, Vice President, PAREXEL Consulting, UK

Jean Marimbert, Directeur General, Afssaps, France

Patrizia Nestby, Senior Consultant, PAREXEL Consulting, UK*

Alastair Nixon, Director, Submission Publishing, GSK, UK

Beatrice Oberlé-Rolle, Head of RA, NobelBiocare, Switzerland*

Ann O'Connor, Director of Human Products Authorisation and Registration, Irish Medicines Board (IMB), Ireland

Jan Petracek, Risk Management Team, EMEA

Lennart Philipson, Director Medical Devices, MPA, Sweden

Christina Rångemark Åkerman, Director General, MPA, Sweden

Ana Rodriguez, Scientific Administrator, Inspection Sector, EMEA

Irene Sacristán Sánchez, Deputy Head Unit F2 Pharmaceuticals, European Commission

Christer Safholm, VP Pre-Clinical Safety Assessment, AstraZeneca, UK

Agnes Saint Raymond, Head of Sector, EMEA

Tomas Salmonson, Vice Chair CHMP, MPA, Sweden

Christian Schneider, Chair of CAT, Paul-Ehrlich-Institut, Germany

Norman Schmuff, Branch Chief ONDQA, CDER, FDA, USA

Annelie Skagerlind, Director RA, Medivir, Sweden

Zena Smith, Regulatory CMC Manager, Pfizer, UK

Steffen Thirstrup, Chief Medical Officer, Lægemedelstyrelsen (Danish Medicines Agency), Denmark

Markku Toivonen, Scientific Director, NDA Advisory Board, NDA Regulatory Science Ltd, UK

Hans-Georg Wagner, Head of Communications and Networking, EMEA

Lynda Wight, Executive Director, TOPRA

From SPIN groups:

TOPRA North America – **Susanne Dorn**, Halozyme Therapeutics, USA*

eRA – **Peter James**, Dao-eRA Ltd, UK*

CMC – **Aine Kane**, Pfizer Ltd, UK*

*Working Party

** Working Party Chair

Other Working Party members include:

Ursula Forner, MPA, Sweden

Henrik Holst, (Veterinary), MPA, Sweden

Tony Humphreys, EMEA

Lennart Philipson, (Medical Devices), MPA, Sweden

Helene Thybo, LEO Pharma A/S, Denmark

Sharon Pichon, AAPS, USA

From SPIN groups:

Medical Devices – **Neil Adams**, BSI Group, UK

Veterinary – **Ray Harding**, Cyton Biosciences, UK

Speakers may be subject to change

Venue, accommodation and travel

The Symposium will take place at the Clarion Hotel, Stockholm which offers all the facilities of an international first-class hotel.

Clarion Hotel Stockholm, Ringvägen 98, Box 20025, 104 60 Stockholm, Tel +46 8 462 10 00 Fax +46 8 462 10 99 cl.stockholm@choice.se

Delegates are responsible for the arrangement and payment of their own travel and accommodation. The Symposium venue has agreed a special bed and breakfast rate of 2095 SEK for a single room and 2295 SEK for a double room, including tax. To reserve accommodation, please visit the special TOPRA page on the Clarion website. A link to this page will be sent in your confirmation letter. The hotel will endeavour to accommodate you at this special rate subject to availability. Please note that the number of rooms held for Symposium delegates is limited and may fill up before the cut-off date.



Wednesday 7th October 2009

Registration, Lunch and Exhibition

Welcome from Lynda Wight, Executive Director, TOPRA

Welcome from Christina Rångemark Åkerman, MPA, Sweden

Welcome to Sweden and introduction to the theme for the 2009 Symposium by Margareth Jorvid, Chair of Symposium Working Party

SESSION 1: Best practice on the use of the Centralised Procedure for Marketing Authorisation in the European Union

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 and reducing the number of rejections.

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 licence 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.

Introduction by the Chairs

Practical experience and best practice – the CHMP rapporteur’s view

Success and risk factors in the Centralised Procedure – Ex-regulator viewpoint

A global perspective on marketing authorisation procedures - EMEA/FDA differences and how these affect innovation

Wednesday 7th 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 applied from December 30, 2008. Representatives of the European Medicines Agency (EMA), the Committee for Advanced Therapies (CAT) and industry will share their experiences with the delegates.

Introduction by the Chair

Experience of the implementation/planned activities

The CAT and challenges with Advanced Therapies

Industry implications

Medical Products Agency – Sweden

An introduction to the activities of the Swedish Medical Products Agency (MPA)

TOPRA ANNUAL MEETING



Programme subject to change

"An excellent presence of speakers from agencies made this TOPRA conference especially worth while"



4

Thursday 8th October 2009

On this second day, two parallel symposia will run: the 4th Veterinary Medicines Symposium and the 4th Medical Devices Symposium – see separate programmes for these

Main Symposium

SESSION 3: Combination Products (drug-device) this session is held jointly between the Main Symposium and Medical Devices Symposium

Combination products are an increasing regulatory challenge to industry and regulators. Drugs and devices 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.

Introduction by the Chairs

Combination products in Europe

Notified Bodies

Combination products in US

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 EUDRAVigilance 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 can other learned actors on the Phv stage play a role together with regulators and industry? What about the cost/benefit analysis of Phv and its real feedback for the citizens? Is the industry getting a better knowledge of the risk associated with its products or is it simply conducting an academic risk management exercises?

Introduction by the Chair

Industry viewpoint

Pharmacists' viewpoint

Physicians' viewpoint

Thursday 8th October 2009

SESSION 5: Paediatrics

This session will look into the overall experiences gained by having the Paediatric Regulation in place for over 2 years. 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 – Is it a success story?

Introduction by Chairs

Global collaboration

Industry Experience – SME

Industry Experience – Ethical Pharmaceuticals

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 the 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, giving assistance through sharing of expertise and capacity building, increasing 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.

Introduction by the Chairs

Global clinical trials – a review of organisational set-up and regulatory challenges

International GCP Inspections- EMEA Perspective

Review of the recent initiatives within the EU model for Clinical Trials

Programme subject to change

"The opportunities for networking were excellent"



Parallel to Session 2 to 7

Parallel break-out sessions covering:

- **CMC:** TOPRA CMC group
- **Regulatory Careers**
- **North America:** TOPRA NA group
- **Electronic Regulatory Affairs:** TOPRA eRA group

Wednesday 7th October 2009

CMC: 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 1st January 2010 and how industry views the new revised Variation Regulation and guidelines.

An Overview of the Revision to the Variations Regulations - A Regulatory Perspective

Preparing for Implementation, an Industry Perspective

Wednesday 7th October 2009

Regulatory Careers

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.

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?

(Continued) Regulatory Careers

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?

Come and join this workshop session which will examine ways in which the RA role has changed and may change in the future.

Interactive Session with invited panellists

Thursday 8th October 2009

North America: Hot topics at FDA

This session will provide an update from the FDA in the USA on the following:

- *New Commissioners*
- *Biosimilars*
- *Comparative effectiveness*
- *Re-importation*
- *Tobacco regulation*

An update from the FDA

Industry perspective on USA

Friday 9th October 2009

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

This session will look at the 'e' working readiness of the regulatory agencies and industry for 1st January 2010

Structuring eCTD Applications - Multiple Strengths, Dosage Forms

Electronic Submissions to FDA: Advantages and Challenges From a Quality Viewpoint

Where do the EU agencies stand on 'e' working – are they ready for 1st January 2010?

Programme subject to change



6

Thursday 8th October 2009

GALA DINNER

The Gala Dinner will be held in Stockholm's City Hall, which is the main symbol for the capital of Sweden and is the building from where the City of Stockholm is being governed. It is one of the most beautiful and well known buildings in the world and contains the most exclusive ballroom in Stockholm, frequently used for functions such as the yearly Nobel Banquet. The City Hall is known for its hospitality, its unique art treasures, magnificent banquettes and an intriguing history attracting close to 400,000 visitors a year.

The Gala Dinner includes the MSc in Regulatory Affairs and MSc in Medical Technology Regulatory Affairs Graduate Ceremonies. It will start with a drinks reception at 7.30pm. The three-day delegate ticket includes a ticket to the Gala Dinner. Please indicate on the booking form if you are NOT intending to attend. The fee for the SME Day and the Parallel Symposia on Medical Devices and Veterinary Medicine do NOT include a ticket to the Gala Dinner, but you can purchase a ticket if you wish by contacting the TOPRA office. (Subject to availability)



Friday 9th 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? Is it market size, cost-chasing, patient access or more?*
- *Regulatory globalisation. Increasing co-operation and number of memoranda of understanding can be counterbalanced by concern about too much data from "unfamiliar" regions. Is it time to re-visit ICHE5 on Ethnic Factors in the Acceptability of Foreign Clinical Data?*
- *Agency outreach - is there an opportunity for increased mutual recognition e.g. of inspections?*
- *What are the opportunities for regional regulatory collaborations outside of the US and EU?*

Introduction by the Chair

US

Japan

Asia-Pacific – Regional Collaboration

Industry Viewpoint

Friday 9th October 2009

SESSION 8: European Union – latest news

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

Introduction by the Chair

The Pharmaceutical Package – latest information

The European Medicines Agency – an update

Heads of Medicines Agencies – an update

Closing Remarks from the Medical Products Agency, Sweden

Thanks and TOPRA Closing Remarks
Paolo Biffignandi – TOPRA President 2009/2010

Programme subject to change



SME DAY
Wednesday 7th October 2009
Morning session devoted exclusively to SMEs
<p>This session will be held prior to the Main Symposium. Delegates will then be able to follow and take part in the Main Symposium during Wednesday.</p> <p>This session will give Small and Medium sized Enterprises (SME) the opportunity to understand regulatory challenges specific to them. Support by the SME office at EMEA will be explored and experience of SME companies shared:</p> <ul style="list-style-type: none"> ● SME Office at EMEA ● Experience of a Swedish SME ● Europharm SMC
Afternoon joins the Main Symposium and covers:
Best practice on the use of Marketing Authorisation Procedures in the European Union
Advanced Therapy Medicinal Products/CAT
Medical Products Agency, Sweden – An introduction to the activities of the MPA
For more information on these sessions, please see page 3
Parallel Sessions
<ul style="list-style-type: none"> ● CMC: TOPRA CMC group ● Regulatory Careers <p>For more information on these sessions, please see page 5</p>

MEDICAL DEVICES SYMPOSIUM
Thursday 8th October 2009
SESSION 1: Combination Products (drug-device)
<p>This session is common to the Main Symposium and Medical Devices Symposium. For more information on this session, please see page 4.</p> <p>The remainder of the Medical Devices Symposium will be held separately from the Main Symposium.</p> <p>This year's Medical Devices Symposium concentrates on regulatory issues of practical importance to medical device manufacturers, large and small.</p>

MEDICAL DEVICES SYMPOSIUM
SESSION 2: Borderline and Classification Issues
<p>Borderline and Classification Work group, National Competent Authority and Industry Perspective</p>
SESSION 3: Implementation of Directive 2007/47/EC
<ul style="list-style-type: none"> ● The 2007/47/EC Implementation; key practical issues and timetable ● Clinical data requirements under 2007/47/EC ● Technical file sampling and review depth requirements for Class IIa and IIb devices
SESSION 4: What Does The Future Hold?
<p>The 'Recast'</p>

VETERINARY SYMPOSIUM
Thursday 8th October 2009
SESSION 1: Keynote presentations on the opportunities for re-organisation of the regulation of veterinary medicines in Europe
<p>The first session will bring together the three main strings shaping the direction of the forthcoming review of the veterinary medicines legislation; the HMA Reflection Paper on opportunities for improvement, the European Commission's impact assessment on the legislative options and the HMA Strategy to develop an efficient European medicines regulatory network.</p>
SESSION 2: Outcomes of recent joint focus group meetings and joint workshops
<p>This session will address how regulatory authorities foresee the implementation of recent scientific and administrative guidelines and the discussion that took place with industry on key issues.</p>
SESSION 3: CMDv initiatives - bringing efficiencies to the system
<p>This session will provide an update on the CMDv 2009 work plan and will be illustrated by the policy initiative on packaging improvement.</p>
SESSION 4: Better regulation - bringing efficiencies to the system
<p>This session will cover the on-going and new initiatives and proposals for better regulation in the veterinary sector.</p>

Programme subject to change



BOOKING FORM 2009

The 6th TOPRA Annual Symposium 2009



Date: 7-9 October 2009 Venue: Clarion Hotel Stockholm, Sweden

Reference: SYM/09

Ways to book

Please complete in block capital letters and return this form with payment to TOPRA using one of the following methods:

Post: TOPRA, Bellerive House, 3 Muirfield Crescent, London E14 9SZ

Fax: +44 (0) 20 7537 2003 **Email:** meetings@topra.org

Online: topra.org/sym09booking

On receipt of your booking form we will confirm your provisional place in writing and provide directions to the venue. An invoice will be sent separately. To ensure admission, payment must be received prior to the meeting.

If you have any queries, contact us on: +44 (0) 20 7510 2560 or meetings@topra.org

Dr Mr Mrs Ms Other

Family name

First name Male Female

Company name

VAT reg. no.

Job title

Telephone

Fax

E-mail

Work Address

City Postcode

Country

Invoice Address
(If different from above address)

City Postcode

Country

Special dietary requirements

Payment method

Cheque enclosed Cheque No.

Bank transfer Date of transfer / /

Please charge my debit/credit card Purchase Order No.

Terms and conditions

(Please note: TOPRA's full standard Terms & Conditions are available on the website at www.topra.org/bookingTandC.)

Payment:

- Cheques:** must be made payable to TOPRA and drawn on a UK bank in either Euro or Sterling.
- Debit/Credit card:** for payment by card please complete the relevant details above. Cards accepted: AMEX, Debit MasterCard, Delta, Electron, Maestro, MasterCard, Solo, Visa. All cards will be charged in Sterling.
- Bank Transfers:** may be made to Lloyds TSB Bank PLC. Please quote the delegate's name and the course reference in the transmission details. The delegate must pay all bank charges.
- Sterling Transfers:** Account No: 00340310, Sort Code: 30-00-09, IBAN: GB45 LOYD 3000 0900 3403 10, BIC LOYDGB21013
- Euro Transfers:** Account No: 86330987, Sort Code: 30-00-09, IBAN: GB19 LOYD 3000 0986 3309 87, BIC LOYDGB21013
- Your place is secured only upon receipt of full payment.

Fees

3 day ticket – Main Symposium

Member: €2,237.50 = €1,790.00 + €447.50 (SE VAT 25%)

Non Member: €2,737.50 = €2,190.00 + €547.50 (SE VAT 25%)

The VAT rate will be the prevailing rate at the time of invoicing.

Gala Dinner: Three-day delegate rate **includes** a ticket to the Gala Dinner. Please tick this box if you do **not** want to attend the Dinner

Single day ticket Parallel Symposia

Please indicate which Parallel Session you would like to attend

Veterinary Symposium **Medical Devices Symposium** **SME Day**

Member: €343.75 = €275.00 (normal price* €575.00) + €68.75 (SE VAT 25%)

Non Member: €406.25 = €325.00 (normal price* €625.00) + €81.25 (SE VAT 25%)

*As charged in 2008, where applicable. The VAT rate will be the prevailing rate at the time of invoicing.

VOUCHER CODE

Debit/credit card details

(For cards accepted, see payment section below)

Debit Card Visa MasterCard American Express

Card No

Expiry date /

Security code Visa, MasterCard, Debit cards: the last 3 digits AFTER the card number in the signature area of the card.

Card holder name (as given on card)

Billing address for card (must be provided if different from the Work Address)

TOPRA will seek authorisation from the card-issuing company before confirming any reservation. (SE VAT Registration No.: SE 5020 6733 4801)

By signing below, I confirm that I agree with TOPRA's Terms & Conditions of Booking. These are available from the office or on the TOPRA website at: www.topra.org/bookingTandC

SIGNATURE

DATE

Please note:

Fee excludes accommodation and travel. The delegate ticket for the 3 day ticket includes refreshments at coffee breaks, buffet lunches as well as drinks reception and Gala Dinner. The delegate ticket for the parallel sessions includes refreshments at coffee breaks and buffet lunch on 8th October 2009 for Veterinary and Medical Devices Symposia and 7th October 2009 for the SME Day but NOT the drinks reception and the Gala Dinner.

Discounted fees:

Personnel in full-time education, working in academia (full-time) or working for a statutory regulatory body will be entitled to a 25% discount on the above fees. Please contact TOPRA for details.

Cancellations:

All cancellations must be received in writing 28 calendar days before the start of the meeting and will be subject to an administration fee of €150 + GBVAT for the 3 day ticket and €100 + GBVAT for the parallel sessions. Payment can be made in Euro or Sterling.

Data Protection:

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