



THE ORGANISATION  
FOR PROFESSIONALS IN  
REGULATORY AFFAIRS

# **TOPRA ANNUAL SYMPOSIUM**

## **SME DAY**

Regulatory challenges for and support to SME companies

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

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

**Organised in conjunction with**  
Swedish Medical Products Agency

<b>Session working party</b>
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<b>SME</b>
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Margareth Jorvid – LSM Group, Sweden
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Melanie Carr - EMEA
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Supported by TOPRA staff

**Wednesday 7<sup>th</sup> October 2009**  
**SME session**

**Session: SME session**

***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.***

*This session will give Small and Medium sized Enterprises (SME) the opportunity to understand regulatory challenges specific to them. Support by SME office at EMEA will be explored and experience by SME companies shared.*

**Chairpersons :**

Margareth Jorvid – LSM group, Sweden  
Melanie Carr - SME Office, EMEA, UK

09.30	<b>Introduction by Chair</b>
09:40	<b>SME Office at EMEA</b>
	Melanie Carr – SME Office, EMEA, UK
	<ul style="list-style-type: none"> <li>• Activities of the Agency's SME office</li> <li>• Experience of EMEA scientific advice process and centralised procedure</li> <li>• Support to SMEs</li> </ul>
10:10	<b>Experience of a Swedish SME</b>
	Annelie Skagerlind – Medivir, Sweden
	<ul style="list-style-type: none"> <li>• SME challenges</li> <li>• Practical experience of scientific advice</li> <li>• Experience of approval procedure</li> </ul>
10:40	<b>Europharm SMC</b>
	Telma Costa – Tecnifar SA, Portugal
	<ul style="list-style-type: none"> <li>• EuroPharm SMC</li> <li>• Interaction with EMEA</li> <li>• Support to SMEs by Europharm SMC</li> </ul>
11:00	<b>Panel Discussion</b> Speakers
	The speakers will take questions from the floor – this is your opportunity to explore topics more fully on issues of interest to you.
11:30	<b>Closure of session</b>

**Main TOPRA Annual Symposium**  
**(the remainder of the SME Day is common to the Main Symposium)**

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

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 Rångemark Åkerman, MPA, Sweden</b>
12:40	<b>Welcome to Sweden and introduction to the theme for the 2009</b>

	symposium by Margareth Jorvid, Chair of Symposium Working Party
<b>SESSION 1: Best practice on the use of Marketing Authorisation Procedures 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 available marketing authorisation procedures 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. For symposium delegates, this session will be a master class in the use of marketing authorisation procedures. Rather than focussing on the issues associated with the procedures themselves, practical recommendations on how to best deal with these issues will be offered.</i></p>	
<b>Chairpersons:</b>	
	Tomas Salmonson – <i>vice chair of Committee for Medicinal Products for human use (CHMP), Medical Products Agency (MPA), Sweden</i>
	Patrizia Nestby – <i>Parexel Consulting, UK</i>
12:50	<b>Introduction by the Chair</b>
12:55	<b>Practical experiences and best practice from the Danish CHMP members perspective</b>
	Steffen Thirstrup – <i>Lægemiddelstyrelsen (Danish Medicines Agency), Denmark</i>
	<ul style="list-style-type: none"> <li>• bullets</li> </ul>
13:15	<b>Practical experiences based on experience at regulatory agency (Finnish NAM) as well as industry</b>
	Markku Toivonen - <i>Scientific Director, NDA Advisory Board, NDA Regulatory Science Ltd</i>
	<ul style="list-style-type: none"> <li>• bullets</li> </ul>
13:35	<b>Practical experiences based on experience at regulatory agency (MHRA) as well as industry</b>
	Carrol Markus - <i>PAREXEL Consulting, UK</i>
	<ul style="list-style-type: none"> <li>• bullets</li> </ul>
	<b>Panel discussion with this sessions speakers</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
<b>Wednesday 7<sup>th</sup> October 2009</b>	
<b>SESSION 2: Advanced Therapy Medicinal Products /CAT</b>	

*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

**Introduction by the Chair**

15:00

**Experience of the implementation/planned activities**

Patrick Celis – *Quality of Medicines, Pre-Authorisation Unit, EMA*

- bullets

15:20

**Challenges with Advanced Therapies and the CAT**

Christian Schneider - *Acting Head, Division EU Cooperation/Microbiology Paul-Ehrlich-Institut Federal Agency for Sera and Vaccines Paul-Ehrlich-Institut and chair of CAT, Germany*

- bullets

15:40

**Industry implications**

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

- bullets

**Panel Discussion**

Speakers plus invited panellist Wing Cheng, MPA, Sweden - TBC

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

**Medical Products Agency - Sweden**

16.45 –  
17.30

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

First 12-months at the MPA – reviewed by Christina Rångemark Åkerman

**TOPRA ANNUAL MEETING**

17:30 to 18:15

**The TOPRA Review of the Year:**

Alan Hunter – *TOPRA President 2008/2009*

18:15 to 19:30

**Drinks Reception** – Delegates are cordially invited to a drinks reception in the exhibition hall. After this you are free to explore the delights of Stockholm