



THE ORGANISATION
FOR PROFESSIONALS IN
REGULATORY AFFAIRS

MEDICAL DEVICES SYMPOSIUM

Understanding Medical Device Regulatory Hurdles - Now
and in the Future

Thursday 8th October 2009

Clarion Hotel, – Ringvägen, Stockholm, Sweden

Organised in conjunction with
Swedish Medical Products Agency (MPA)

Conference working party
Medical Devices
Neil Adams – BSI Group
Lennart Philipson - Associate Professor Scientific Director Medical Devices Medical Products Agency, Sweden
Margareth Jorvid – LSM Group, Sweden

Supported by TOPRA staff

Thursday 8th October 2009
Medical Devices Symposium

Session 1: Combination Products (drug-device)

THIS SESSION IS COMMON TO THE MAIN SYMPOSIUM AND MEDICAL DEVICES SYMPOSIUM

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.

Chairpersons :

Margareth Jorvid – *Senior Director, LSM group, Sweden*

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

08:30 **Introduction by the chairs**

08:35 **Combination products in Europe**

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

- Drug or Device
- Ancillary action
- Consultation procedure / dossier requirements
- Competent Authority perspective

08:55 **Notified Body**

Gert Bos - *Head of clinical and regulatory affairs, BSI, UK*

- Notified Body role
- Consultation procedure
- Working with different Competent Authorities

09:15 **Combination products in US**

Margareth Jorvid – *Senior Partner, LSM group, Sweden*

- Office of Combination Products (OCP)
- Request for Designation (RFD) and Primary Mode of Action (PMOA)
- Lead center review
- GMP/QSR

09:35 **Panel Discussion** with this sessions speakers plus invited panellists:

Lennart Philipson, *Scientific Director Medical Devices, MPA, Sweden*
and
Janice Soreth, *Deputy Director, Europe/US FDA and Liaison to EMEA*

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 **Coffee and Tea**

Medical Devices Symposium (the remainder of the Medical Devices symposium will be held separately from the main symposium)	
<i>This year's medical devices symposium concentrates on practical regulatory issues of practical importance to medical device manufacturers, large and small.</i>	
Chairpersons for the rest of the day : Neil Adams - <i>Director, Operations and Delivery, BSI, UK</i> Lennart Philipson – <i>Director Medical Devices, Medical Products Agency (MPA), Sweden</i>	
10:30	Introduction
	Neil Adams - <i>Director, Operations and Delivery, BSI, UK</i>
	<ul style="list-style-type: none"> • Today's programme outlined
Session 2: Borderline and Classification Issues	
10:40	Borderline and Classification Work Group
	Neil Adams - <i>Director, Operations and Delivery, BSI, UK</i>
	<ul style="list-style-type: none"> • Output to date and the status of the manual of decisions • Products currently under discussion • How to request a decision about a product • Revision of MED DEV on device classification
11:00	Borderline and Classification Work Group – National Competent Authority
	Gert W. Bruse - <i>MPA, Sweden</i>
	<ul style="list-style-type: none"> • Issues of concern to member states • How should industry approach competent authorities • What does the future hold for classification changes
11:20	Borderline and Classification Work Group – Industry Perspective
	Mika Reinikainen – <i>Managing Director, Abnovo Ltd, UK</i>
	<ul style="list-style-type: none"> • Issues of concern to industry • Classification anomalies that need addressing • Global/GHTF classification issues
11:40	Panel Discussion with this sessions speaker: The speakers will take questions from the floor – this is your opportunity to explore topics more fully on issues of interest to you
12:10	Lunch
Session 3: Implementation of Directive 2007/47/EC	
13:30	The 2007/47/EC Implementation: Key Practical Issues and Timetable
	Matthias Neumann - <i>Bundesministerium für Gesundheit, Federal Ministry of Health Division 116 "Medical Devices", Germany</i>
	<ul style="list-style-type: none"> • Lack of a transitional period - How to deal with it? • Consequences and to-do list for manufacturers • Case studies: new essential requirements, changed classifications, changed

	<ul style="list-style-type: none"> conformity assessment modules Validity of certificates
13:50	Clinical Data Requirements under 2007/47/EC
	Suzanne Halliday - <i>BSI, UK</i>
	<ul style="list-style-type: none"> Ten changes 2007/47/EC makes regarding clinical data What Notified Bodies will look for after 21 March 2010 Standards and guidance to meet the requirements
14:10	Technical File Sampling and Review Depth Requirements for Class IIa and IIb Devices
	Valérie Viejo - <i>Project Manager Certification Medical Devices Northern countries, KEMA Quality B.V., The Netherlands</i>
	<ul style="list-style-type: none"> Changes in the directive affecting Class IIa and IIb devices How manufacturers should prepare for these changes Open issues that still need addressing
14:30	Panel Discussion: The speakers will take questions from the floor – this is your opportunity to explore topics more fully on issues of interest to you
15:00	Afternoon tea
Session 4: What Does The Future Hold?	
15:30	Introduction
	Lennart Philipson – <i>Director Medical Devices, MPA, Sweden</i>
15:40	The Recast: Views of the Medical Device Industry
	Malcolm Carlisle OBE – <i>Chairman Technical and Regulatory Policy Group, ABHI, UK</i>
	<ul style="list-style-type: none"> Recast issues that still need addressing by regulators Best way to deal with the issues
16:00	Recast of the legal framework for medical devices: Notified Body ideas to improve and strengthen the regulatory system and offer a uniform level of protection to public health.
	Sébastien Hardy - <i>LNE/G-MED, France</i>
	<ul style="list-style-type: none"> Recast issues that still need addressing by regulators Best way to deal with the issues
16:20	Panel Discussion with today's speakers - including global outlook The speakers will take questions from the floor – this is your opportunity to explore topics more fully on issues of interest to you
17:00	Close