

GENERAL INFORMATIONS

Venue of the congress - Lieu du congrès

Hotel CIOTEL LE CAP Corniche du Liouquet - 13600 LA CIOTAT France

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Registration - Inscription

EMDW is a seminar by invitation only : The invitations to participate aim at a balance between experts of university, regulation and industrial environments. The participants will be encouraged to exchange information on a dedicated Web site, so as to prepare resolutions which will be finalized, presented and discussed first on a restricted, then on a general basis at the EMDW. These resolutions will be on line within a very short period and complementarized by a detailed argumentary file within 3 months.

EMDW est un séminaire sur invitation nominative : Les invitations des participants visent à maintenir un équilibre entre experts des milieux académiques, réglementaires et industriels. Les participants seront encouragés à préparer les résolutions qui seront finalisées, présentées et discutées de manière restreinte puis générale lors des EMDW. Ces résolutions seront mises en ligne dans un très bref délai, complétées par un argumentaire détaillé dans les 3 mois.

Official Language - Langue de travail

The official language of the meeting is English

La langue officielle du congrès est l'anglais.

Housing - Hébergement

The participants in the EMDW seminar will be housed in Hôtel CIOTEL Le Cap or near La Ciotat at EMDW organizers expenses.

L'hébergement des participants aux rencontres EMDW est assuré par les organisateurs à l'Hôtel CIOTEL Le Cap.

Contact - Correspondance

EMDW-2008 Co / Esil Dpt Biomédical

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Photos: Office du Tourisme de la Ciotat
Impression: la platine marseille 04 91 62 30 07

La Ciotat European Medical Devices Workshop

EMDW 2008

November 14-15, 2008

*Under the patronage of Günter Verheugen,
European Commissioner for Enterprise and Industry*

PRELIMINARY PROGRAM

www.EMDW.org

LA CIOTAT, Marseille-Provence-Métropole
Hôtel CIOTEL Le Cap

The EMDW International Organisation Committee

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*En 1895, les frères LUMIERE inventent le cinématographe à La Ciotat et tournent le premier film de l'histoire du 7ème Art, "L'Entrée du Train en gare de La Ciotat".
En 1910, Jules LENOIR, infirme rhumatisant, invente le jeu de la Pétanque à La Ciotat en jouant "les deux pieds tanqués au sol" d'où le nom de pétanque.*

In 1895, LUMIERE brothers have invented moving cinema at La Ciotat and made the first movie film "the train arrival in la Ciotat railways station"

In 1910, Jules LENOIR, who was a cripple, invented the Petanque game in La Ciotat.



Assistance Publique
Hôpitaux de Marseille



In the next few years in Europe, medical devices (MDs) will be doubtless evaluated before and after they are placed on the market. Which rules will be applied ?

Today, only a labelling of the European Community is requested before they are on the market. The 2007/47 European directive published in the Official Journal of the European Union (OJEU) in September 2007 tightens the rules concerning clinical data before and after marketing application authorization. However the issue on how clinical evaluations will have to be done in the European Union is not yet settled : which criteria must be used ?

Under the authority of ORPHEME (competitiveness cluster of emerging pathologies and orphan diseases), and organized by ORPHEME and ESIL, European Medical Devices Workshop (EMDW) is the European workshop for biomedical devices. EMDW is a private yearly seminar inviting for the second time in November 2008, some seventy European experts in medical research, industry and ruling of MDs. These guests will be selected by an international scientific council and play an important part in evaluating and establishing rules for MDs within the European Commission (General Directions of Enterprises and Industry), within Competent Authority from several European countries, on the national level (HAS, AFSSAPS, CNAM, DGS, AFNOR, INSERM, ...) or within notified bodies (GMed, TUV, SGS,...). They will exchange information concerning innovation, evaluation and regulation with persons acting on the industrial field (European Syndicates of Mds, or private companies, such as ABBOTT, BBRAUN, EDWARDS, GE, J&J, MEDTRONIC, SORIN, etc..).

This seminar is not based on a conventional congress but on workshops and meetings which will mostly deal with the prior art in innovation, evaluation and application of medical devices, so as to anticipate mutations and be able to express proposals on measures to be taken. It will deal with consensual agreement and action feasibilities, methods enhancement and improvement of services performed by health technologies.

EMDW-2008, dedicated to the changing legislative environment of MDs authorisation and evaluation, will have three ambitious goals :

- Deciphering the current evolution in the MDs legislative environment.
- Anticipating to the future legislative evolution in the light of technological progress/discoveries.
- Foreseeing and getting organised to be a proposition force at European level

Let us note that one of the topics carried by France during its Presidency of the Council of the European Union from July 1st, 2008 concerns precisely clinical trials relating to the medical devices.

The EMDW Local Organisation Committee

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- Alain YVORRA, Director of ORPHEME : alain.yvorra@orpHEME.org

Friday November 14, 2008

- 10h15 / 10h30 **Opening of EMDW 2008**
Jean-Michel DUBERNARD, Haute Autorité de Santé, France
Michel LETORT, SORIN, Italy
- 10h30 / 12h00 **Thematic lecture** : The refund of the medical devices.
Strategy in France. Overview on strategies of other countries of the European Union.
With the participation of peoples from Competent Authorities from European Countries.
- 12h00 / 12h30 **Lecture** : Molécular medicine : Tools to decipher molecular interactions in drug discovery and perspectives in clinical diagnostic.
Gérard MATHIS, Head of Research and Development CISBio R&D, France
- 14h00 / 17h15 **Working Groups** (Pannel Discussions in parallel sessions)
WG1 : MDs & Orthopaedics - Coordinator : Paul-Henri VALLOTON, Director R&D Symbios Orthopédie SA, Switzerland.
WG2 : Telemedicine & ICT for eHealth: How to implement a European common policy
Coordinator : Michel SCHALLER, GIXEL(*) Vice President, France
WG3 : Cardiovascular Drug delivery MDs - Coordinator : Michel LETORT, SORIN, Italy
WG4 : Biodegradable Mds - Coordinator : Marc BOHNER - Robert Mathys Fondation, Switzerland
- 17h15 / 18h45 **Pause / Free discussions**
- 18h45 / 19h30 **Official Welcome Ceremony**
- 19h30 / 20h00 **Lecture** : Mankind and the Conquest of Interplanetary Space : The Technological Spin-offs for Practitional Medecine.
Antonio GUELL, Head of Strategy and Partnership, CNES, France
- 20h15 **Dinner**

(*)GIXEL (Groupement Industriel de l'interconneXion et des systèmes Electroniques France

Saturday November 15, 2008

- 08h30 / 10h30 **Thematic lecture** : Clinical evaluation of the medical devices.
What clinical studies ? Is it possible to issue general rules ?
With the participation of peoples from Competent Authorities and Notified Bodies from European Countries.
- 10h30 / 10h45 **Pause**
- 10h45 / 11h15 **Lecture** : How to solve issues linked to clinical trials for Premarket Approval ?
Linda R. HORTON, Hogan & Hartson LLP, Washington, USA
- 11h15 / 12h30 **Synthesis of the 4 Specific Workshops**
Paul-Henri VALLOTON, Symbios Orthopédie SA, Switzerland
Michel SCHALLER, GIXEL, France
Michel LETORT, SORIN, Italy
Marc BOHNER, Robert Mathys Fondation, Switzerland
- 12h30 / 13h15 **EMDW-2008 synthesis**
- 13h15 **End of EMDW-2008 - Buffet lunch**