Thursday, 4 December 2014

Multi-Stakeholder Workshop of the Joint EFGCP-MedTech Europe Medical Technology Working Party on 'Mitigating Risks in the Lifecycle of Medical Devices: Options and Challenges in Building Clinical Evidence' - The Hotel, Brussels, Belgium

The upcoming European Regulation on Medical Devices will change the landscape for the development of medical devices. This multi-stakeholder workshop of the new joint EFGCP-MedTech Europe Working Party will offer the floor for an exchange of views and opinions on topics of particular complexity and concern in the new Regulation with a view to providing input to the relevant decision-makers.

Setting effective ethical and quality clinical standards for medical technology studies is critical to ensuring that patients have access to safe and effective treatment. For the first time, patient representatives, healthcare providers, ethicists, competent authorities, industry and policymakers will be able to present and discuss their needs and expectations, the options and opportunities for mitigating risks in the development and full life cycle of medical devices and the best ways of building clinical evidence.

Objectives:

• Understand the differences between clinical trials with medicines and medical devices

• Identify suitability of concepts and lessons learned in medicines development for clinical development of medical devices

• Discuss how best to ensure the required ethical and quality standards in medical device trials

Last update: 31 October 2014