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The new EU Medical Device Regulation - How will it change our lives?

It is almost 4 years passed since in September 2012 EU Commission published the proposal for Medical Device and In Vitro Diagnostics Regulation (MDR & IVDR). Since then intense discussions among stakeholders has taken place and various draft versions from EU Parliament and Council have been published. In May 2016, the Dutch Presidency published reaching agreement on the MDR & IVDR which now will pass Council and Parliament with aim to get final text adopted end 2016 (or latest early 2017). The final text may differ significantly from Commission proposal however fact is that the new Regulation will impact heavily stakeholders including but not limited to Medtech industry, Pharma companies developing drug & device combination products or companion diagnostics, Regulators, Notified Bodies, CROs and suppliers.

One of the major criticisms and heavily discussed in media of the current medical device law has been the lack of sufficient clinical data, with a traditional reliance on claimed equivalence and the competence of Notified Bodies to assess and judge clinical evaluation reports.

Given the long legislative process for adoption of proposed Regulation , the EU Commission implemented in September 2013 some emergency measures to address these concerns, including; the requirement for Notified Bodies to conduct unannounced audits of Device Manufacturers, critical subcontractors and crucial suppliers and the re-designation of all Notified Bodies, with particular emphasis on the demonstration of competence of NB Personnel and the Notified Body assessment of clinical evaluation reports. One key subject of such audit has been the review of clinical data and Notified Bodies assessment of clinical evaluation reports.

This session will give an overview of key changes of proposed Regulation and highlights impact on stakeholders with especial focus on requirements for performing clinical investigations, clinical evaluation, and post marketing clinical follow up.