

The new proposal for a regulation on medical devices in the EU - What to expect?

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On 26 September 2012, the European Commission adopted a package on innovation in health consisting of

- the Communication on safe, effective and innovative medical devices and *in vitro* diagnostic medical devices for the benefit of patients, consumers and healthcare professionals
- the Proposal for a Regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009
- the Proposal for a Regulation of the European Parliament and of the Council on *in vitro* diagnostic medical devices

This presentation will focus on the updates introduced by this proposal and the possible effect it could have on manufacturers in the EU. Topics covered will include:

1. What is the new regulation about?
2. The need and background for the update (including issues such as non-harmonized interpretation and implementation in Member States, issues related to traceability, access to information, clinical evidence and transparency).
3. Expected Benefits (patients, healthcare professionals, manufacturers).
4. What exactly will change (Wider, clearer scope for EU legislation on medical devices, Eudamed database, Better traceability, clinical evidence, Updated classification rules and Better Coordination).
5. Timeline for implementation.

Biography

Salma Michor is founder and CEO of Michor Consulting, Europe, serving such clients as Johnson & Johnson, Novartis, Valeant Pharma and Colgate Palmolive. Previously, Michor worked for Chiesi-Torrex, Wyeth Whitehall Export Croma Pharma GmbH. She teaches regulatory affairs and clinical strategies at the University of Krems, Austria, and is an independent expert to the European Commission. Michor is a member of the RAPS European Advisory Committee. She holds a Ph.D. in thermal process engineering and a M.Sc. in food and biotechnology from the University of Applied Life Sciences in Vienna, Austria; a M.Sc. from King's College, University of London in food technology; and an MBA from Open University, and has earned the EU RAC.

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