Revising Medical Devices Regulation - The Legal Challenges

Conference: Tuesday, 29 January 2013

Het Corpac Huis | Tilburg, the Netherlands

Critical updates on the revised regulation for MD

PROGRAMME

Session I:
Revision of the EU Regulatory Framework

- Overview of the European Commission's proposal: Key elements
- Recast of the current legislation: Who will benefit? What are the main challenges?
- Impact of the new Regulations on the stakeholders

Session II:
Data Protection vs. Regulatory Obligations

- Interface between EU medical devices law and the proposed General Data Protection Regulation (GDPR)
- Consequences of the proposed GDPR for data collection and processing for medical devices companies
- Company's regulatory obligations to collect safety and performance data

Session III:
Procurement and Health Technology Assessment (HTA)

- HTA - an obstacle to innovative products and/or services in healthcare?
- The role of governments in procurement procedures and HTA
- How does the increased influence of HTA in decision making influence the route to the market?

Session IV:
Supervision

- Post Market Surveillance in a highly innovative industry as the key to safer medical devices
- Action levels, pro-active surveillance and "proven safety" are the keywords?
- The role of Notified Bodies under the new Regulations proposed by the European Commission

SPEAKERS

Gert BOS, Head of Regulatory and Clinical Affairs Medical Devices, BSI Assurance UK Limited
John BRENNAN, Director Regulatory and Technical Affairs, Eucomed
Jean-Claude GHISLAIN, Head of European Coordination Division, National Agency for Safety of Medicines and Healthcare Products
Leigh HANCHER, Professor, University of Tilburg (TILEC); Allen & Overy LLP
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and many more

Visit www.lexxion.eu/conferences for the full programme and registration form! Closing date: 15 January 2013.
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FEES

Conference 29 January 2013

€ 595,– (regular fee)
€ 295,– (reduced fee for public authorities)
€ 100,– (reduced fee for full-time academics)

VAT will be added if applicable. The participation fees include the conference material, coffee, tea and cold drinks during the breaks as well as lunch. Special rates for students available on request.

For further information and online registration, please visit www.lexxion.eu/conferences

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