Joint EDMA / Eucomed Workshop on *Implementation of a UDI system A focus on US FDA Rules*

Thursday, 15 May 2014 - 9:30-16:30

Sheraton Airport Hotel – Zaventem (Brussels)

MORNING SESSION *(Galaxy 1 meeting room)*

09:30	***Registration and welcome coffee***
10:00	**Opening of Workshop** Andrew Rutter (EDMA – J&J) / Mike Kreuzer (Eucomed – ABHI)
10:05	**Meet regulatory requirements of the US FDA** **Final UDI Rule - Focus on Labeling/Marking** • Implementation of FDA Rules – Jay Crowley (USDM) • Manufacturer's perspective – Jenny Gough (Mölnlycke) / IVD manufacturer • Q&A
11:00	**Meet regulatory requirements of the US FDA** **Draft Guidance on Global Unique Device Identification Database** • Implementation of FDA Rules – Jay Crowley (USDM) • Manufacturer's perspective – Andrew Rutter (J&J) • Q&A
12:00	**Policy aspects on UDI implementation** – Rodolphe Munoz
12:30	**Conclusions and Short explanation regarding afternoon session**
12:30	***Workshop lunch***

AFTERNOON SESSION

13:30 *14:10*	**Breakout sessions** • **Labelling/Marking** *(Galaxy 1 meeting room)* Moderated by: Jenny Gough (Mölnlycke) • **Global Unique Device Identification Database** *(Satellite 6 meeting room)* Moderated by: Andrew Rutter (J&J) • **QMS aspects of UDI implementation** *(Satellite 7 meeting room)* Moderated by: To be confirmed *Move back to plenary Galaxy 1 meeting room*
14:15	**Questions and Answers session** *(Galaxy 1 meeting room)* Panel of experts
15:15	***Coffee Break***
15:30	**Questions and Answers session – continued** *(Galaxy 1 meeting room)* Panel of experts
16:30	**Conclusions and closing remarks** Andrew Rutter (EDMA – J&J) / Mike Kreuzer (Eucomed – ABHI)
16:30	***Closing of workshop***