

Meeting Minutes

Workshop around the new European “Medical Device Regulations” (MDR) and specifically the regulations concerning “Post Market Surveillance” (PMS).

Hotel Säröhus May 16th 2018,

Agenda

08.00	Welcome and Introduction of BFCC.	Anders Jönsson
08.15	The new Medical Device Directive (MDR) and Post Market Surveillance (PMS)	Karl Hagström
08.45	Discussion	All
09.30	Adjourn	

Attendees

Anders Jönsson, BFCC project responsible at Dept. of Orthopaedic Surgery, Sahlgrenska University Hospital, Gothenburg, Sweden.

Karl Hagström, Senior QA/RA consultant, MEDOS AB, Linköping, Sweden.

Alexandra Logothetis, assistant, Dept. of Orthopaedic Surgery, Sahlgrenska University Hospital, Gothenburg, Sweden.

Representatives from the Medical Device Industry in Sweden



Minutes

The induction by Anders Jönsson focused on the BFCC's organisation and special emphasis on the work with implementing new fracture registries in the Baltic Sea region. Specially highlighted was the possibilities for the registries to serve as a source for patient related data with as demanded in the MDR.

The following meticulous presentation by Karl Hagström was very much appreciated and it is attached to this report for details.

The following session with questions and discussions were intensive and it was obvious that still a lot of uncertainty exists.

The following Issues, among others were discussed:

- Post-market surveillance reports.
- Patient-specific data to be collected for all products or a sample
- Implant cards
- GDPR (Restriction of Information Information)

Conclusions

- The degree of awareness of the new Medical Device Regulations varied among the participants
- Some of the attendees are not direct working with or have responsibilities that covers in depth these topics
- To some degree, it is not clear what the authorities nor the Notified Bodies are expecting from the industry

- Registries will play an import role in the Post Market Surveillance process
- The BFCC project was of interest for in particular the implant manufacturers attending the meeting



<http://www.bfcc-project.eu>