Swiss MedBRAID

Medical Devices - Seminar 2010

Development, Manufacturing, Release

6th September 2010

Radisson Blu Hotel, 8058 Zürich Airport

Switzerland

SCHEDULE

From 8:00	Registration and welcome coffee
09:00	**Organizers and Chairman's welcome and opening**
09:15 Dr. G. BOS: British Standard Institution	**Clinical evaluations and clinical trials for medical devices**
10:00 Mrs. S. SONIEC: Meditec	**US-FDA 510(k) submissions- Requirements and their practical implementation**
10:45	**Questions and answers session**
10:55	Networking break and coffee – 25min
11:20 G. MITCHEL: Johnson & Johnson	**Method for prediction of ethylene oxide lethality and cycle development**
12:05 Dr. C.GIANINAZZI : Medistri SA	**Microbiological Monitoring of Medical Devices and Clean Rooms – Importance and Approaches based on ISO 11737-1 and ISO 14698 -1/ -2**
12:50	**Questions and answers session**
13:00	Lunch break – 75min
14:15 P-A. SOMMER: Geskal	**Directive 2007/47 EC - Successful implementation of the key revisions to the medical device directives**
15:00 Dr. K. HEATON Anderson Caledonia	**Water used in Medical Devices Manufacturing – European and US pharmacopeias**
15:45	**Questions and answers session**
16:10	Networking break and coffee – 20min
16:30 B. STEFFEN Confinis AG	**Software Development Lifecycle (IEC 62304)**
17:15 M. FANGON Amcor	**EN ISO 11607(2006): Packaging for terminally sterilized medical devices**
18:00	**Questions and answers session**
18:10	Chair's closing remarks and of the seminar

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