

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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