ANNEX 6

AHWP SPECIAL MEETING

Musik und Kongresshalle
Lübeck, Germany
28 June 2006
in conjunction with the 10th GHTF Conference, 26 – 30 June 2006

SUBJECT/SYNOPSIS FOR PRE-MEETING WORKSHOP

11th AHWP Meeting, Pre-Meeting Workshop

13 – 15 Sept 2006, Seoul Olympic Parktel, Seoul, Korea

Subject/Synopsis	Speaker
Plenary Session I – What's Really Happening in Conformity Assessments Procedure? What does conformity assessment mean to you as a regulator? What is it that is really happening when conformity assessment is performed by a 3rd party conformity assessment body? What will be the impact on you (as a regulator) if you accept the results of conformity assessment performed by a 3rd party? This session is your chance to hear about the processes, procedures and safeguards that go into the conformity assessment of a new medical device before it is placed on the market.	Proposed Number of Speaker: 1 from EU Notified Bodies
Plenary Session II – **Adoption of the Summary Technical Documentation (STED): An Efficient Submission Format** STED describes a format that can potentially be used to obtain national marketing authorizations. This session will discuss updates and new features, and how the format is utilized and perceived by regulators and industry to be an efficient and effective format for meeting regulatory requirements.	Proposed Number of Speaker: 1, Mr Johan Brinch, VP Regulatory Affairs, Cochlear Implants; Member of SG1 and SG5
Plenary Session III – Implementing Risk Management to your Advantage Implementing risk management is a continuing process throughout the lifetime of a medical device. However, the activities used for risk management may be changed by technical, scientific and legislative developments, as well as by information available, perceived risks and estimated public health impact, and where a product lies in its lifecycle. This session will also provide an overview on the latest developments in risk management standards and discuss how medical device manufacturers can implement and utilize these standards to their advantage.	Proposed Number of Speaker: 1 (to cover 2 sessions) from USFDA
Plenary Session IV – Practical Issues in Combination Products Combination products represent a growing market. For example, a recent survey performed by RAPS indicated that close to 30 percent of products under development are combining drug and devices. This session will discuss drug/device combination products. In this session, speakers will provide an understanding of the regulatory framework for	Proposed Number of Speaker: 1 (to cover 2 sessions)

Subject/Synopsis	Speaker
developing and ensuring marketing success of combination products. At the end of the session, it is hoped that you will be equipped with increased knowledge in the following topics to meet regulatory requirements for drug-device combination products. ❖ What is a Combination Product? ❖ How is the Primary Mode of Action (PMOA) determined? ❖ How to effectively navigate the jurisdictional pathway? ❖ What do you do when the PMOA is unclear? ❖ What are the challenges of labeling combination products? ❖ How to determine which aspects of labeling to include? ❖ What are the relationships between the two manufacturers in a cross-labeled product? ❖ Strategies and case studies. ❖ Global regulation of combination products.	
Workshop 1: Evidence Gathering in Clinical Trials In this session, speakers will discuss Clinical Evidence, Clinical Investigation, update on the latest developments in GHTF SG5 on clinical evaluation, and the MEDDEV guidance document on Clinical Evaluation.	Proposed Number of Speaker: 1 (to cover 2 sessions) from Johnson & Johnson Medical
Workshop II – Experiences Implementing Global Medical Device Nomenclature (GMDN) as a Regulatory Requirement The Global Medical Device Nomenclature (GMDN) is a collection of internationally recognized terms with a unique code number to accurately describe and catalogue medical devices. Since 2002, Australia has implemented a regulatory framework whereby sponsors are required to select from the available GMDN codes to describe the medical device for registration of all classes of devices. In this session, Australia's Therapeutic Goods Administration (TGA) will be sharing with you Australia's experiences in implementing the GMDN codes as a pre-market device registration requirement. Specifically, it will also seek to address issues relating to the grouping of "kinds of medical devices", industry experiences with GMDN and incorporation of GMDN within TGA's Device Electronic Application Lodgement (DEAL) system.	Proposed Number of Speaker: 1 from Australia TGA
Workshop III – Surviving a Regulatory Inspection on your Quality System A robust and effective quality system will keep you out of trouble and prevent many hardships, headaches and stress. A robust and strategic solution can both ensure survival and add business benefits. Solutions that address collaboration, communication, proactive decision support, risk modeling and resource allocation offer a powerful combination to help device manufacturers manage its quality system. In this session, the speaker will discuss the following strategies to ensure compliance during inspection: ❖ Identifying regulated operations areas	Proposed Number of Speaker: 1 (to cover 2 sessions), Khosravi, Ben from St Jude Medical

Subject/Synopsis	Speaker
❖ Establishing risk-based compliance program priorities ❖ Planning, implementing and monitoring compliance initiatives ❖ Enforcing internal corrective and preventive responses to regulatory violations ❖ Clarifying compliance responsibilities of organization personnel and external partners ❖ Instituting management accountability and evaluating results	
Workshop IV – Ensuring the Safety of Marketed Medical Devices: Vigilance Reporting Systems Medical devices, ranging from surgical sutures and contact lenses to prosthetic heart valves and diagnostic imaging systems, are an integral part of the healthcare system. More importantly, after introduction into the market, many devices remain in use for 10-20 years. The responsibility for ensuring the quality, safety and performance of medical devices rests with the manufacturers and competent authorities. In this session, the speaker will be discussing the various post-market programs aimed at monitoring the safety of devices already in use and a case study on how to take remedial action when needed. This session will summarize the special challenges in implementing the program and lists a series of recommended action steps to strengthen the effectiveness of your post-market initiatives.	Proposed Number of Speaker: 1 (to cover 2 sessions), Tim Missios from BSI