DRAFT AGENDA
(Revised 6-Nov-12)

Proposed WHO Workshop on Stability Evaluation of Pharmaceuticals and Vaccines
(3rd Implementation Workshop on Stability Evaluation of Vaccines)

30 January – 1 February 2013

Bangkok, Thailand

Proposed Chair: Dr Elwyn Griffiths
Proposed Rapporteur: Dr Michael Pfleiderer
Proposed Co-Rapporteur : TBC

Refreshment breaks 10:30 – 11:00 & 15:30 – 16:00
Lunch break: 12:30 – 14:00

Timeline	Topic	Speaker/Facilitator	Aim
DAY 1: Wednesday, 30 January (14:00 – 18:00)			
Session 1: Plenary	**Welcome and introduction (30 min)**		
	Welcoming remark	TBD	
	Self-introduction		
	House-keeping announcement		
Session 2: Plenary	**Workshop goals (1 hour)**		**To present goals, objectives, and expected outcomes of the workshop**
	Global perspective in implementing WHO guidelines on stability evaluation of pharmaceuticals and biologicals		To give an overview on the past developments of stability guidelines and their implementation in the area of medicines & vaccines

Timeline	Topic	Speaker/Facilitator	Aim
	- Pharmaceuticals (20 min)	Dr S Kopp	
	- Vaccines (20 min)	Dr I Knezevic	
	- Discussion - Issues in implementing WHO guidelines: Feedback from the audience (20 min)	Chair	To identify barriers in the region and discuss potential solutions
Session 3: Plenary	**Current issues (90 min)**		**To get the audience updated on the latest developments and activities**
	Controlled temperature chain (40 min)	TBD	To update the audience of Dec/2012 Ottawa meeting
	Regulatory experiences on vaccine licensing, changes of post-licensure, or outcome of investigations (25 min)	Regulator	To share regulatory experiences on stability issues
	Industry experiences on vaccine licensing, changes of post-licensure, or outcome of investigations (25 min)	Industry	To share industry experiences on stability issues
DAY 2: Thursday, 31 January (09:00 – 18:00)			
Session 4: Plenary	**Core topics (3 hours)**		**To facilitate common understanding of guidelines' core principles and approaches.** **Speakers are advised to develop a few questions for small group discussion during the presentation to facilitate interaction.**
	Determining shelf-life	TBD	To review in details what is shelf-life, how it is determined

Timeline	Topic	Speaker/Facilitator	Aim
	Determining lot-release specifications	TBD	To review in details how lot-release specifications are determined
	Supporting manufacture consistency	TBD	To review how manufacture consistency testing is designed and interpreted
	Predicting stability	TBD	To review forced degradation studies that are useful in clinical development, heat-stable formulation, demonstration of production consistency
Session 5: Breakout	**Discussion on case studies (3 hours)**		**To facilitate exchange of views on real-life examples**
	Case 1 (TBD) 90 min including study question briefing, group discussion & conclusions	TBD	
	Case 2 (TBD) 90 min	TBD	
DAY 3: Friday, 1 February (09:00 – 15:30)			
Session 6: Plenary	**Conclusion and feedback on case studies (3 hour)**		
	Case 1 (TBD) 90 min including group presentations and responses from the audience	TBD	
	Case 2 (TBD) 90 min	TBD	
Session 7:	**Panel discussion & wrap-up (90 min)**		

Timeline	Topic	Speaker/Facilitator	Aim
Plenary			
	Panel discussion (80 min) Workshop evaluation (5 min) Closing remarks (5 min)		To interact with the audience on specific questions raised during the workshop by the audience To identify further needs of support
15:30	*Close of workshop*		