

## National Validation Forum II - Agenda

Day 1 - Wednesday, 27th June 2012					
Start time		Topic	Presenter		
8:30	9:00	Registration			
9:00	9:10	Welcome and Introduction	Trevor Schoerie		
9:10	9:30	Regulatory update (PIC/S)	Trevor Schoerie	PIC/S updates, PDA-PIC/S conference in Geneva	
9:30	10:10	Reflections on NVF I & DQ	Gordon Farquharson	International perspective	
10:10	10:30	TGA Current Industry issues	Mark Dickson - TGA	Validation	
10:30	11:00	Morning Tea			
11:00	11:20	Common Audit Deficiencies	Mark Dickson - TGA		
11:20	11:40	Risk & criticality assessments	John Montalto		
11:40	12:20	Computer Systems	Andrew Giles - TGA	Validation	
12:20	12:45	Keypad Session	Andrew Watson		
12:45	13:45	Lunch			
<b>Drugs</b>					
13:45	14:45	Validation - Industry perspective	Paul McDonald		
14:45	15:00	Process Validation - Draft EMA vs FDA	Eoin Hanley		
15:00	15:30	Afternoon Tea			
Start time	Topic - Sterile Stream		Facilitator	Topic - Non Sterile Stream	Facilitator

15:30	17:00	Introduction to Product & Facility QTPPs CQAs CPPs Overall Risk Assessment	John Montalto *1	Introduction to Product & Facility QTPPs CQAs CPPs Overall Risk Assessment	Marc Fini *1
15:30	17:00	Day close			
<b>Day 2 - Thursday, 28th June 2012</b>					
Start time		Topic - Sterile Stream	Facilitator	Topic - Non Sterile Stream	Facilitator
9:00	9:10	Recap from Yesterday	John Montalto *1	Recap from Yesterday	Marc Fini *1
9:10	10:30	QBD Control Strategy Risk Assessment for Validation	John Montalto *1	QBD Control Strategy Risk Assessment for Validation	Marc Fini *1
10:30	10:50	Morning Tea		Morning Tea	
10:50	12:45	DQ, IQ, OQ, PQ	John Montalto *1	DQ, IQ, OQ, PQ	Marc Fini *1
12:45	13:45	Lunch		Lunch	
13:45	15:00	Continued Process Verification	John Montalto *1	Continued Process Verification	Marc Fini *1
15:00	15:30	Afternoon Tea		Afternoon Tea	
		Sterile and Non Sterile	Presenter		
15:30	17:00	Q and A panel	TGA and Industry		
17:00	17:00	<b>Day close</b>			

\*1 TGA - Mark Dickson, Noel Fraser and Andrew Giles will circulate