



ACVM Manufacturing Workshop Agenda (WELLINGTON)

Date: Friday 28th July

Time: 9.00am - 4.30pm

Location: Te Papa, Te Huinga Centre (Rangimarie Room 1 & 2), 55 Cable Street, Wellington

Topic	Presenter	Time
Arrive and Network (08:30 - 09:00)		
➤ Welcome & Introductions	HJJ	09:00-09:05
➤ ACVM Update	GB	09:05-09:15
➤ Quality Management	CMO/HJJ/FO	09:15-10:00
➤ Deficiencies/compliance matters & Associated Risks	HJJ	10:00-10:30
Morning Tea (10:30 - 11:00)		
➤ Adverse Event Reporting (AERs)	FO	11:00-11:15
➤ TBD	TBD	11:15-11:45
➤ APIs/Raw Mats (why quality is important)	HJJ	11:45-12:00
➤ TBD	TBD	12:00-12:30
Lunch (12:30 - 13:15)		
➤ Validation (Concept, Process & Cleaning)	CMO	13:15-14:00
➤ Contract Manufacturing	FO	14:00-14:15
➤ VM Chem & Manufacturing Information Req.	AB	14:15-14:45
Afternoon Tea (15:00 - 15:20)		
➤ Split into two groups (Registrants & Manufacturers) - Case Studies & Questions		15:20-16:20
<ul style="list-style-type: none"> • Manufacturers (HJJ, CM, GB) <ul style="list-style-type: none"> - Manufacturing related workshop discussion topics TBD - GMP Programme Review - Questions • Registrants (AB, FO, RB) <ul style="list-style-type: none"> - Discuss registrants' responsibilities when notified of product issue - Application variations, what data to supply and why (Chemistry & Manufacturing related) - Questions 		
➤ Closing Summary	GB/HJJ	16:20-16:30
Closing (16:20-16:30)		

Presenters:

Glen Bradbury (GB) - Manager ACVM Programmes & Appraisals
Holly Jeboult-Jones (HJJ) - Senior Adviser, Manufacturing
Francie Olliver (FO) - Auditor, Regulatory Programmes
Christian Morales Orea (CMO) - Auditor, Regulatory Programmes
Awilda Baoumgren (AB) - Senior Adviser, Food and Trade
Rafael Barbieri (RB) - Adviser, Agricultural Compounds
Guest Speakers - TBD