CARDIFF UNIVERSITY/BRAPP

POSTGRADUATE COURSE IN PHARMACEUTICAL MEDICINE

Drug Safety, Pharmacovigilance and Pharmacoepidemiology

Wednesday 18 October 2017 **etc venues Marble Arch**

08:00 Breakfast available for all delegates

08:30 Welcome and Registration

09:00 Introduction to Module 6 — Dr Madhu Davies

Basics of PV Regulation
ICH, CIOMS – terms and definitions
Brief background history Syllabus coverage 11.2

10:00 Pre-marketing drug safety/clinical trials — Dr Tina Strutt
Syllabus coverage 11.4 and 11.5

11:00 Coffee

11:15 Post-marketing pharmacovigilance — Dr Cheryl Key
Syllabus coverage 11.7, 11.8, 11.10, 11.14

12:15 Lunch

13:00 Risk Mitigation — Tina
Syllabus coverage 11.15, 11.16

14:15 Mechanisms and Classification of ADRs — Tina
Syllabus coverage 11.6

Break

15:30 From Signal to ADR – Detection and Evaluation — Tina
Syllabus coverage 11.13

17:00 Depart

Thursday 19 October 2017 **etc venues Marble Arch**

08:30	**Welcome and breakfast**	
09:00	**Benefit Risk**	Madhu
	Syllabus coverage 11.3	
10:00	**Coffee**	
10:30	**Signal detection exercise**	Madhu
11:30	**Maintaining a PV system (including regulatory inspections and importance of end-to-end cross-functional processes)**	Ruth Casserley
	Syllabus coverage 11.1	
12:15	**Lunch**	
13:00	**Safety Workshop**	Dr Madhu Davies
	With refreshment break	
14:30	**Pharmacoepidemiology**	Madhu
	Syllabus coverage 11.11, 11.12	
15:30	**Review of Module and exam prep**	Madhu
16:00	**Depart**	