



CARDIFF UNIVERSITY/BRAPP
POSTGRADUATE COURSE
IN PHARMACEUTICAL MEDICINE

Medicines Regulation Session

Wednesday 28 November 2018

etc venues Marble Arch

08:00 Breakfast available for all delegates

08:30 Welcome and Registration

09:00 Introduction to Module 7

Dr Madhu Davies

**Background
General Principles
Philosophy of regulatory oversight**

10:00 Refreshment break

Licensing: Routes to approval

12:15 Lunch

**13:00 Advanced Therapy Medicinal Products (ATMP),
Early Access to Medicines Scheme (EAMS)
and Adaptive Pathways**

**Dr Jon Sisson
MHRA**

15:00 Tea

15:15 Renewal and Variations

**Dr Debbie D'Oyley
MHRA**

17:00 Day 1 close

Thursday 29 November 2018**08:30 Welcome and breakfast****09:00 Summary of Product Characteristics****09:30 Reclassification**Dr James Walmsley
Snakestick

10:00 Coffee

11:30 Paediatric Investigation Plans

12:30 Lunch

13:00 Medical Devices

14:15 Refreshment break

14:30 Product defects and recalls**15:00 Drugs of abuse, off-label use/compassionate use****15:30 Orphan drugs****15:55 Recap****16:00 Depart**