Module 21: US Regulation of Medical Devices:

LOCATION: TOPRA OFFICE, LONDON, UK

Module Leader(s): Jonathan Hughes

Date: 25 – 27 September 2019

Wednesday 25th September 2019

Time	Activity	Speaker
13.00 -13.15	**Registration**	
13.15 – 14.00	**Introduction and Housekeeping**	Jonathan Hughes
14.00 – 15.15	**Lecture 1: Introduction to US FDA** History, Structure and Mission of FDA	Jonathan Hughes
15.15 – 15.45	**Refreshment break**	
15.45 -17.15	**Lecture 2: Overview of US Regulatory Process and Pathway** Q-subs	Jonathan Hughes
17.15 – 18.15	**Lecture 3: Classification, Drug Device Listing, Establishment Registration**	Jonathan Hughes
18.15 – 19.00	Student Tutorial Wine Reception	

Date: **Thursday 26th September 2019**

Module 21: US Regulation of Medical Devices:

Time	Activity	Speaker
08.30 – 10.00	**Lecture 4: Submissions: Pre-Market Notification** 510(k)/*De Novo*	Jonathan Hughes
10.00 – 10.30	**Refreshment break**	
10.30 – 11.30	**Lecture 5: Submissions: Pre-Market Approval** PMA, IDE HDE	Jonathan Hughes
11.30 – 12.30	**Lecture 6: Combination Products** RFD	Jonathan Hughes
12.30 – 13.15	Lunch	
13.15 – 17.00	**Case Study**	Jonathan Hughes
17.00 – 19.00	**Case Study** Wrap up and feedback	

Module 21: US Regulation of Medical Devices:

Date: Friday 27th September 2019

08.30 – 09.00	**Review of day 2 and Introduction to day 3**	Jonathan Hughes
09.00 – 10.30	**Lecture 7: *In-Vitro* Diagnostics**	
10.30 – 11.00	**Refreshment Break**	
11.00 – 13.00	**Lecture 8: Labelling and Advertising**	Jonathan Hughes
13.00 – 13.45	**LUNCH**	
13.45 – 14.45	**Lecture 9: Medical Device Reporting**	Jonathan Hughes
14.45 – 15.00	**Refreshment Break**	
15.00 – 16.30	**Lecture 10: Quality Systems Regulations & Inspections**	
16.30	Close of Module	