Generics: Understanding the Regulatory Considerations

Programme
(subject to change)

Chair: Francesca Buttigieg, Novartis

Time	Session	Speaker
09.00	**Registration**	
09.30	**Introduction to TOPRA**	**Samantha Alsbury** TOPRA
09.35	**Welcome and introduction to course**	**Francesca Buttigieg** Novartis
09.45	**Introduction to Generic Medicines** • What is a generic? – Comparison with regions outside the EU **The legislation** • Legal Basis of Generic Applications • Application types • Well established use	**Karin Bracht** MHRA
10.45	**Tea and coffee break**	
11.05	**European Procedures for Generics** • Centralised Procedure • National, MRP and DCP • Referrals • Discussion of Brexit and UK Procedures	**Francesca Buttigieg** Novartis
12.05	**Bioequivalence studies and Biowaivers** • CHMP Bioequivalence Guidance • Design of studies • Evaluation of data • Biowaivers for new submission and variations • New EMA guidance	**Jon Sisson** MHRA
13.00	**Lunch**	
13.45	**Generic medicines: a regulator's perspective** • Potential pitfalls and practical issues experienced with regulatory strategies and dossiers for generic medicines • An agency perspective on common findings arising during regulatory review o Current experience and advice on preparation of the dossier for a generic medicine. Specific considerations for:	**Karin Bracht** MHRA

Time	Session	Speaker
	○ Administrative data (Module 1) ○ Summaries and Overviews (Module 2) ○ Chemistry and Pharmacy (Module 3) ○ Nonclinical data and references (Module 4) ○ Clinical data and references (Module 5) • Overviews and Summaries for generics –what reviewers want to see	
14.25	**Brexit discussion**	
14.55	**Regulatory strategy for a generic pharmaceutical** • Complexities involved when considering the regulatory strategy • Choosing the Reference product • Summary Product Characteristics • Which application procedure to use • How good is your dossier • Impact of Brexit	**Eleanor Higham** Mylan
15.55	**Case Study**	
16.25	**Conclusion**	
17.00	**Close**	