

# 2011 TOPRA Lifelong Learning Hours Overview

Event	Number of LLL hours (per event)
<b>Foundation Courses</b>	
Basics of Regulatory Affairs	5
Veterinary Basics	5
Spring Regulatory Affairs Introductory Course	39
Autumn Regulatory Affairs Introductory Course	39
<b>CRED Courses</b>	
CRED-Introduction to e-working	6
CRED-Advanced e-working	6
CRED- Clinical Development	6 per day
CRED- SmPC, PILs and Labelling	6
CRED-European Regulatory Procedures: strategy and practice	6 per day
CRED Clinical trials	6 per day
CRED Variations	6
CRED Renewals	7
	6
<b>Hot Topic Courses</b>	
Joint TOPRA/EMA European Paediatric Network	6
EMA Annual legislation update	12
<b>TOPRA Annual Symposium</b>	
Pharmaceutical	15
Medical Technologies	7
Veterinary	7
<b>MSc in Regulatory Affairs</b>	
Module 7, Regulatory Strategy for Established Active Substances	120
Module 8, Data Requirements for Abridged Applications and Specialised Products	120
Module 12, Medical Devices Regulatory Affairs	120
Completing the MSc dissertation	240
Completing the MSc: 8 modules 120 hrs each= 960+dissertation 240= 1200 hours per MSc	
<b>MSc in Medical Technology Regulatory Affairs</b>	
Module 1, Principles of European Medical Technology Regulatory Affairs	120
Module 2, Design, Development and Testing of Medical Technology	120
Module 8, Regulatory Strategy in the Market Place	120
Completing the MSc: 8 modules 120 hrs each= 960+dissertation 240= 1200 hours per MSc	

The above hours are subject to review