

2008 TOPRA Lifelong Learning Hours Overview

Event	Number of LLL hours (per event)
Foundation Courses	
Basics of Regulatory Affairs	5
Spring Regulatory Affairs Introductory Course	42
Autumn Regulatory Affairs Introductory Course	29
CRED Courses	
CRED Life Cycle Management: Regulatory Maintenance Activities	7
CRED- Biotechnology: Proteins as Biopharmaceuticals	7
CRED-The Evolving Pharmaceutical Dossier: drug substance and medicinal product	7 per day
CRED-Summary of Product Characteristics, Patient Information Leaflets and Labelling: The SmPC and promotion – strategic issues and planning	6
CRED-European Regulatory Procedures: strategy and practice	6 per day
Hot Topic Courses	
Biotechnology Process validation workshop	6
EMA Annual legislation update	12
TOPRA Annual Symposium	
Pharmaceutical	14
Medical Technologies	6
Veterinary	6
MSc in Regulatory Affairs	
Module 3, Regulatory Requirements for a new active substance: Chemistry and Pharmacy	120
Module 4, Regulatory Strategy for new active substance: Global clinical development	120
Module 12, Medical Devices Regulatory Affairs	120
Module 5, Clinical Research	120
Module 11, US Regulatory	120
Completing the MSc dissertation	240
Completing the MSc: 8 modules 120 hrs each= 960+dissertation 240= 1200 hours per MSc	
MSc in Medical Technology Regulatory Affairs	
Module 3, Clinical evaluation of Medical Technologies	125
Module 4, Management of Regulatory Affairs and its contribution to the Medical Technology lifecycle	125
Module 5, Medical Technology vigilance, post-market surveillance and risk management	125
Module 6, Regulation of <i>in-vitro</i> diagnostic technology and tissue engineered products	125
Completing the MSc dissertation	
Completing the MSc: 8 modules 125 hrs each= 1000+dissertation 200= 1200 hours per MSc	