

# 2008 TOPRA Lifelong Learning Hours Overview for Working Party Members

<b>Event</b>	<b>Number of LLL hours (per event)</b>
<b>Foundation Courses</b>	
Basics of Regulatory Affairs	7
Spring Regulatory Affairs Introductory Course	30
Autumn Regulatory Affairs Introductory Course	30
<b>CRED Courses</b>	
CRED Life Cycle Management: Regulatory Maintenance Activities	15
CRED- Biotechnology: Proteins as Biopharmaceuticals	15
CRED-The Evolving Pharmaceutical Dossier: drug substance and medicinal product	15
CRED-Summary of Product Characteristics, Patient Information Leaflets and Labelling: The SmPC and promotion – strategic issues and planning	15
CRED-European Regulatory Procedures: strategy and practice	15
<b>Hot Topic Courses</b>	
Biotechnology Process validation workshop	17
EMA Annual legislation update	17
<b>TOPRA Annual Symposium</b>	
Pharmaceutical	40
Medical Technologies	21
Veterinary	21
<b>MSc in Regulatory Affairs</b>	
Module 3, Regulatory Requirements for a new active substance: Chemistry and Pharmacy	40
Module 4, Regulatory Strategy for new active substance: Global clinical development	40
Module 12, Medical Devices Regulatory Affairs	40
Module 5, Clinical Research	40
Module 11, US Regulatory	40
MSc Course Director	524
<b>MSc in Medical Technology Regulatory Affairs</b>	
Module 3, Clinical evaluation of Medical Technologies	40
Module 4, Management of Regulatory Affairs and its contribution to the Medical Technology lifecycle	40
Module 5, Medical Technology vigilance, post-market surveillance and risk management	40
Module 6, Regulation of <i>in-vitro</i> diagnostic technology and tissue engineered products	40
<b>Speakers</b>	4 ½ (per 1 ½ hour session)
<b>Chairs of working parties – in addition to above</b>	4 hours (Symposium and other)

special meetings may  
require 2-3 times this)