

Title	The Pharmaceutical Industry - an overview of drug development, manufacture & registration		
Credits	2.5		
Module Places	30		
Elective Places			
Semester			
Level			
Coordinator (UCD)	Michael McGlinchey		
Coordinator (TCD)	Susan Quinn		
Provider	Dr. Cormac Dalton (IMB)		
Indicative Module Descriptor:			
<p>The course is designed to provide students with an overview of the many activities within the pharmaceutical industry. The course will start at the beginning of the drug development process and assess the transition through clinical trials, manufacturing issues and final regulatory approval.</p> <p>Specific areas which will be reviewed include: Drug Development, Manufacturing, Good Manufacturing Practices (GMP), Process Development, Controls & Standards, Registration & Post Marketing Surveillance</p> <p>Indicative Learning Outcomes On successful completion of this module, students should:</p> <ul style="list-style-type: none"> • Have an understanding of wide range of elements in drug development • Appreciate the regulatory and legal elements for drug development • Be able to assess specific chemistry related scenarios and present solutions to every challenges within the pharmaceutical industry <p>Structure Students will attend a total of nine hours of lectures and three hours of discussion tutorials. Lectures will be given in the evening time.</p>			
Workload:	50		
Class Contact:	9		
Workshop	3		
Specified Assignments	13		
Autonomous Student learning {Pre-practical reading and laboratory reports}	25		
Assessment			
	type	% of marks	timing
Successful completion of assignments from workshops and literature assignment	Group problem solving sessions Oral Presentation 100%		