Course code	**IRL106**		
Course title	**DRUG DEVELOPMENT AND REGISTRATION**		
General information			
Study programme	Graduate study „Drug research and development“, Graduate study „ Biotechnology in medicine“, Graduate study „Medical chemistry“	Academic year	1
Lecturer	Dr. Sc. Danijela Štanfel		
Status	**Required**	Elective	
ECTS system			**5**

Course objectives

The goal of this course is to give the basic knowledge of drag development and drag registration in Croatia, EU and global.

Course description

Lectures:	Keynote lecture Regulative aspects of pharmaceutical industry Kind of authorisation procedures Agency for Medicinal Products and Medical Devices of the Republic of Croatia Development of generic medicines Dissolution study and bioequivalence study Registration dossier – CTD format Modul 3 – Quality Modul 4 – Non clinical study reports Modul 5 – Clinical study reports Control of replacement and renewal of registration Patent
Seminars:	EU- legislature and agencies (EMEA, CpMP) USA- legislature and agencies (FDA) Croatian legislature (Croatian Pharmacopoeia 2007) Standardization – ICH Pharmacovigilance
Labs:	Dissolution testing

Learning outcomes

The students will become familar with development way of generic medicine and the CTD registration dossier. They will be able to make the quality evaluation of purchased Registration Dossier and Active Substance Master File retrospectively. They will be able take through the marketing authorisation for a pharmaceutical product.