

Course-No.	Course Title	No. of CPs (according to ECTS):
FCC 1-12	FIRST Core Curriculum	18 (1.5 per FCC-module)

Type of Course	Responsible for the course	Email / tel.-no.
mandatory	Brigitte Held + module coordinator	held@pharmchem.uni-frankfurt.de ; 069 – 798 – 29 801

Course Description

1. Aims
<p>Course participants learn the value chain of drug research, drug development and drug safety</p> <p>Course participants know which tasks and abilities, which knowledge is necessary at the various stations along the value chain</p> <p>Course participants have the ability to communicate with others at the different stations of the value chain</p>

2. Content
<p>Drug research, drug development and drug safety, Value chain (see individual course modules)</p>

3. Course modules					
Module/Course title	type of module/course	hours per week in a semester	CPs	mandatory (M)/elective (e)	Module coordinator
FCC1: Basics of drug development, production and approval	L	2	15	M	Schubert-Zsilavec
FCC2: Genomics, proteomics and pharmacogenomics in target identification	L, S	2	15	M	Stein-hilber
FCC3: Lead identification and optimisation	L, E	2	15	M	Stark
FCC4: Patent law & Project management	L, S, P	2	15	M	Von Laer, together with Schubert-Zsilavec and Alexandrov

<i>FCC5: GLP, GMP and quality control</i>	<i>L, S</i>	<i>2</i>	<i>15</i>	<i>M</i>	<i>Schubert-Zsilavec</i>
<i>FCC6: Pharmacodynamics, pharmacokinetics</i>	<i>L, S</i>	<i>2</i>	<i>15</i>	<i>M</i>	<i>Klein (Geißlinger?)</i>
<i>FCC7: Preclinical pharmacology and toxicology; animal models</i>	<i>L, S</i>	<i>2</i>	<i>15</i>	<i>M</i>	<i>Kalinke (?)</i>
<i>FCC8: Basics in clinical trial management</i>	<i>L, S</i>	<i>2</i>	<i>15</i>	<i>M</i>	<i>Geißlinger (?)</i>
<i>FCC9: Advanced clinical trial management</i>	<i>L, S</i>	<i>2</i>	<i>15</i>	<i>M</i>	<i>Geißlinger (?)</i>
<i>FCC10: Advanced biostatistics</i>	<i>L, S, P</i>	<i>2</i>	<i>15</i>	<i>M</i>	<i>N.N.</i>
<i>FCC11: Regulatory affairs</i>	<i>L, S</i>	<i>2</i>	<i>15</i>	<i>M</i>	<i>Cichutek</i>
<i>FCC12: Business plan, marketing and international trends in drug markets</i>	<i>L, S, P</i>	<i>2</i>	<i>15</i>	<i>M</i>	<i>Schöffski (FAU Erlangen-Nürnberg)</i>

L = lecture; S = Seminar/working in small groups; P = practical; E = excursion

4. Description of teaching and learning format
<p><i>Lectures: overview of the topic, with examples</i></p> <p><i>Working in small groups (ca. 5 participants): developing a (possible) solution to a question arising during the module with subsequent presentation of the results in front of the entire group</i></p> <p><i>Practicals: homework, as course assessment</i></p>

5. Qualification/condition for attendance
<p><i>Registration with Brigitte Held</i></p> <p><i>Prerequisite for module 9 is attendance of module 8</i></p> <p><i>Recommended for all: module 1 (Basics in drug development, production and approval)</i></p>

6. Applicability
<p><i>Getting to know and to develop an understanding of the value chain, drug research, drug development and drug safety</i></p>

7. Amount of work and credit points (CPs)				
Per module:	weeks	hours/week	hours (total)	CPs
<i>Each module</i>	<i>1</i>	<i>14</i>	<i>14</i>	
<i>Exam</i>	<i>1</i>	<i>5</i>	<i>5</i>	
<i>Pre- and postpreparation of the module</i>	<i>1</i>	<i>4</i>	<i>4</i>	
<i>Exam preparation</i>	<i>5</i>	<i>2</i>	<i>10</i>	
			285	15

8. Examination and marking of the course
<i>Regular attendance (attendance list), working in small groups with presentation, practical excercises as homework (e.g. business plan), exam after modules 1-5, 6-9, 10-12 (after one year), MCQ pass/fail (no marks)</i>

9. Duration of the course
<i>3 years (during the semester holidays – Feb./March, Sept./Oct.)</i>

10. Number of participants
<i>Limited (min. 20, max. 36)</i>

11. Registration
<i>With Brigitte Held</i>

12. Literature; lecture notes
<i>Lecture notes will be handed out; further referenced will be given during the modules</i>

13. Other
<i>PhD students: attendance of at least 10 modules, exam for all modules Postdocs, industry employees and others: attendance of individual modules Each module on 2 consecutive days (in agreement with the lecturers/instructors),</i>