



General Information

Module Title *Basics of the development process for regenerative therapies and biopharmaceuticals*

Tutor Name(s) *B. Pfüller*

Location where module takes place *Charité, Charité Campus Virchow Klinikum
Berlin Brandenburg Center for Regenerative Therapies
CVK, Südstraße 2
Seminar room 0.19
19 to 20 August 2009, 09:00 to 12:00 and 13:00 to 16:00*

Suitable for the tracks	<input checked="" type="checkbox"/> <i>Biology/Biochemistry Track</i>		
	<input checked="" type="checkbox"/> <i>Chemistry/Physics/Engineering Track</i>		
	<input checked="" type="checkbox"/> <i>Clinical Scientist</i>		
Type	<i>Workshop;</i>	Level	<i>beginner</i>
Days	<i>3</i>	Max. Participants	<i>20</i>

Objectives this module

The workshop will contain 5 modules

- 1. Basics of the development of regenerative therapies and biopharmaceuticals, production and regulatory affairs*
- 2. GMP, GLP, GCP – Quality standards and quality assurance and its relevance for the development of biopharmaceuticals*
- 3. Non-clinical safety testing of biopharmaceuticals – in vitro and in vivo (pharmacology & toxicology)*
- 4. Clinical safety testing – Basics of Clinical Trials*
- 5. Project Management in biopharmaceutical development and will enable the PhD students to gain an overview on the development process of regenerative therapies and biopharmaceuticals from the first lab experiment to pivotal clinical studies and marketing authorization. It consists of presentations, case studies and group exercises.*

Which course materials, software, or instruments do students use in this module?

What are the prerequisites for taking this subject?



**Berlin-Brandenburg School for Regenerative Therapies
Module Information Sheet**