Module	**Drug Formulation and Biological Test Systems**
Code	MSLS_V2_4
Degree Programme	Master of Science in Life Sciences (MSLS)
ECTS Credits	5
Workload	150 h: Contact 60 h; Self-study 90 h
Module Coordinator	Name Dr. Steffi Lehmann Phone +41 (0) 58 934 50 64 Email steffi.lehmann@zhaw.ch Address ZHAW Zurich University of Applied Sciences Life Sciences and Facility Management Campus Reidbach PO Box CH-8820 Wädenswil
Lecturers	• Steffi Lehmann • Lukas Neutsch • Jack Rohrer • Evelyn Wolfram • Guests
Entry Requirements	The particular Master's module builds on a standard Bachelor's level courses which convey basic knowledge in the following fields (see also textbooks given in brackets): • Pharmaceutical Technology (Bauer K H., Frömming K.-H., Führer C., 2012) Pharmazeutische Technologie, Wissenschaftliche Verlagsgesellschaft Stuttgart) • Molecular Biology of the Cell (Alberts B., Johnson A., Lewis J., Raff M., Roberts K., Walter P., 2007. Molecular Biology of the Cell; Garland Science) • Pharmakologie und Toxikologie (Lüllmann, Mohr, Hein, 2010)
Learning Outcomes and Competences	After completing the module students will be able to: • develop drug formulation and delivery approaches according to known biopharmaceutical, biophysical and biochemical parameters • evaluate the industrial manufacturability and market potential of different drug delivery systems • work out strategies for cell or organ targeting according to available literature data • select the correct configuration of in vitro and in vivo assays (including preclinical imaging readouts) and to assess as well as validate the potency of a future active pharmaceutical ingredient • interpret the test results, to conclude if the drug fulfills the requirements and to determine the point of starting animal experiments

	• use their skills to prepare concepts for the application of medicinal products (especially biological and biotechnological ones) • read and to find the documents to prepare specifications as well as the process and quality documentation for medicinal products • differentiate between functional food, medicinal products and medical devices
Module Content	Course contents of the module “Drug Formulation and Biological Test Systems” comprise innovative strategies of drug formulation, delivery and targeting as well as assays to pre-clinically evaluate the potency of novel drug candidates. Specifically, different approaches for drug delivery used and evaluated today will be discussed. Furthermore, in vitro und in vivo test systems employed for the characterization of pharmacological profiles and assessment of the efficacy of novel drug candidates will be introduced. Some attention will be given to the development of biologics as drug candidates, in particular in the context of novel immune-therapies. In addition, an overview of the current guidelines and regulations related to the administration of pharmaceuticals, medicinal products and foods will provide a basic understanding of the drug approval process. The following topics will be covered: Development and preclinical assessment of biopharmaceuticals/biologics: • Drug design, lead compound identification • Pharmacokinetic and pharmacodynamics profiling of biopharmaceutical drugs • Parenteral drug formulation • Micro- and nanoparticles, liposomes and microvesicles as controlled delivery systems • Therapeutic vaccines, immune-therapies targeting cancer • Drug targeting: active and passive targeting, intracellular and cell-specific targeting • Cell therapy and cell encapsulation (bioencapsulation) The following test systems will be examined in detail: • *In vitro* assays using tissue culture cells: metabolic pathways (molecular biological, biochemical and immunological assays using tissue culture cells), cytotoxicity and genotoxicity assays, microarrays as miniaturized bioassays • Tissue models: skin models, models for the blood-brain barrier, full blood assays • Co-cultures: epithelial tissue in combination with macrophages or leucocytes to check the interaction of the tissue cells with the immune systems The most important guidelines for the application of medicinal products, medical devices and functional food in Switzerland and the European Community will be presented and discussed: • Basic documents for Switzerland: Schweizerisches Heilmittelgesetz, Arzneimittelzulassungsverordnung AMZV, Verordnung über die vereinfachte Zulassung von Arzneimitteln, Medizinprodukteverordnung, Verordnung über Speziallebensmittel (no English versions available) • Basic documents for the EU: DIRECTIVE 2002/46/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the approximation of the laws of the Member States relating to food supplements. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use. Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. • Document applicable worldwide: PIC/S-Guidelines: Quality of Biotechnological Products

Teaching / Learning Methods	contact lessons, group work, case studies, literature search, media supported search for specific documents
Assessment of Learning Outcome	• Written exam 100%
Bibliography	Guidelines mentioned above • Hillery A.M., Lloyd A.W., Swarbrick J. 2001. Drug delivery and targeting for pharmacists and pharmaceutical scientists. Taylor & Francis, London • Mitra A.K., Kwatra D., Vadlapudi A.D., 2014. Drug Delivery. Jones & Bartlett Learning, Burlington, USA • Jorgensen L., Mørck Nielsen H. 2009. Delivery technologies for biopharmaceuticals: peptides, proteins, nucleic acids, and vaccines. John Wiley & Sons, Hoboken, New Jersey • Lovchik R, von Arx C, Viviani A, Delamarche E. 2008. Cellular microarrays for use with capillary-driven microfluidics. Anal Bioanal Chem. 390(3):801-8. • Luginbuehl V., Meinel L., Merkle H.P., Gander B. 2004. Localized delivery of growth factors for bone repair, Eur J Pharm Biopharm. 58(2):197-208. • Mahato R. I. and Narang A. S. 2010. Targeted delivery of small and macromolecular drugs. CRC press, Taylor & Francis, London • Rathore A.S. and Mhatre R. 2009. Quality by design for biopharmaceuticals: principles and case studies. John Wiley & Sons, Hoboken, New Jersey •
Language	English
Comments	
Last Update	13.08.2021