Module Compendium
for the Master`s Degree Program

Pharmaceutical Science & Business,
Master of Science

Status March 1, 2020

Hochschule Reutlingen
Fakultät Angewandte Chemie
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72762 Reutlingen
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Prof. Dr. Alexander Schuhmacher
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M. Sc. Pharmaceutical Science & Business
School of Applied Chemistry
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Status: March 1, 2020
INTRODUCTIVE REMARKS

1. QUALIFICATION PROFILE

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1.2 TARGET GROUP OF THE PROGRAM
1.3 DEGREE AWARDED
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PS2 – PHARMACEUTICAL R&D & INNOVATION
PS3 – THERAPEUTIC MODALITIES & PERSONALIZED MEDICINE
PS4 – PROJECT & PORTFOLIO MANAGEMENT
PS5 – ANALYTICS & QUALITY CONTROL
PS6 – PHARMACEUTICAL DEVELOPMENT & PROCESS DEVELOPMENT
PS7 – PHARMACEUTICAL PRODUCTION & TECHNOLOGY
PS8 – MANAGING ORGANIZATIONS & LEADERSHIP
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Introductive Remarks

This module compendium has been written and the competence profiles (K1-K6) have been defined in accordance with module description principles of the Technical University of Munich (see for this [https://www.ei.tum.de/fileadmin/tueifei/www/Studium_Pruefer/EN_Wegweiser_Modulbeschreibungen_Stand_November_2014-1.pdf](https://www.ei.tum.de/fileadmin/tueifei/www/Studium_Pruefer/EN_Wegweiser_Modulbeschreibungen_Stand_November_2014-1.pdf)).

Competence profiles (according to Anderson and Krathwohl’s Taxonomy):

<table>
<thead>
<tr>
<th>K1</th>
<th>remembering</th>
</tr>
</thead>
<tbody>
<tr>
<td>K2</td>
<td>understanding</td>
</tr>
<tr>
<td></td>
<td>compare, explain, present, translate, illustrate, classify, argue, adapt,</td>
</tr>
<tr>
<td></td>
<td>describe, extrapolate, illuminate, discuss</td>
</tr>
<tr>
<td>K3</td>
<td>applying</td>
</tr>
<tr>
<td></td>
<td>carry out, demonstrate, execute, measure, solve, conduct, predict, modify,</td>
</tr>
<tr>
<td></td>
<td>operate, use, implement</td>
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<tr>
<td>K4</td>
<td>analyzing</td>
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<tr>
<td></td>
<td>comparing, organizing, deconstructing, attributing, outlining, structuring,</td>
</tr>
<tr>
<td></td>
<td>integrating</td>
</tr>
<tr>
<td>K5</td>
<td>evaluating</td>
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<tr>
<td></td>
<td>checking, hypothesizing, critiquing, experimenting, judging, testing,</td>
</tr>
<tr>
<td></td>
<td>detecting, monitoring, differentiating</td>
</tr>
<tr>
<td>K6</td>
<td>creating</td>
</tr>
<tr>
<td></td>
<td>designing, constructing, planning, producing, inventing, devising, making,</td>
</tr>
<tr>
<td></td>
<td>generating</td>
</tr>
</tbody>
</table>

Fig. 1: Competence profiles according to Anderson and Krathwohl’s taxonomy; taxonomy and format derived from [https://www.ei.tum.de/fileadmin/tueifei/www/Studium_Pruefer/EN_Wegweiser_Modulbeschreibungen_Stand_November_2014-1.pdf](https://www.ei.tum.de/fileadmin/tueifei/www/Studium_Pruefer/EN_Wegweiser_Modulbeschreibungen_Stand_November_2014-1.pdf)

The module compendium serves the purpose of providing participants and lecturers a detailed and comprehensive description of the curriculum of the degree program M.Sc. Pharmaceutical Science & Business. In addition to language and type of course, it presents the module goals and desired outcomes as well as details the content of the individual courses. Furthermore, it describes the examination type and duration as well as the literature recommended.
1. Qualification Profile

1.1 Aim of the program

The study program is designed to qualify graduates for various functions and roles in the pharma and biotech industry. It aims at developing pharma generalists with

- a profound understanding of the pharma and biotech industry and its principles,
- specialized knowledge of the various concepts, methods and regulations of pharmaceutical product development and manufacturing,
- a profound skill set and practice-oriented competencies to work in agile and project-driven organizations,
- an international and integrative mindset, and
- an understanding of technological trends and future directions in the life science sector.

1.2 Target group of the program

- Graduates of bachelor programs (or comparable degrees) who want to start their professional career in the pharma and biotech sector.
- Experienced professionals with an academic background (minimum bachelor degree), who are seeking new career paths and that have identified the pharma and biotech sector as an attractive branch for their professional goals.
- Future managers who want to shape their professional career in a growth industry.

1.3 Degree awarded

Master of Science (M.Sc.)

1.4 Concept of the program and duration of studies

The program is conceptualized to be studied in 4 semesters (90 ECTS) while working in a pharma, biotech or life science-related company.

1.5 Learning goals and objectives

Graduates of the M.Sc. Pharmaceutical Science & Business will have acquired

- academically well-founded professional competencies enabling them to perform in the science-driven pharma and biotech industry,
• a wide range of professional, personal and social skills to successfully interact in an international environment,

• an understanding of the significance of quality standards and the impact of personal commitment thereto,

• profound presentation and communication skills to behave in a way appropriate to a professional environment, and

• intercultural competencies to reflect upon the cultural context of risk-adjusted and sustainable corporate decisions.
2. Structure of the study program

The study program consists of fourteen modules. Each module is composed of various courses contributing to the learning outcome of the module. The curriculum comprises four core areas:

- **Pharma fundamentals (modules PS1-3):** introduction to pharmaceutical industry and business; pharmaceutical R&D and innovation; therapeutic modalities and personalized medicine
- **Functional themes (modules PS5-7):** analytics and quality control; pharmaceutical development and process development; pharmaceutical production and quality management
- **Emerging themes (modules PS9, PS10, PS12):** exponential technologies and future perspectives; agile working and workforce of the future; transformation projects (elective, international module)
- **Integrative subjects (modules PS4, PS8, PS11 and PS13):** project and portfolio management; managing organizations and leadership; business development and business planning; data science and scientific working.
- **Master thesis (module PS14)**
- **Research project, internship practical experience (optional module PS15)**

The following figure provides an overview of the program structure and sequence:

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1 Mandatory for students with a bachelor degree of less than 180 ECTS
## 4. Module Description

### PS1 – Introduction to pharmaceutical industry & business

#### Studienprogramm / Course of studies:
- Pharmaceutical Science & Business (M.Sc.)

#### Modulverantwortlicher / Responsible person for the module:
- Prof. Dr. Alexander Schuhmacher

<table>
<thead>
<tr>
<th>Modul / Module:</th>
<th>Introduction to pharmaceutical industry &amp; business</th>
<th>Dozent(inen) / Lecturer(s):</th>
</tr>
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<tbody>
<tr>
<td>Code</td>
<td>PS1</td>
<td>1: Prof. Dr. Alexander Schuhmacher</td>
</tr>
<tr>
<td>Semester</td>
<td></td>
<td>2: Prof. Dr. Alexander Schuhmacher</td>
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<td>Sprache / Language:</td>
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<td>3: Prof. Dr. Alexander Schuhmacher</td>
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<td>Studien / Status:</td>
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<tr>
<td></td>
<td></td>
<td>5: Prof. Dr. Alexander Schuhmacher</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6: Prof. Dr. Alexander Schuhmacher</td>
</tr>
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</table>

#### Veranstaltungstyp / Type of course:
- Kurs / course: 6

<table>
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<th>Kurs / course:</th>
<th>Unterricht / class:</th>
<th>Selbststudium / Self-study:</th>
<th>Gesamt / total:</th>
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<tr>
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</tr>
<tr>
<td>1</td>
<td>general considerations in the healthcare and pharma industries</td>
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<td>X</td>
</tr>
<tr>
<td>2</td>
<td>the pharma industry challenges: science, technology, pipeline, sourcing, regulation</td>
<td>16.15</td>
<td>12.5</td>
</tr>
<tr>
<td>3</td>
<td>basic principles of inventions and patentability</td>
<td>12.5</td>
<td>12.5</td>
</tr>
<tr>
<td>4</td>
<td>basic principles of drug pricing and reimbursement</td>
<td>12.5</td>
<td>12.5</td>
</tr>
<tr>
<td>5</td>
<td>excursion: pharmaceutical company</td>
<td>12.5</td>
<td>12.5</td>
</tr>
</tbody>
</table>

#### Arbeitsaufwand / workload (h):
- V: 12.5, U: 12.5, E: 12.5, C: 12.5

#### ECTS-Punkte / ECTS-Credits:
- 5

#### Modulziele / module goals and desired outcomes:

**Professional competencies**
- to understand how pharmaceutical business works and how it changes. (K2)
- to analyze the pharmaceutical industry and its key players. (K4)
- to evaluate the key challenges that are driving the industry and its R&D models. (K5)
- to outline the pharmaceutical value chain (from idea to market). (K4)
- to apply the basic principles of patentability and patents. (K3)
- to apply the basic principles of drug pricing and reimbursement. (K3)
- to compare pharma business models. (K4)

**Methodologische Fähigkeiten / Methodological competencies:**
- to discuss legal (patent right) and scientific information. (K2)
- to carry out a patent search. (K3)
- to apply the basic criteria for a patentability analysis. (K3)

**fachliche Fähigkeiten / Professional competencies**
- to compare the various concepts and combine it with practical thinking. (K2)
- to argue with integrative ability. (K2)
- to argue objectively. (K2)
- to discuss potential problems. (K2)

**Erkenntnisse / Knowledge:**
- General considerations of the healthcare sector and the pharmaceutical industry:
  - Role of healthcare, healthcare segments, role of pharmaceutical and biotech industries, economics, development of pharmaceutical sector, key trend and growth drivers, ethical vs. generic/biosimilar business, OTC business, pharmaceutical markets, blockbuster drugs
  - The productivity paradox, the blockbuster imperative, patent cliffs, five forces of the drug industry, drug discovery technologies, in- and outsourcing, internationalization of R&D, basic principles of the regulatory framework, e.g. Food and Drug Administration (FDA), European Medical Agency (EMA), Orphan Drugs, orphan medicines, Good Laboratory Practices (GLP), Good Clinical Practice (GCP), Orphan Drugs, orphan medicines, Good Laboratory Practices (GLP), Good Clinical Practice (GCP), Good Manufacturing Practices (GMP), pharmaceuticals and new device regulation, trends for the coming years
  - Leading pharma and biotech companies and pharmaceutical pipelines:
    - Top 20 pharmaceutical companies (profiles, positioning, markets, R&D franchises): Top 20 pharma companies, technologies used, main therapeutic areas and franchises, value creation in R&D, R&D spendings
    - R&D pipelines of leading pharmaceutical companies (therapeutic areas, core technologies, future perspectives)
    - Global biotech industry, leading biotech companies, market positioning and economics value added
    - Number of new drug approvals at the Food and Drug Administration (FDA) over time, market shares
  - Basic principles of inventions and patentability:
    - European Patent Convention (EPC), Patent Cooperation Treaty (PCT), Paris Convention, invention, patentability criteria according to the EPC, priority, patent term, right to the patent, right of the patent, patent life cycle, Arbeitsnehmerrfähigkeitszusage, Diensterfindung, Frei-Einführung, Infringsfähigkeit, frei-Einführung, Einführungsfähigkeit, Einführungsvorgang
  - Basic principles of pricing and reimbursement:
    - Health care challenges, market access (definition, gatekeepers, national pricing committees, prices), drug purchasing, prices and value assessments (incremental / comparative health benefit, cost-effectiveness assessment), health economics (health technology assessment [HTA], process, cost-benefit analysis, cost minimization analysis), pricing (setting the right price, pricing policy, therapeutic reference pricing, internal / external reference pricing, value-based pricing), reimbursement (pricing and reimbursement process in key European markets, market entry strategies, early patient access, managed entry agreements, market access trends)

**Ausbildung / Training:**
- visiting a pharma company, e.g. a manufacturing site (Vetter Pharma)
### PS1 – Introduction to pharmaceutical industry & business (cont.)

<table>
<thead>
<tr>
<th>Prüfungsort und Dauer / examination type and duration:</th>
<th>Presentation (50%), Written examination (50%), 1h</th>
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</thead>
<tbody>
<tr>
<td>Medienutzung / media used:</td>
<td>Script to download, student presentation, digital projector, handouts, flip chart</td>
</tr>
<tr>
<td>Lehren und Lernmethodik / teaching and learning methodology:</td>
<td>A mixture of methodologies is applied, e.g. primarily lecture and interactive teaching with case-studies, combined with team works, case-in-points and an excursion; students need to write a term paper in preparation of this module</td>
</tr>
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</table>
### PS2 – Pharmaceutical R&D & Innovation

#### Studiengang / Course of studies:
- Pharmaceutical Sciences & Business (M.Sc.)

#### Modul / Module:
- Pharmaceutical R&D & Innovation

#### Dozent(en) / Lecture(s):
1. Prof. Dr. Alexander Schuhmacher
2. Prof. Dr. Alexander Schuhmacher
3. Prof. Dr. Markus Hinder
4. Prof. Dr. Markus Hinder
5. Prof. Dr. Rumen Krastev

#### Code:
- PS2

#### Semester:
- 1

#### Sprache / Language:
- DE/EN

#### Status:
- Mandatory

#### Veranstaltungsart / Type of course:

<table>
<thead>
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<th>Kurs / course:</th>
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<th>U</th>
<th>E</th>
<th>C</th>
<th>CO</th>
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<tr>
<td>2. Pharmaceutical innovations and breakthrough therapies</td>
<td>X</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Principles of drug discovery and development</td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Clinical trials, clinical safety/efficacy, and translational medicine</td>
<td>X</td>
<td>X</td>
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</tr>
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<td>5. Excursion: drug discovery</td>
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</table>

#### Arbeitsaufwand / Workload (h):

<table>
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<tr>
<th>Kurs / course:</th>
<th>Unterricht / class:</th>
<th>Selbststudium / self-study:</th>
<th>Gesamt / total:</th>
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<td>18.75</td>
<td>37.5</td>
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<td>25</td>
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<tr>
<td>3. Principles of drug discovery and development</td>
<td>12.5</td>
<td>12.5</td>
<td>25</td>
</tr>
<tr>
<td>4. Clinical trials, clinical safety/efficacy, and translational medicine</td>
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<td>18.75</td>
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<td>Gesamt / total:</td>
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<td>62.5</td>
<td>125</td>
</tr>
</tbody>
</table>

#### ECTS-Punkte / ECTS-Credits:
- 5

#### Voraussetzungen für die Teilnahme am Kurs / Prerequisites for attending the course:
- None

#### Moduleziele bzw. erwünschte Ergebnisse / module goals and desired outcome:
- Upon successful completion of this module, students are able...
  - to outline how pharmaceutical R&D works principally. (K4)
  - to outline the relevance of innovation for the pharmaceutical industry. (K4)
  - to describe the scientific principles of drug discovery and development. (K2)
  - to describe the role of translational medicine in context of drug development. (K2)

  **Methodological competencies:**
  - ... to apply the systems of drug classification and drug names. (K3)
  - ... to understand the prototypic drug discovery technologies. (K2)
  - ... to understand the clinical trial management principles. (K2)

  **Social competencies:**
  - ... to execute team work. (K3)
  - ... to build relationship with an open mind. (K6)

  **Personal competencies:**
  - ... to apply conceptual thinking. (K3)
  - ... to discuss with integrative ability. (K2)
  - ... to judge objectively. (K5)

#### Inhalt / content:
- **Basic principles of pharma R&D process and innovation management:**
  - Basic terms and basic principles of innovation/innovation management, such as idea, ideation, innovation, strategic and operational innovation management, innovation process, key drivers of innovation, innovation trends, product innovation, process innovation business model innovation, pharma R&D process (phases, stages, key milestones, timing, probabilities, costs), basics are supplemented by pharma-specific case-in-points and specific examples

- **Pharmaceutical innovations and breakthrough therapies**
  - Drug classification, drug nomenclature, chemical names, non-proprietary names, generic naming system, drug classes, key pharma innovations and breakthrough therapies exemplified by antiviral drugs, antibiotics, monoclonal antibodies, proton-pump inhibitors, beta-blockers, and PDE5-inhibitors; drug action and medical uses

- **General principles of drug discovery and development:**
  - Principles, process, content, milestones and deliverables of target identification, target validation, lead finding, lead optimization, preclinical development, clinical development (Phase 1-3), and proof-of-concept basics are supplemented by pharma-specific examples and case-in-points

- **Excursion: drug discovery**
  - Visit of the NMI Reutlingen (https://www.nmi.de/de/) and get insights into the topics of biomarker development, proteomics and bioanalytics, molecular cell biology and cellular test systems.
<table>
<thead>
<tr>
<th>Prüfungsform und Dauer / examination type and duration:</th>
<th>Written examination (100%), 1h</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mediennutzung / media used:</td>
<td>Script to download, student presentation, digital projector, handouts, flip chart</td>
</tr>
<tr>
<td>Lehre- und Lernmethodik / teaching and learning methodology:</td>
<td>A mixture of methodologies is applied, e.g. primarily lecture and interactive teaching with discussions, combined with team works, case-in-points and an excursion; students need to write a term paper in preparation of this module</td>
</tr>
</tbody>
</table>
| Empfohlene Literatur / Recommended literature: | Oliver Gassmann, Alexander Schuhmacher, Max Zedtwitz, Gerrit Reepmeyer. Leading pharmaceutical Innovation: How to Win the Life Science Race. Springer. 2018  
Ena Ray Banerjee. Perspectives in Translational Research in Life Sciences and Biomedicine: Translational Outcomes Research in Life Sciences and Translational Medicine. Springer. 2018  
Gassmann, O.; Sutter, P. Praxiswissen Innovationsmanagement: Von der Idee zum Markterfolg. HANSER. 2013  
Recent scientific publications in the respective field |
# PS3 – Therapeutic Modalities & Personalized Medicine

**Studienprogramm / Course of studies:** Pharmaceutical Sciences & Business (M.Sc.)

**Modulverantwortlicher / Responsible person for the module:** Prof. Dr. Ralf Kemkemer

**Modul / Module:** Therapeutic Modalities & Personalized Medicine

**Sprache / Language:** DE/EN

**Semester:** 1

**Sprache / Language:** DE/EN

**Veranstaltungsart / Course:**

<table>
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<tr>
<th>Type of course</th>
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<td>1. Basics in pharmacology and drug targets</td>
</tr>
<tr>
<td>U</td>
<td>2. Basics of biologicals</td>
</tr>
<tr>
<td>E</td>
<td>3. Principles of pharmaceuticals and biopharmaceuticals</td>
</tr>
<tr>
<td>C</td>
<td>4. Principles of personalized medicine and related technologies</td>
</tr>
</tbody>
</table>

**Arbeitsaufwand / workload (h):**

<table>
<thead>
<tr>
<th>Course:</th>
<th>Unterricht / class</th>
<th>Selbststudium / self-study</th>
<th>Gesamt / total</th>
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<tr>
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<td>12.5</td>
<td>25</td>
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<tr>
<td>2. Basics of biologicals</td>
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<td>12.5</td>
<td>25</td>
</tr>
<tr>
<td>3. Principles of pharmaceuticals and biopharmaceuticals</td>
<td>12.5</td>
<td>12.5</td>
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<tr>
<td>4. Principles of personalized medicine and related technologies</td>
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<td>50</td>
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<tr>
<td>Total</td>
<td>62.5</td>
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**ECTS-Punkte / ECTS-Credits:** 5

**Voraussetzungen für die Teilnahme am Kurs / prerequisites for attending the course:** None

**Moduleziele bzw. erwünschte Ergebnisse / module goals and desired outcome:**

- upon successful completion of this module, students are able...

**Professional competencies:**

- to outline the various drug target classes. (K4)
- to discuss drug formats and the basics of the underlying pharmacology. (K2)
- to understand therapeutic modalities. (K2)
- to outline the principles and options of personalized medicine and to illustrate the underlying paradigms and technologies. (K4)

**Methodological competencies:**

- to define and renew technical depth and breadth in the field of therapeutic modalities. (K1)
- to describe principles of drug targets. (K2)
- to explain "the rule of five". (K2)
- to classify physicochemical properties with respect to ADME parameters. (K2)

**Social competencies:**

- to execute team work. (K3)

**Personal competencies:**

- to apply conceptual thinking. (K3)
- to demonstrate analytical thinking. (K3)
- to demonstrate the ability to read and understand scientific publications. (K3)
- to demonstrate the ability to do scientific research and to present scientific findings. (K3)

**Inhalt / content:**

**Basics in pharmacology and drug targets:**

- Mechanism-of-action, receptors, agonism/antagonism, pharmacodynamics, pharmacokinetics, efficacy, safety, target classes, G-protein-coupled receptors, ion channels, kinases, proteases, drug/ligand interaction, drug-drug interactions, metabolism, clearance, pharmacogenetics, therapeutic index, therapeutic window, therapeutic monitoring

**Basics of biologicals:**

- Recombinant DNA, biology of biologicals (recombinant proteins, peptides, monoclonal antibodies, nucleic acids (siRNA), vaccines, hormones), drug formats, therapeutic uses of biologicals (e.g. cancer treatments, treatments of autoimmune diseases), breakthrough therapies (Rituximab, Trastuzumab, adalimumab)

**Principles of pharmaceuticals and biopharmaceuticals:**

- Pharmaceutical drug product, active product ingredient (API), drug (chemical) properties, drug administration, drug formulation, Lipinski rule of five, drug pharmacokinetics in the human body (ADME)

**Principles of personalized medicine and related technologies:**

- Disease stratification, disease subtypes, endotypes, enrichment, prediction, surrogate markers, genomics, genetics, epigenetics, transcriptomics, proteomics, metabolomics, microbiomics, radiomics, imaging, diagnostics, companion diagnostics, complementary diagnostics, digitals, disease-risk assessment, drug development process, population screening, reimbursement
### PS3 – Therapeutic Modalities & Personalized Medicine (cont.)

| Prüfungsform und Dauer / examination type and duration: | Presentation (50%)  
| Written examination (50%), 1h |
| Mediennutzung / media used: | Script to download, student presentation, digital projector, handouts, flip chart |
| Lehr- und Lernmethodik / teaching and learning methodology: | A mixture of methodologies is applied, e.g. primarily lecture and interactive teaching with discussions, combined with team works and case-in-points; students need to write a term paper in preparation of this module |
Recent scientific publications in the respective field |
### Modul / Module: Project & Portfolio Management

#### Code: PS4

#### Responsible person for the module:
- 1. Michael Kuss
- 2. Ul. Fördertmarter
- 3. Michael Kuss
- 4. Prof. Dr. Alexander Schuhmacher

#### Lecturer(s):
- 1. Michael Kuss
- 2. Dr. Friedrich Harder

#### Language: DE/EN

#### Status: Mandatory

#### Type of course:
- 1. Basics in project management
- 2. Case study: Pharma project management
- 3. Agile project management
- 4. Portfolio management and product life cycle management

#### Course:
<table>
<thead>
<tr>
<th>Course</th>
<th>Unterricht / class</th>
<th>Selbststudium / self-study</th>
<th>Gesamt / total</th>
</tr>
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<tbody>
<tr>
<td>1. Basics in project management</td>
<td>25</td>
<td>25</td>
<td>50</td>
</tr>
<tr>
<td>2. Case study: Pharma project management</td>
<td>12.5</td>
<td>12.5</td>
<td>25</td>
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<tr>
<td>3. Agile project management</td>
<td>12.5</td>
<td>12.5</td>
<td>25</td>
</tr>
<tr>
<td>4. Portfolio management and product life cycle management</td>
<td>12.5</td>
<td>12.5</td>
<td>25</td>
</tr>
</tbody>
</table>

**Total:** 62.5

#### ECTS-Credits:
- 5

### Prerequisites for attending the course:
- None

### Upon successful completion of this module, students are able...

#### Professional competencies:
- ... to discuss the principles of portfolio and product life cycle management. (K2)
- ... to execute the principles of project management. (K3)
- ... to use the principles of risk management. (K3)
- ... to structure the project work and tasks. (K4)

#### Methodological competencies:
- ... to carry out a SWOT analysis (K3)
- ... to execute a risk analysis (K3)
- ... to conduct a stakeholder analysis (K3)
- ... to conduct a NPV calculation. (K3)
- ... to organize a project team. (K4)
- ... to monitor the project progress. (K5)
- ... to plan a project. (K6)

#### Social competencies:
- ... to communicate with impact. (K5)
- ... to build relationship with an open mind. (K3)
- ... to organize team work. (K4)
- ... to personally compare with the pharmaceutical industry. (K4)

#### Personal competencies:
- ... to develop a result-oriented and creative working culture. (K6)

### Inhalt / content:

#### Basics in project management:
Project, exemplary projects, basic considerations, guidance to project management, ISO21500, scope, terms and definitions, project management concepts, project management process, project process groups, project planning, project progress, monitoring, resolving issues, PMI triangle, SWOT analyses, SMART method, risk analysis, risk response plan, stakeholder analysis, project phases and milestones, work breakdown structure (WBS), project team, team composition, team meetings, project team leadership, role of the project leader, role of the team members

#### Case study Pharma project management:
Organizational structures (matrix types), Project types, project governance, project committees, project decision-making, project as social system, project crisis and escalation, lessons learnt from historical projects, project management standards in Pharma, project life cycle, stakeholder management (internal and external / customers) and -communication

#### Agile project management:
Agile manifesto, principles of agile project management, agile roles, agile methodologies, agile teams, agile tools, scrum framework, sprint planning, tracking progress, sprint review, value-driven project management, benefits of agile project management,

#### Portfolio management and product life cycle management:
Pharma projects, programs, portfolio, stage-gate-model, portfolio analysis, evaluation criteria (drugability, patentability, freedom-to-operate, technical feasibility, market share), portfolio management, costs, time, probabilities, cost of goods (COGS), pricing, net present value (NPV), project prioritization, resource allocation, portfolio optimization

Product life cycle in the pharmaceutical industry, effects of life cycle management, options in product life cycle management, prevention (strategic patenting, supplementary protection certificate, orphan drug status), extraction (harvesting full potential, licensing), adaptation (generic strategy), innovation (line extension, broaden indication scope, follow-on strategy, prescription (Rx)-to-over-the-counter (OTC) switch)
### PS4 – Project & Portfolio Management (cont.)

<table>
<thead>
<tr>
<th>Prüfungsf orm und Dauer / examination type and duration:</th>
<th>Written examination (50%), 1h</th>
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<tr>
<td>Medienutzung / media used:</td>
<td>Script to download, student presentation, digital projector, handouts</td>
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<tr>
<td>Lehr- und Lernmethodik / teaching and learning methodology:</td>
<td>A mixture of methodologies is applied, e.g. primarily lecture and interactive teaching with discussions, combined with team works and case-in-points</td>
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### PSS – Analytics & Quality Control

<table>
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<th>Modul / Module:</th>
<th>Analytics &amp; Quality Control</th>
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<tr>
<td>Code:</td>
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<tr>
<td>Prerequisite</td>
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<tr>
<td>Type of course</td>
<td>Mandatory</td>
</tr>
<tr>
<td>ECTS-Credits</td>
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</table>

#### Course Goals and Desired Outcomes:

- Basics in analytics:
- Risk and resilience management:
- Insight into the regulatory framework:
- Quality control, quality assurance and quality management systems:

#### Course Content:

- Basics in analytics:
- Risk and resilience management:
- Insight into the regulatory framework:
- Quality control, quality assurance and quality management systems:

#### Professional Competencies:

- To illustrate chemical and bio-analytical methods used in pharmaceutical development and manufacturing. (K2)
- To outline analytical questions and suggest appropriate analytical methods. (K4)
- To describe the various guidelines relevant for pharmaceutical development and manufacturing. (K2)
- To demonstrate a profound understanding of QC- and QA-systems and processes including the GMP-QC lab responsibility. (K3)
- To compare the strategic and operational impact of regulatory affairs in the drug R&D and production process. (K4)
- To analyzing the various regulations relevant for developing and manufacturing drugs. (K4)

#### Methodological Competencies:

- To understand the various analytical methods underlying regulatory rules and quality standards. (K2)
- To compare and differentiate regulatory standards and practices. (K4, K5)

#### Social Competencies:

- To demonstrate accountability for other. (K3)

#### Personal Competencies:

- To demonstrate customer-orientation. (K3)
- To demonstrate commitment to job and responsibility. (K3)
- To demonstrate personal accountability. (K3)
- To integrate pro-active quality thinking. (K4)

#### Inhalt / content:

- Basics in analytics:
- Risk and resilience management:
- Insight into the regulatory framework:
- Quality control, quality assurance and quality management systems:

#### Australia / semester / module goals and desired outcome:

- Basics in analytics
- Risk and resilience management
- Insight into the regulatory framework
- Quality control, quality assurance and quality management systems
### Prüfungsform und Dauer / examination type and duration:

| Written examination (100%), 1h |

### Mediennutzung / media used:

| Script to download, student presentation, digital projector, handouts, flip chart |

### Lehr- und Lernmethodik / teaching and learning methodology:

| A mixture of methodologies is applied, e.g., primarily lecture and interactive teaching with discussions, combined with team work and an on-site training |

### Empfohlene Literatur / recommended literature:

| AMWHV – Arzneimittel und Wirkstoffherstellungsverordnung; https://www.gesetze-im-internet.de/amwhv/ |
| AMG – Arzneimittelgesetz; https://www.gesetze-im-internet.de/amwhv/ |
| http://academy.gmp-compliance.org/guidemgr/files/GMP-LEITFADEN_TEIL%20II%20WIRKSTOFFE_ERGAENZT.PDF |
| https://www.gmp-berater.de/showdoc/GMP-BERATER/GMP-Regularien/H-EU-GMP-Leitfaden/H33-EU-GMP-Leitfaden-Teil-III-8211-GMP-bezogene-Dokumente?docId=docs/h03_3.html&alias=GMPReg_H_3_3_EndAll&activeToolbarTab=document&startSite=false&fdl=false&event=navigation&from=tree |
| Amborn, J et al. (2009) GMP/FDA-Anforderungen an die Qualitätssicherung - Qualitätssicherungssystem, GMP-Compliance, Lieferantenqualifizierung, GMP-relevante Verträge. Edlito Cantor Verlag |
### PS6 – Pharmaceutical Development & Process Development

**Course of studies:** Pharmaceutical Sciences & Business (M.Sc.)

**Module:** Pharmaceutical Development and Process Development

**Module responsible person:** Prof. Dr. Günter Lorenz

**Type of course:** Lecture(s) / Seminar / Lab

**ECTS credits:** 6

**Voraussetzungen für Teilnahme am Kurs / prerequisites for attending the course:** None

<table>
<thead>
<tr>
<th>Arbeitsaufwand / workload (h)</th>
<th>Unterricht / class</th>
<th>Selbststudium / Self-study</th>
<th>Praktikum / Practicum</th>
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</thead>
<tbody>
<tr>
<td>1. Basics and principles of pharmaceutical development</td>
<td>25</td>
<td>12.5</td>
<td>37.5</td>
</tr>
<tr>
<td>2. Basics and principles of drug-device combinations</td>
<td>12.5</td>
<td>7.5</td>
<td>25</td>
</tr>
<tr>
<td>3. Basics and principles of pharmaceutical process development</td>
<td>25</td>
<td>12.5</td>
<td>37.5</td>
</tr>
<tr>
<td>4. Case studies: Lyophilization and Pharma project review</td>
<td>25</td>
<td>5</td>
<td>30</td>
</tr>
<tr>
<td>Gesamt / Total</td>
<td>87.5</td>
<td>37.5</td>
<td>125</td>
</tr>
</tbody>
</table>

### Professional competencies:
- To outline the principles of pharmaceutical development and pharmaceutical process development. (K4)
- To describe quality by design. (K2)
- To understand how pharmaceutical dosage forms are developed and qualified. (K3)
- To understand the principles of process validation. (K2)
- To outline QC method development and transfer. (K4)
- To understand pharmaceutical unit-operations including lyophilization. (K2)
- To understand the setting of analytical product specifications. (K2)
- To outline devices and drug device combinations. (K4)
- To understand the principles of lyophilization, its principles, technologies and applications. (K2)

### Methodological competencies:
- To outline the different steps of pharmaceutical development. (K4)
- To assess which physicochemical criteria the active product ingredient need to meet. (K3)
- To develop solution concepts for bioavailability problems. (K3)
- To adhere to regulatory rules and quality standard practices. (K3)
- To understand the method of continuous process verification. (K2)

### Social competencies:
- To execute team work. (K3)
- To build relationship with an open mind. (K3)

### Personal competencies:
- To apply conceptual and practical thinking. (K3)
- To develop commitment to job. (K6)

### Inhalt / content:
**Basics and principles of pharmaceutical development:**
- Pharma R&D process and context of pharmaceutical development, principles of preclinical development, basics in physicochemistry and biopharmacy, basics of Quality by Design (QbD), drug administration forms, analytical procedures and validation, regulatory rules in context of pharmaceutical development (e.g. ICH Q2 Validation of Analytical Procedures, ICH Q8 Pharmaceutical Development, ICH Q9 Quality Risk Management, ICH Q10 Pharmaceutical Quality System), GLP quality requirements, EU legal framework, Directives 2004/9/EC and 2004/10/EC

**Basics and principles of drug-device combinations:** material science, components, regulations
- Components: glass, rubber, polymers and others
- How are they made? How are combinations developed?
- Regulatory framework for medical devices and combination products
- Qualification and functional testing of combination products
- Device development: pens, autoinjectors, wearable injectors etc.

**Basics and principles of pharmaceutical process development:**
- Development of qualified processes according to ICH Q8 and other guidelines
- Quality by design, risk-based approaches with bracketing and matrrixing, and examples. Also examples on abridged development for orphan drugs. Also examples of authorities not accepting ICH Q8 and how to deal with this
- Continuous process verification (CPV): data monitoring and evaluation on a continuous basis

**Case studies:** Lyophilization and pharma project review
1. Lyophilization (principles, technologies and applications)
   - Physical principles for lyophilisation, lyophilisation technology, process development for state-of-the-art drying processes based on physical formulation properties, lab-scale work, at-scale work including robustness-runs and multi-dosage, multi-vial qualification
2. Pharma project review from the pharmaceutical-technical and product perspective
   - Review of an executed final dosage form project from start to commercialization including adaptations to the original plan, learnings and how they will be applied to future projects
### PS6 – Pharmaceutical Development & Process Development (cont.)

<table>
<thead>
<tr>
<th>Prüfungsfund und Dauer / examination type and duration:</th>
<th>Written examination (100%), 1h</th>
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<tbody>
<tr>
<td>Mediennutzung / media used:</td>
<td>Script to download, student presentation, digital projector, handouts, flip chart</td>
</tr>
<tr>
<td>Lehrr- und Lernmethodik / teaching and learning methodology:</td>
<td>A mixture of methodologies is applied, e.g. primarily lecture and interactive teaching with discussions, combined with team works and an excursion</td>
</tr>
<tr>
<td>Empfohlene Literatur / recommended literature:</td>
<td>Bauer, Frömmig, Führer (2016) Lehrbuch der Pharmazeutischen Technologie: Mit Einführung in die Biopharmazie und Biotechnologie. WVG mbh Stuttgart</td>
</tr>
<tr>
<td></td>
<td>Rey, Louis; May, Joan (2010) Freeze-Drying/Lyophilization of Pharmaceutical and Biological Products. Informa Healthcare</td>
</tr>
<tr>
<td></td>
<td>Recent scientific publications in the respective field</td>
</tr>
</tbody>
</table>
### PS7 - Pharmaceutical Production & Technology

#### Module / module:
- **Pharmaceutical Production and Technology**

#### Responsible person for the module:
- Prof. Dr. Stefan Höfer

#### Codes:
- P7

#### Language:
- English

#### Type of course:
- Mandatory

#### Workload (h):
- **1. Basics in Supply Chain Management**
  - 18.75
- **2. Basics of Lean Enterprise Management**
  - 18.75
- **3. Principles of Pharmaceutical Manufacturing**
  - 9.25
- **4. Principles and Processes of Aseptic Filling**
  - 9.125
- **5. Packaging and Packaging Processes**
  - 6.25
- **6. Visual Inspection**
  - 2.5
- **7. Production Systems and Technologies**
  - 18.75

#### ECTS-Credits:
- 5

#### Prerequisites for attending:
None

#### Professional competencies:
- to outline the principles of supply chain management. (K4)
- to understand the principles of lean enterprise management. (K2)
- to outline the pharmaceutical production process. (K4)
- to outline production process control systems. (K4)
- to outline aseptic manufacturing and differentiate the respective processes/principles. (K4, K5)
- to adhere to regulatory rules and quality standards (K4).

#### Methodological competencies:
- to apply the principles of production processing and production management. (K3)
- to demonstrate accountability for others. (K3)
- to apply conceptual and practical thinking. (K3)
- to differentiate customer and other stakeholder’s needs. (K5)
- to develop commitment to job. (K8)

#### Inhalt / content:
- **Basics in supply chain management:**
  The complexity of supply chains, international procurement, synchronized production, distribution
- **Basics in Lean Enterprise Management:**
  Lean Thinking, Learning to see and eliminate waste in production and administration, Business simulation games synchronized production

#### Details:

<table>
<thead>
<tr>
<th>Course / Kurs</th>
<th>Unterricht / class</th>
<th>Selbststudium / self-study</th>
<th>Gesamt / total</th>
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<td>1. Basics in Supply Chain Management</td>
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<td>6</td>
<td>24.75</td>
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<tr>
<td>2. Basics of Lean Enterprise Management</td>
<td>18.75</td>
<td>6</td>
<td>24.75</td>
</tr>
<tr>
<td>3. Principles of Pharmaceutical Manufacturing</td>
<td>9.25</td>
<td>3.5</td>
<td>12.75</td>
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<tr>
<td>5. Packaging and Packaging Processes</td>
<td>6.25</td>
<td>2.5</td>
<td>8.75</td>
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<tr>
<td>6. Visual Inspection</td>
<td>2.5</td>
<td>2.5</td>
<td>5</td>
</tr>
<tr>
<td>7. Production Systems and Technologies</td>
<td>18.75</td>
<td>6</td>
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<td><strong>Gesamt / total</strong></td>
<td><strong>57.5</strong></td>
<td><strong>16.5</strong></td>
<td><strong>74</strong></td>
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#### Vorlesung / Lectures:
- Gerald Bürkle, Uwe Hemminghorst
- Gerald Bürkle
- Gerald Bürkle, Uwe Hemminghorst

#### Seminar / Seminars:
- Prof. Dr. Günter Lorenz
- Prof. Dr. Stefan Höfer

#### Lab / Labs:
- Gerald Bürkle, Uwe Hemminghorst

#### Case studies / Case studies:

#### Voraussetzungen für die Teilnahme am Kurs / prerequisites for attending the course:

- None

#### Modulziele bzw. erwünschte Arbeitsaufwand (h):
- **Basics in Supply Chain Management**
- **Basics of Lean Enterprise Management**
- **Principles of Pharmaceutical Manufacturing**
- **Principles and Processes of Aseptic Filling**
- **Packaging and Packaging Processes**
- **Visual Inspection**
- **Production Systems and Technologies**

#### Status:
- Mandatory

#### Course goals and desired outcome:
- to differentiate customer and other stakeholder’s needs. (K5)
- to apply conceptual and practical thinking. (K3)
- to apply the principles of production processing and production management. (K3)
- to outline the principles of supply chain management. (K4)
- to understand the principles of lean enterprise management. (K2)
- to outline the pharmaceutical production process. (K4)
- to outline production process control systems. (K4)
- to outline aseptic manufacturing and differentiate the respective processes/principles. (K4, K5)
- to adhere to regulatory rules and quality standards (K4).

#### Professional competencies
- to apply the principles of production processing and production management. (K3)
- to demonstrate accountability for others. (K3)
- to apply conceptual and practical thinking. (K3)
- to differentiate customer and other stakeholder’s needs. (K5)
- to develop commitment to job. (K8)

#### Methodological competencies
- to apply the principles of production processing and production management. (K3)
- to demonstrate accountability for others. (K3)
- to apply conceptual and practical thinking. (K3)
- to differentiate customer and other stakeholder’s needs. (K5)
- to develop commitment to job. (K8)

#### Inhalt / content:
- **Basics in supply chain management:**
  The complexity of supply chains, international procurement, synchronized production, distribution
- **Basics in Lean Enterprise Management:**
  Lean Thinking, Learning to see and eliminate waste in production and administration, Business simulation games synchronized production

#### Principles of pharmaceutical manufacturing:
- Introduction to drug product development, active pharmaceutical ingredients (APIs), basic technologies and unit operations, regulatory aspects of pharmaceutical production, principles of Quality by Design (QbD) and knowledge-based production, scale-up considerations and economical aspects, supplemented by case studies
- Basics and processes of aseptic filling:
  demonstration of complete production process including compounding, material preparation and aseptic filling, various compounding systems and processes, material preparation processing including equipment and primary packaging materials, sterilization, processing of bulk and pre-sterilized primary packing material, use of different dosing and stopping techniques, inline and offline filtration processes, liquid and freeze-dried formulated drug products, process flow (material, operator, equipment, product)
- Packaging and packaging processes:
  demonstration of complete secondary packaging processes, labeling, assembly of safety devices and tools, blistering, cartoning, serialization and track&trace, autoinjectors and pen systems and assembly, anti-counterfeiting systems, manual and automated packaging processes
- Visual inspection:
  Methods and processes of manual and automated VI processes. AQL-approaches, validation of manual and automated systems, training and qualification programmes including test-kit handling. VI special qualities (Japanese quality), automated camera systems and defect recognition
- Basics of production systems and technologies:
  production systems: master batch record handling, application systems (electronic weighing system, material tracking systems, in process control systems), production excellence processes (human error avoiding, process optimization, KPIs), technologies. Vetter clean room technology, utilities (HVAC, water, power, gases, etc), function and setup of major primary equipment (equipment washer, glass barrel washer, autoclave and dry heat tunnel, filling machines), flexible production cells (filling cells, co-robot assisted processes), smart production technologies (Industry 4.0)
<table>
<thead>
<tr>
<th>Examination type and duration:</th>
<th>Written examination (100%), 1h</th>
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<tr>
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<tr>
<td></td>
<td>Recent scientific publications in the respective field</td>
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</table>
PS8 – Managing Organizations & Leadership

Inhalt / content:

desired outcome:

Modulziele bzw. erwünschte the course:

prerequisites for attending Teilnahme am Kurs /

Voraussetzungen für die

ECTS

workload (h):

Arbeitsaufwand /

type of course:

Veranstaltungsart /

Status:

Sprache / Language:

Semester:

Code:

Modul / Module:

Studienprogramm / Course of studies:

Credits:

Gesamt / total:

6.

5.

4.

3.

2.

Kurs / course:

Mandatory

DE/EN

2

PS8

Managing Organizations and Leadership

Pharmaceutical Sciences & Business (M.Sc.)

M.Sc. Pharmaceutical Science & Business

Upon successful completion of this module, students are able

Professional competencies

... to apply the key approaches of leadership especially and build profound leadership competencies. (K3)

Methodological competencies:

... to carry out leadership tools, such as the Eisenhower matrix or specific leadership styles, in order to solve leadership tasks. (K4)

... to methodologically operate the single phases of change management. (K3)

... to apply change management tools such as Kotter’s 8 steps of change in organisational change projects. (K3)

Social competencies:

... to engage productivity in complex and changing environments. (K3)

... to create value through generating a variety of perspectives and solutions. (K6)

... to improve their communicative skills, specifically for communicating in leadership situations. (K6)

... to develop a sense for leadership during changes. (K6)

... to know how to communicate and persuade people to be part of the change and managed challenging situations. (K5)

Personal competencies:

... to develop accountability for others. (K6)

... to generate self-management. (K6)

... to handle stress. (K6)

... to make realistic expectations.

... to develop role awareness and sensitivity to others. (K6)

... enhance their personal competencies by increasing reflexivity about their influence on others (self and role awareness) in social situations. (K6)

... to understand how they can leverage their competencies in order to positively influence others (i.e. applying leadership; change management). (K2)

... to reflect on oneself. (K5)

Organizational behavior and leading change:

Resulting from evermore dynamic and complex environments, researchers and practitioners see learning and change of organizations as an important factor for achieving sustainable competitive advantages. Hence, planning and managing change is crucial for organizations to survive. Following an individual, group and organizational level of analysis (individual and organisational behavior), this course elaborates upon fundamentals of how organizations learn and change, and discusses management models/frameworks and tactics of intentional change (‘best practices’) for managing change (cooping with resistance, leadership styles, effective communication).

Leading myself and others:

Students understand that leadership is a crucial variable for achieving sustainable competitive advantage. The module focusses on skills for doing leadership. It focusses on specific leadership behavior and the individual preferences, abilities and professional skills of leaders. The course interacitively elaborates contemporary leadership behavior and introduces students into current debates on sustainable leadership.

Case study: Corporate values and pharma leadership principles

Apply the leasons learnt from leading business, leading myself and leading others on the specific situation of a pharmaceutical company with its highly regulated environment and its science-driven culture.

Personal development and coaching:

Students experience the power of targeted development. They learn to find a starting point for personal development (define + measure), identify key development objectives and create a personal development plan for themselves. They understand the methodology and systematic behind combined with personal insight and reflection offered in the course. The course provides some theoretical background but focuses primarily on opportunities for growth and personal development such as self reflection, feedforward, peer consulting, coaching and mentoring.
PS8 – Managing Organizations & Leadership (cont.)

<table>
<thead>
<tr>
<th>Prüfungsform und Dauer / examination type and duration:</th>
<th>Written examination (100%), 1h</th>
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<tr>
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<td>Lehr- und Lernmethodik / teaching and learning methodology:</td>
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<table>
<thead>
<tr>
<th>Empfohlene Literatur / recommended literature:</th>
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### PS9 – Exponential Technologies & Future Perspectives

**Modul / Module:** Exponential Technologies and Future Perspectives

**Responsible person for the module:** Prof. Dr. Ralf Kemkemer

**Code:** PS9

**Language:** DE/EN

**Status:** Mandatory

<table>
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<tr>
<td>1. Principles and applications of emerging biomedical technologies</td>
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<tr>
<td>2. New therapeutic modalities</td>
<td>12.5</td>
<td>12.5</td>
<td>25</td>
<td></td>
</tr>
<tr>
<td>3. Principles of artificial intelligence and applications in pharma</td>
<td>12.5</td>
<td>12.5</td>
<td>25</td>
<td></td>
</tr>
<tr>
<td>4. Digital production process of the future</td>
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<td>12.5</td>
<td>37.5</td>
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<td><strong>Total:</strong></td>
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<td><strong>50</strong></td>
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</table>

**ECTS-Punkte / ECTS-Credits:** 6

**Voraussetzungen für die Teilnahme am Kurs / prerequisites for attending the course:** None

**Inhalt / content:**

- **Principles and applications of emerging biomedical technologies:**
  - Design and function of artificial cells and biohybrid systems
  - Design, function and applications of synthetic micro-robots for health applications
  - Engineering and application of in-vitro and in-vivo chip technologies (organ on a chip) for diagnostics and therapies

- **New therapeutic modalities:**
  - Basics and principles of antibody-drug conjugates, immune therapies, stem cells, CRISPR/Cas9, oligonucleotides, hybrids, molecular conjugates, as well as new uses of classical small molecules.

- **Principles of artificial intelligence and applications in pharma:**
  - Artificial intelligence (AI) technologies, machine learning, neural networks, deep learning, natural language processing, chatbots, AI applications in healthcare, AI application in pharmaceutical R&D, AI application in project management, manufacturing and marketing/sales, changing business models, appropriability of AI-based innovations

- **Digital production process of the future:**
  1. Technological basics, such as sensoric and process analytics, optofluidic system technology, optical spectroscopy (UV/Vis, NIR, IR, Raman Fluorescence), separation methods (chromatography, mass spectrometry), electrochemical analyzer (Potentiometry, Conductometry)
  2. Opportunities and applications of digital technologies: Introduction to the Industrial Internet; Industrial Internet Use-Cases; The Technical and Business Innovations of the Industrial Internet; IIoT Reference Architecture; Designing Industrial Internet Systems
  3. Excursion: Visiting a digital pharma production (e.g. Vetter Pharma)
PS9 – Exponential Technologies & Future Perspectives (cont.)

| Prüfungsform und Dauer / examination type and duration: | Presentation (50%)  
 Written examination (50%), 1h |
<table>
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<tr>
<td>Mediennutzung / media used:</td>
<td>Script to download, student presentation, digital projector, handouts, flip chart</td>
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<tr>
<td>Lehr- und Lernmethodik / teaching and learning methodology:</td>
<td>A mixture of methodologies is applied, e.g. lecture with interactive teaching and discussions, combined with team works and case-studies</td>
</tr>
</tbody>
</table>

Empfohlene Literatur / recommended literature:

- Tony J. Prescott et al. (2018) Living machines: A handbook of research in biomimetics and biohybrid systems. Published to Oxford Scholarship Online: June 2018; DOI: 10.1093/oso/9780199674923.001.0001
- Rabus, Rebrner, Sada: Optofluidics, Process Analytical Technology, De Gruyter, 2018
- Recent scientific publications in the respective field
Pharmaceutical Sciences & Business (M.Sc.)

Module / Module:
Agile Working & Workforce of the Future

Dozent(en) / lecturer(s):
1. Prof. Dr. Alexander Schuhmacher
2. Michael Kuss
3. Prof. Dr. Stefan Höfer
4. Prof. Dr. Julian Node

Semester:
3

Sprache / Language:
DE/EN

Veranstaltungsart / Kurs / course:
V U E C CO

1. Principles of open innovation and business model innovation
2. Principles and methodology of design thinking
3. Agile organization and processes
4. Administrative process excellence
5. Principles of open innovation and business model innovation

Arbeitsaufwand / workload (h):

<table>
<thead>
<tr>
<th>Kurs / course</th>
<th>Unterricht / class</th>
<th>Selbststudium / self-study</th>
<th>Gesamt / total</th>
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<tbody>
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</tbody>
</table>

ECTS-Punkte / ECTS-Credits:
5

Voraussetzungen für die Teilnahme am Kurs / prerequisites for attending the course:
None

Modulziele bzw. erwünschte Professional competencies:
... to apply the key approaches of design thinking and agile working. (K3)
... evaluate the various business options provided by the open innovation paradigm. (K5)

Methdological competencies:
... to apply the 55 business model innovators to the pharmaceutical practice. (K3)
... to carry out design thinking principles. (K3)
... to methodologically operate the phases of design thinking. (K3)
... to apply agile tools in organisational transformation project. (K3)

Social competencies:
... to engage productivly in a business transformation. (K3)
... to create value through generating a variety of perspectives and solutions. (K6)
... to improve their communicative skills, specifically for communincating in a transformation. (K6)
... to develop a sense for business innovation. (K6)
... to know how to communicate and persuade people to be part of a business transformation. (K5)

Personal competencies:
... to develop accountability for others. (K6)
... to generate self management. (K6)
... to handle stress. (K6)
... to develop proactive thinking. (K6)
... to develop conceptual thinking. (K6)
... to analyze, evaluate and create new business opportunities. (K3, K4, K6)
... to evaluate potential problems and future opportunities. (K5)

Inhalt / content:
Principles of open innovation and virtual business models:
Innovation paradigms, closed innovation, open innovation, crowdsourcing, public-private-partnerships, innovation hubs, virtual R&D models, outsourcing, outubation, off-shoring, virtualization of R&D, supplemented by case-in-points

Methodology and principles of design thinking:
Basic considerations, creativity, calisical creativity models, creativity in pharmaceutical R&D, design thinking process, methodologies, customer journey map, case-in-points of various industries, design thinking in pharma, hybrid thinking, design thinking for business innovation

Agile organization and processes:
Agile organizations, use cases, agile transformation, journey to an agile organization, building agile capabilities, new ways of working, agility in the daily business, agile culture, agile leadership

Administrative process excellence:
Learning to see, understand, and quantify waste in administrative processes, designing optimized workflows with Administrative Value Stream Design, implementing process changes sustanably
### PS10 – Agile Working & Workforce of the Future (cont.)

| Prüfungform und Dauer / examination type and duration: | Project report (50%)  
Written examination (50%), 1h |
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<tbody>
<tr>
<td>Medienutzung / media used:</td>
<td>Script to download, student presentation, digital projector, handouts</td>
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<tr>
<td>Lehre- und Lernmethodik / teaching and learning methodology:</td>
<td>A mixture of methodologies is applied, e.g. lecture with interactive teaching and discussions, combined with team works and case-in-points, as well as a design thinking work shop; students need to write a term paper in preparation of this module</td>
</tr>
</tbody>
</table>
Recent scientific publications in the respective field |
PS11 – Business Development & Business Planing

Inhalt / content:

desired outcome:

Ergebnisse / module goals and
Modulziele bzw. erwünschte
the course:

prerequisites for attending
Teilnahme am Kurs /
Voraussetzungen für die
ECTS

workload (h):

type of course:

Veranstaltungsart /
Status:

Sprache / Language:

Semester:

Code:

Modul / Module:

Course of studies:

Studienprogramm /
-
-
- Punkte/

- Kurs / course:

- Mandatory

DE/EN

- 3

PS11

Business Development & Business Planning

Pharmaceutical Sciences & Business (M.Sc.)

Simulation, elevator pitch training, feedback session

Executive perspective, executive agenda, decision making, executive meeting preparation, execution and follow-up, executive meeting

... to create sensitivity to others. (K6)

... to act proactively, result-oriented and customer-oriented. (K6)

... to outline complex contexts and to present them professionally. (K4)

... to negotiate professionally. (K5)

... to analyze the peculiarities and challenges of corporate business development. (K4)

... to understand the pharmaceutical business environment. (K2)

... to differentiate between the challenges that corporate business development poses on the organisation’s ability to optimise efficiency and
outcome on the one hand and its ability to react to change in a flexible and agile manner on the other. (K5)

... to judge the effect of change – especially disruptive technologies and scenarios have – on the organisational structure of corporations,
the interaction of their employees and the ability to develop and/or grow business. (K5)

... to identify and differentiate efficiency and outcome related success factors for internationally active companies. (K4, K5)

Methdological competencies:

... to evaluate operational and motivational effects of organisational structures and business models. (K6)

... to analyze and evaluate stakeholders and generate a stakeholder analysis. (K5, K6)

... to evaluate operational and motivational effects of organisational structures and business models. (K5)

... to judge the effect of change – especially disruptive technologies and scenarios have – on the organisational structure of corporations,
the interaction of their employees and the ability to develop and/or grow business. (K5)

Concerning the interaction of employees and the ability to develop or grow business. (K5)

Personal competencies:

... to lead and motivate teams. (K6)

... to lead and motivate teams. (K6)

... to act proactively, result-oriented and customer-oriented. (K6)

... to create sensitivity to others. (K6)

Corporate governance and managing organizations:

Corporate governance and structure, strategy, corporate functions, board structure and leadership, corporate responsibility and
sustainability, reputation and stakeholder relations, transparency and integrity

Principles and options of corporate growth and business development:

- Case study: Coping with disruption

- Objectives of corporate business development.

- Internal and external reach of corporate business development.

- Organisational structures of product, process and service oriented business models.

- Methods, barriers and implementation of corporate business development and growth.

Executive client interaction:

Executive perspective, executive agenda, decision making, executive meeting preparation, execution and follow-up, executive meeting
similation, elevator pitch training, feedback session

Financial management and accounting:

Management & controlling, financial accounting and management accounting, financial statement, profit, statement of income, cash
outflow, expenditure, expenses, costs, basic figures for financial success, key performance indicators and cash cycle, cost structures,
cost and activity accounting, full cost accounting vs. direct costing, business analytics in controlling

Case study: Operational and strategic planning in pharma

Basics of corporate planning, operational planning, strategic planning, balanced scorecard, value-driver models, pricing and reimbursement,
change management and controlling, use case: planning and pricing exercise
### PS11 – Business Development & Business Planning (cont.)

<table>
<thead>
<tr>
<th>Prüfungsform und Dauer / examination type and duration:</th>
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<td>Mediennutzung / media used:</td>
<td>Lecture, script to download, student presentation, digital projector, handouts</td>
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<td>A mixture of methodologies is applied, e.g. lecture with interactive teaching and discussions, combined with team works and case-studies</td>
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<td></td>
<td>Davis, Roger: The relevance and importance of business development and licensing in the biopharmaceutical industry, in Journal of Commercial Biotechnology (2013) 19(3), 49–56</td>
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<td>Horvath, Peter; Gleich, Ronald; Seiter, Mischa (2015) Controlling. Vahlen Verlag</td>
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<td>Coenenberg, Adolf; Fischer, Thomas; Günther, Thomas (2016) Kostenrechnung und Kostenanalyse. Schäffer Poeschel Verlag</td>
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<td></td>
<td>Schöffski, Oliver; Fricke, Frank; Guminski, Werner (2008) Pharmabetriebslehre. Springer Verlag</td>
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<td></td>
<td>Waniczek, Mirko; Ruthner, Raoul; Feichter, Andreas (2016) Unternehmensplanung und -steuerung: Von der Strategie zum Cashflow. Linde Verlag</td>
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</table>
### PS12.1 – Transformation Project „Business & Innovation“

#### Studienprogramm / Course of studies:
- Pharmaceutical Sciences & Business (M.Sc.)

#### Modulverantwortlicher / Responsible person for the module:
- Prof. Dr. Alexander Schuhmacher

#### Modul / Module:
- Transformation project: „Business and Innovation“

#### Code:
- PS12.1

#### Sprache / Language:
- DE/EN

#### Status:
- Mandatory

#### Arbeitsaufwand / workload (h):

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<tr>
<th>Kurs / course:</th>
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<th>Selbststudium / self-study:</th>
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<td>100</td>
<td>125</td>
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#### ECTS-Punkte / ECTS-Credits:
- 5

#### Voraussetzungen für die Teilnahme am Kurs / prerequisites for attending the course:
- None

### Inhalt / content:

Students can select between 4 different modules PS12.1 - 12.4: "Business and Innovation", "Science & Technology", "Pharmaceutical Development & Process Development" and "Pharmaceutical Production & Technology".

The modules are split in six sections: (1) presentation of the case (incl. teaching) and coached preparation of the case, (2) coached team work to answer a RFI (request for information, around 20 questions to the case), (3) submission of RFI answers and feedback to the team, (4) business trip to the U.S., (5) RFP (request for project proposal) to the teams, (6) coached team work in the US and preparation of a project proposal.

Project proposals (to be drafted) refer to business transformation themes with relevance for the pharmaceutical industry, such as application of crowdsourcing to increase R&D effectiveness or use of artificial intelligence in pharma production.

The team work is (ideally) done on cross-functional teams (of at least 4 students) on a "real" business transformation project (real-life case).

Students’ performance is evaluated based on the written answers to RFI and RFP.

### Empfohlene Literatur / recommended literature:
PS12.2 – Transformation Project „Science & Technology“

Studienprogramm / Course of studies: Pharmaceutical Sciences & Business (M.Sc.)

Modulverantwortlicher / Responsible person for the module: Prof. Dr. Alexander Schuhmacher

Responsible person for the module: Prof. Dr. Ralf Kemkemer

Modul / Module: Transformation project: „Science and Technology“

Lecturer(s):
1. Prof. Dr. Ralf Kemkemer

Module code / Code: PS12.2

Semester / Semester: 3

Language / Language: DE/EN

Status / Status: Mandatory

Type of course / Kurs / course:
1. Transformation project: „Science and Technology“
2. C
3. V
4. E
5. U
6. C

Workload (h):

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<th>Kurs / course:</th>
<th>Unterricht / class:</th>
<th>Selbststudium / self-study:</th>
<th>Gesamt / total:</th>
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<tbody>
<tr>
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<td>100</td>
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<tr>
<td>Gesamt / total:</td>
<td>25</td>
<td>100</td>
<td>125</td>
</tr>
</tbody>
</table>

ECTS-Punkte / ECTS-Credits: 5

Voraussetzungen für die Teilnahme am Kurs / prerequisites for attending the course: None

Ergebnisse / module goals and desired outcome:

Upon successful completion of this module, students are able...

Professional competencies:
- To understand how business transformation works. (K1)
- To analyze the specific business environment of the given case. (K4)
- To evaluate the given case and to create own concepts and business ideas. (K6)

Methodological competencies:
- To create a project proposal. (K6)
- To plan a project and execute the plan. (K6, K3)

Social competencies:
- To leverage the potential of a cross-functional project team. (K6)
- To create a network and to leverage it. (K6)

Personal competencies:
- To develop a global mindset. (K6)
- To lead and motivate teams. (K6)
- To act proactively, result-oriented and customer-oriented. (K6)
- To handle stress. (K6)
- To develop proactive thinking. (K6)
- To develop conceptual thinking. (K6)

Inhalt / content:
Students can select between 4 different modules PS12.1 - 12.4: “Business and Innovation”, “Science & Technology”, “Pharmaceutical Development & Process Development” and “Pharmaceutical Production & Technology”.

The modules are split in six sections: (1) presentation of the case (incl. teaching) and coached preparation of the case, (2) coached team work to answer a RFI (request for information) around 20 questions to the case, (3) submission of RFI answers and feedback to the team, (4) business trip to the U.S., (5) RFP (request for project proposal) to the teams, (6) coached team work in the US and preparation of a project proposal.

Project proposals (to be drafted) refer to business transformation themes with relevance for the pharmaceutical industry, such as application of crowdsourcing to increase R&D effectiveness or use of artificial intelligence in pharma production.

The team work is (ideally) done on cross-functional teams (at least 4 students) on a “real” business transformation project (real-life case).

Students’ performance is evaluated based on the written answers to RFI and RFP.

Prüfungform und Dauer / examination type and duration:
Answer to RFI (50%)
Project proposal (50%)

Mediennutzung / media used:
Script to download, digital projector, handouts, flip charts

Lehr-/ und Lernmethodik / teaching and learning methodology:
Team work and a real-life case (including coaching)

Empfohlene Literatur / recommended literature:
Young Sop Ahn, Ten Megatrends Changing our Lives (2019)
Linz, Carsten; Müller-Stewens, Günter; Zimmermann, Alexander. Radical Business Model Transformation: Gaining the Competitive Edge in a Disruptive World. KoganPage, 2017

M.Sc. Pharmaceutical Science & Business

Studienprogramm / Course of studies: Pharmaceutical Sciences & Business (M.Sc.)
Modulverantwortlicher / Responsible person for the module: Prof. Dr. Alexander Schuhmacher

Modul / Module: Transformation project: Pharmaceutical Development & Process Development
Dauer / Duration: 3 Semester
Sprache / Language: DE/EN

Arbeitsaufwand / workload (h):
2. 
3. 
4. 
Gesamt / total: 25 150 125

ECTS-Punkte / ECTS-Credits: 33

Veranstaltungsart / Kurs / course:
2. 
3. 
4. 

Modulziele bzw. erwünschte Ergebnisse / module goals and desired outcome:
Upon successful completion of this module, students are able...

- to understand how business transformation works. (K1)
- to analyze the specific business environment of the given case. (K4)
- to evaluate the given case and to create own concepts and business ideas. (K6)

Professional competencies:
- to create a project proposal. (K6)
- to plan a project and execute the plan. (K6, K3)

Methodological competencies:
- to leverage the potential of a cross-functional project team. (K6)
- to create a network and to leverage it. (K5)

Social competencies:
- to develop a global mindset. (K6)
- to lead and motivate teams. (K6)
- to act proactively, result-oriented and customer-oriented. (K6)
- to create sensitivity to others. (K6)
- to handle stress. (K6)
- to develop proactive thinking. (K6)
- to develop conceptual thinking. (K6)

Empfohlene Literatur / Recommended literature:
- Linz, Carsten; Müller-Stewens, Günter; Zimmermann, Alexandar, Radical Business Model Transformation: Gaining the Competitive Edge in a Disruptive World. KoganPage. 2017

Prüfungsform und Dauer / examination type and duration:
- Written to RFI (50%)
- Project proposal (50%)

Mediennutzung / Media used:
- Script to download, digital projector, handouts, flip charts

Lern- und Lernmethodik / Teaching and learning methodology:
- Team works and a real-life case (including coaching)

Inhalt / content:
Students can select between 4 different modules PS12.1 - 12.4: "Business and Innovation", "Science & Technology", "Pharmaceutical Development & Process Development" and "Pharmaceutical Production & Technology".

The modules are split in six section: (1) presentation of the case (incl. teaching) and coached preparation of the case, (2) coached team work to answer a RFI (request for information, around 20 questions to the case), (3) submission of RFI answers and feedback to the team, (4) business trip to the U.S., (5) RFP (request for project proposal) to the teams, (6) coached team work in the US and preparation of a project proposal.

Project proposals (to be drafted) refer to business transformation themes with relevance for the pharmaceutical industry, such as application of crowdsourcing to increase R&D effectiveness or use of artificial intelligence in pharma production.

The team work is (ideally) done on cross-functional teams (of at least 4 students) on a "real" business transformation project (real-life case).

Students' performance is evaluated based on the written answers to RFI and RFP.
**PS12.4 – Transformation Project „Pharmaceutical Production & Technology“**

**Study Program / Course of Studies:** Pharmaceutical Sciences & Business (M.Sc.)

**Module / Module:** Transformation project: "Pharmaceutical Production & Technology"

**Code:** PS12.4

**Semester:** 3

**Language:** DE/EN

**Status:** Mandatory

**Type of Course:**
- 1. Transformation project: "Pharmaceutical Production & Technology" (V)
- 2. (X)
- 3. (X)
- 4. (X)
- 5. (X)

**ECTS-Points / Credits:** 5

**Prerequisites for Attending the Course:** None

**Module Goals and Desired Outcome:**

- **Methodological competencies:**
  - ... to create a project proposal. (K6)
  - ... to plan and execute the plan. (K6, K3)

- **Social competencies:**
  - ... to leverage the potential of a cross-functional project team. (K6)
  - ... to create a network and to leverage it. (K6)

- **Personal competencies:**
  - ... to develop a global mindset. (K6)
  - ... to lead and motivate teams. (K6)
  - ... to act proactively, result-oriented and customer-oriented. (K6)
  - ... to create sensitivity to others. (K6)
  - ... to handle stress. (K6)
  - ... to develop proactive thinking. (K6)
  - ... to develop conceptual thinking. (K6)

**Inhalt / Content:**

Students can select between 4 different modules PS12.1 - 12.4: "Business and Innovation", "Science & Technology", "Pharmaceutical Development & Process Development" and "Pharmaceutical Production & Technology".

The modules are split in six sections: (1) presentation of the case (incl. teaching) and coached preparation of the case, (2) coached team work to answer a RFI (request for information, around 20 questions to the case), (3) submission of RFI answers and feedback to the team, (4) business trip to the U.S., (5) RFP (request for project proposal) to the teams, (6) coached team work in the US and preparation of a project proposal.

Project proposals (to be drafted) refer to business transformation themes with relevance for the pharmaceutical industry, such as application of crowd-sourcing to increase R&D effectiveness or use of artificial intelligence in pharma production.

The team work is (ideally) done on cross-functional teams (of at least 4 students) on a "real" business transformation project (real-life case).

**Evaluation Type and Duration:**
- Answer to RFI (50%)
- Project proposal (50%)

**Media Used:**
- Script to download, digital projector, handouts, flip charts

**Teaching and Learning Methodology:** Team work and a real-life case (including coaching)

**Recommended Literature:**
- Young Sop Ahn, Ten Megatrends Changing our Lives (2019)
### PS13 – Data Science & Scientific Working

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<th>Modul / Module:</th>
<th>Data Sciences &amp; Scientific Methodology</th>
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<tbody>
<tr>
<td>Luise (equivalent) / Lecturer(s):</td>
<td>1. Philip Rosenauer</td>
</tr>
<tr>
<td>2. Prof. Dr. Marc Brecht</td>
<td></td>
</tr>
<tr>
<td>3. Prof. Dr. Jörg Lennert</td>
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<tr>
<td>4. Prof. Dr. Jörg Lennert</td>
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<td>5. Prof. Dr. Andreas Kandelbauer</td>
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<td>Code:</td>
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<th>Verantwortung</th>
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<tr>
<td>Modulverantwortlicher / Responsible person for the module:</td>
<td>Prof. Dr. Andreas Kandelbauer</td>
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<tr>
<td>1. Data security and compliance</td>
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<tr>
<td>2. Mathematical and statistical fundamentals</td>
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<tr>
<td>3. Information retrieval and evaluation</td>
</tr>
<tr>
<td>4. Data analytics and data visualization</td>
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<tr>
<td>5. Generation of scientifically valid data and data calculation</td>
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<td>6. Scientific writing</td>
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<th>Unterricht / class:</th>
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<td>5. Generation of scientifically valid data and data calculation</td>
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| ECTS-Punkte / ECTS-Credits: | 6 |

### Inhaltsübersicht / content:

**Data security and compliance:**
Introduction into the General Data Protection Regulation, definition of personal data and sensitive data, building a data protection governance framework, data protection impact assessments, cybersecurity risks, introduction into ISO 27000 (Information Security Management Systems)

**Mathematical and statistical fundamentals:**
Sequences, series and functions, interpretation of functions (including differential calculus and integral calculus, probability calculus, fundamentals of mathematical statistics

**Information retrieval and evaluation:**
Reference data bases, search engines, citation managers, literature search examples/exercises based on concrete scientific questions

**Data analytics and data visualization:**
Terminology and classification; exploratory data analysis; statistical learning and model selection; dimensions reduction methods; variable selection; linear regression; modeling non-linear relationships

**Generation of scientifically valid data and data calculation:**
Structured Data Sets vs. non-structured Data Sets, Basic & Advanced Experimental Design: causal relationships vs. descriptive analyses

**Scientific writing:**
Target-group oriented writing; sections and their function; writing reports, scientific papers, project applications, reviews using headlines, tables, figures and schematics

### Professional competencies:

- ... to outline the basics of the European data protection regulation and respective applications. (K4)
- ... to carry out scientific searches and to use scientific data bases. (K3)
- ... to understand the basics of quantitative models and statistical methods and to apply them respectively. (K2, K3)
- ... to understand and apply the basic principles of macro programming. (K2, K3)
- ... to apply a basic knowledge in multivariate statistical data evaluation. (K3)
- ... to understand the principle limitations of various experimental design strategies in order to obtain scientifically valid data. (K2)
- ... to apply the general principles of writing scientific data reports and publications. (K3)

### Methodological competencies:

- ... to use software and tools for statistics, data and image analysis as well as data visualization. (K3)
- ... to exploit statistical software tools to explore the design space (for product development and identification of causal relationships). (K5)
- ... to write concisely and address selected target groups (scientific community, public, funding agencies, ...). (K2)

### Social competencies:

- ... to work responsibly. (K2)

### Personal competencies:

- ... to work target-oriented and systematically. (K3)
- ... to work self-responsibly. (K3)
### PS13 – Data Science & Scientific Working (cont.)

<table>
<thead>
<tr>
<th>Prüfungsfom und Dauer / examination type and duration:</th>
<th>Presentation (50%) / written examination (50%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mediennutzung / media used:</td>
<td>Manuscripts (electronic and hardcopy), boards, overheads, and all other usual classroom appliances, student computer/laptop</td>
</tr>
<tr>
<td>Lehr- und Lernmethodik / teaching and learning methodology:</td>
<td>A mixture of methodologies is applied, e.g. lecture with interactive teaching and discussions, combined with team work sessions, case studies, and computer practicals</td>
</tr>
<tr>
<td></td>
<td>Iannarelli/O'Shaughnessy, Information Governance and Security: Protecting and Managing your company’s proprietary information (2014)</td>
</tr>
<tr>
<td></td>
<td>Papula, L., Mathematik für Ingenieure und Naturwissenschaftler, Band 1 und 3</td>
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<tr>
<td></td>
<td>Bilo (2011) Excel for Chemists, Wiley</td>
</tr>
<tr>
<td></td>
<td>Deutsche Forschungsgemeinschaft (2019) Sicherung guter wissenschaftlicher Praxis, Denkschrift / Safeguarding Good Scientific Practice, Memorandum, Wiley/DFG</td>
</tr>
</tbody>
</table>
**PS14 – Master Thesis**

<table>
<thead>
<tr>
<th>Studienprogramm / course of studies:</th>
<th>Pharmaceutical Sciences &amp; Business (M.Sc.)</th>
<th>Modulverantwortlicher / responsible person for</th>
<th>All professors and lecturers of the study programm</th>
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<tbody>
<tr>
<td>Modul / module:</td>
<td>Master thesis</td>
<td>Dozent / lecturer(s):</td>
<td>Depending on the topic</td>
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<tr>
<td>Code:</td>
<td>PS14</td>
<td>Sprache / language:</td>
<td>DE/EN</td>
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<tr>
<td>Semester:</td>
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<td>Semester:</td>
<td>Mandatory</td>
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**Veranstaltungstyp / type of course:** Research / scientific project with practical / professional background

**Arbeitsaufwand / workload (hours):** 625 h

**ECTS-Punkte:** 25

**Voraussetzungen für die Teilnahme am Kurs / prerequisites for attending the course:** Application for the master thesis at the earliest possible with a deliverable of 50 ECTS (80 ECTS in case of a bachelor degree with 180 ECTS). Latest application required 2 months after successfully passing all modules of the study programm.

**Modulziele bzw. erwünschte Ergebnisse / module goals and desired outcome:** The thesis project usually is conducted on basis of a practical / professional projects in collaboration with the participant’s employer. In-depth problem-solving competencies have to be applied by selecting and applying appropriate business research methods to solve project-related business problems in the domain of the pharma and biotech industry.

**Inhalt / content:** Content varies according to thesis project / subject

**Prüfungsform und Dauer / examination type and duration:** Master thesis with 25,000 - 30,000 words 6 months duration

**Lern- und Lernmethoden / Project and individual coaching

**Empfohlene Literatur / recommended literature:** Research methods - see module PS13 "data science and scientific working" Depending on the topic or issue
<table>
<thead>
<tr>
<th>Modul / module:</th>
<th>Research project, internship or practical experience</th>
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</thead>
<tbody>
<tr>
<td>Code:</td>
<td>PS15</td>
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<td>Sprache / language:</td>
<td>DE/EN</td>
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<tr>
<td>Semestern:</td>
<td>Mandatory for candidates with a bachelor degree with 180 ECTS</td>
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<tr>
<td>Modulverantwortlicher / responsible person for the module:</td>
<td>Prof. Dr. Alexander Schuhmacher (technically) and examination committee (formally)</td>
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<tr>
<td>Dozent / lecturer(s):</td>
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