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REPUBLIC OF TURKIYE

BAHÇEŞEHİR UNIVERSITY

SCHOOL OF PHARMACY

INTERNSHIP NOTEBOOK

PHAR 5998 INTERNSHIP IV-

PHARMACEUTICAL INDUSTRY

NAME:

STUDENT NO:

SIGNATURE (INTERN):

INTERNSHIP COMPANY:

INTERNSHIP START AND END DATE:

INTERNSHIP DURATION (TOTAL WORK DAYS):

STAMP AND SIGNATURE (SUPERVISING PHARMACIST):

***Every page of the report, including the cover, must be signed and stamped individually**

1. Work reports must be filed daily throughout the duration of the internship per the attached report format.
2. Work reports must be signed and stamped daily by the supervising pharmacist.
3. At the end of the internship period, the Internship Benchmark Report must be filed by the intern and approved (via stamp and signature) by the supervising pharmacist.
4. Disciplinary action will be taken for students who are found to have plagiarized, AI-generated, purchased third party services, or otherwise engaged in unethical conduct to write their report forms.
5. At the end of the internship period, an Internship Evaluation Form must be completed by the supervising pharmacist and delivered by hand to the department secretariat in a sealed envelope.
6. Deadlines for internship reports and evaluation forms will be announced by the department during the Fall semester. The final documents that must be submitted are as follows:
    a. The **student internship notebook**, containing **daily Work Reports** and the **Internship Learning Outcomes Report** bound together as a single book.
    b. The **Internship Evaluation Form**, to be filed and delivered in a sealed envelope by the supervising pharmacist.

DAILY REPORT

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Daily Practices and Outcomes:

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BAHÇEŞEHİR UNIVERSITY

SCHOOL OF PHARMACY

PHAR5998 INTERNSHIP IV: PHARMACEUTICAL INDUSTRY INTERNSHIP

Per The Faculty's Internship Learning Outcomes, The Following Topics Must Be Defined And Described In The Intern's Final Report

The following objectives **must be detailed comprehensively based on the specific department(s) of the internship** and must be formally approved (signed and stamped) by the supervising pharmacist.

Internship Evaluation Questions

This set of questions has been prepared on the basis of the learning outcomes of the pharmaceutical industry and R&D internship. Your answers will show whether you have achieved these outcomes by the end of the internship.

Each student must answer two sections:

1. **A. Common Questions:** Regardless of the unit where the internship was completed, all students must answer all 7 questions in this section.
2. **B. Unit-Specific Questions:** Each student must answer only the 7 questions in the subsection under heading B that corresponds to the unit where they completed their internship (B1. Manufacturing, B2. Quality Assurance, B3. Quality Control, B4. Regulatory Affairs, B5. Research and Development, or B6. Medical Affairs / Clinical Research / Pharmacovigilance).

Thus, each student will answer a total of 14 questions.

A. Common Questions

1. What is the organizational structure of the pharmaceutical industry and of drug-related research and development (R&D) centers? Explain the fields of activity and operations of these institutions.
2. What are the professional roles of pharmacists working in the pharmaceutical industry and in R&D centers? Define their duties and responsibilities.

3. Explain the processes of drug research and development, manufacturing, quality control, quality assurance, marketing authorization and post-marketing surveillance. How are these processes related to one another?
4. What are the activities of the institution or unit where you completed your internship? Describe the main methods, technologies and work processes used in the unit.
5. Which legislation and quality standards govern the activities of the unit where you completed your internship? Explain the standard operating procedures (SOPs) and documentation processes applied in the unit.
6. How are the principles of professional ethics, occupational health and safety, data integrity, research ethics and confidentiality reflected in the professional practices of the unit where you completed your internship? Evaluate with examples.
7. Report, using scientific and technical terminology, the professional practices you observed or participated in under supervision during your internship.

B. Unit-Specific Questions

B1. Manufacturing

1. Explain the pharmaceutical manufacturing processes and manufacturing stages carried out in the unit where you completed your internship.
2. Which equipment is used in manufacturing processes? Explain at which manufacturing stage and for what purpose each piece of equipment is used.
3. How are the principles of Good Manufacturing Practice (GMP) reflected in the practices of the manufacturing unit? Evaluate.
4. How is process validation planned and carried out in the manufacturing unit? Evaluate.
5. Which in-process controls are performed during manufacturing? Explain the purpose of these controls and how their results are evaluated.
6. Which SOPs are used in manufacturing processes? Explain with examples.
7. How are batch manufacturing records kept and how are documentation practices carried out? Explain.

B2. Quality Assurance

1. Explain the structure and main activities of the quality assurance system.
2. What is the relationship between the quality assurance system and Good Manufacturing Practice (GMP)? Explain.

3. How do SOP and document management processes work in the unit where you completed your internship? Evaluate.
4. How are deviation and change control processes carried out? Evaluate.
5. How is the corrective and preventive action (CAPA) process initiated, carried out and followed up? Evaluate.
6. Which audits are carried out within the scope of quality assurance? Explain how these audits are conducted.
7. How are records management and data integrity practices carried out within the scope of quality assurance? Explain.

B3. Quality Control

1. How does the quality control process for starting materials work? Explain.
2. How do the quality control processes for intermediate and finished products work? Explain.
3. Which analytical methods are used in quality control studies? Explain.
4. How are the analytical methods used in quality control validated? Explain.
5. How are test results evaluated? Explain.
6. How are sampling and analysis processes carried out? Evaluate.
7. How are analytical results recorded and reported? Evaluate.

B4. Regulatory Affairs (Marketing Authorization)

1. What stages does the marketing authorization process for medicinal products for human use consist of? Explain.
2. What are the national and international regulations related to the marketing authorization process? Explain.
3. What does the Common Technical Document (CTD) contain and how is it prepared? Describe.
4. What does the Summary of Product Characteristics (SmPC) contain and how is it prepared? Describe.
5. What does the Patient Information Leaflet (PIL) contain and how is it prepared? Describe.
6. What role do data on the quality of medicines play in the marketing authorization process? Evaluate.
7. What role do data on the safety and efficacy of medicines play in the marketing authorization process? Evaluate.

B5. Research and Development (R&D)

1. Which research and development activities are carried out in drug and pharmaceutical product development processes? Explain.

2. Depending on the field of activity of the center where you completed your internship, evaluate the preformulation, formulation development, analytical method development or other experimental research processes.
3. Which basic laboratory techniques, instruments and experimental methods are used in research studies? Explain.
4. What are the properties of the active substances, excipients or other components under investigation? Evaluate the roles of these components in the research process.
5. What are the objectives, experimental designs and methods of the research conducted at the center where you completed your internship? Explain.
6. How are experimental data recorded, analyzed, interpreted and scientifically reported? Evaluate.
7. What are the potential contributions of the research conducted to drug development, pharmaceutical technology or other pharmacy-related fields? Discuss.

B6. Medical Affairs / Clinical Research / Pharmacovigilance

1. What are the duties of the medical affairs unit? How is scientific information managed in this unit? Explain.
2. Which scientific communication activities directed at healthcare professionals does the medical affairs unit carry out? Explain.
3. How are clinical trials planned, conducted, monitored and reported? Evaluate.
4. Which ethical principles, Good Clinical Practice (GCP) requirements and related legislation apply to clinical trials? Explain.
5. What are the structure and main activities of the pharmacovigilance system? Explain the legal regulations related to this system.
6. How are adverse drug reaction reports collected, assessed, coded and reported? Explain.
7. Describe the processes of risk management plans, periodic safety update reports (PSURs) and the evaluation of safety signals.