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REPUBLIC OF TURKIYE

BAHÇEŞEHİR UNIVERSITY

SCHOOL OF PHARMACY

INTERNSHIP NOTEBOOK

PHAR 5997 INTERNSHIP III-

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

Date:

Working Hours:

Daily Practices and Outcomes:

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Daily Approval of the Responsible Pharmacist

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PER THE FACULTY'S INTERNSHIP LEARNING OUTCOMES, THE FOLLOWING TOPICS MUST BE DEFINED AND DESCRIBED IN THE INTERN'S FINAL REPORT

PHAR5997 INTERNSHIP III: PHARMACEUTICAL INDUSTRY INTERNSHIP

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.

1. Industry Orientation: Demonstrates a comprehensive understanding of the pharmaceutical industry structure.

2. Professional Role: Evaluates the professional standing, legal duties, and ethical responsibilities of the pharmacist within the industrial setting.

3. Organizational Structure:

   a. Administrative Departments: Evaluates the operational functions of Regulatory Affairs, Marketing and Sales, Quality Assurance, Patent Law, and Data Protection units.

   b. Technical Departments: Analyzes the core functions of R&D, Quality Control, and Production departments.

4. Production & Validation: Describes routine manufacturing processes, contributes to process validations, and executes in-process control (IPC) analyses.

5. Quality Assurance (QA) Management:

   a. Defines the scope of QA within the framework of medicinal product manufacturing.

   b. Manages professional filing and technical documentation systems.

   c. Organizes retrospective databases and maintains systematic records.

   d. Identifies and defines the operational flow of relevant GxP network systems.

e. Executes control protocols from raw material procurement to final production and analyzes operational flowcharts.

f. Implements Good Manufacturing Practices (GMP) and ensures adherence to Standard Operating Procedures (SOPs).

6. Quality Control (QC) Protocols:

a. Conducts QC testing, documentation, quarantine, and storage procedures for active pharmaceutical ingredients (APIs) and excipients.

b. Monitors and implements QC procedures throughout the manufacturing stages.

c. Performs IPC and finished product analyses while summarizing relevant SOPs.

d. Defines finished product and packaging specifications and explains the mandated controls.

e. Evaluates post-marketing stability tests and plans finished product monitoring.

7. Regulatory Affairs:

a. Defines the specific pharmaceutical properties of finished dosage forms.

b. Contributes to the preparation of the Summary of Product Characteristics (SmPC) and regulatory dossiers.

c. Explains the technical components of the registration dossier.

d. Identifies and applies analytical methodologies for APIs and excipients.

e. Executes preformulation and stability studies.

f. Conducts analytical method validation and dissolution profile evaluations.

g. Performs quantitative assays and impurity determinations.

h. Evaluates pilot-scale production, process validation reports, and technical documentation.

i. Ensures documentation complies with Common Technical Document (CTD) standards.

8. Research and Development (R&D):

a. Conducts preformulation and formulation development studies.

b. Implements quantitative analytical methods and purity testing.

c. Evaluates manufacturing controls and optimization parameters.

9. Medical and Clinical Research:

a. Demonstrates proficiency in the Regulation on Clinical Trials, the Declaration of Helsinki, and relevant pharmaceutical legislation.

b. Comprehends the "Regulation on Promotional Activities of Medicinal Products for Human Use."

c. Contributes to the preparation of PSUR, SmPC, and PIL (Patient Information Leaflet) documents.

d. Designs medical training modules for medical sales representatives.

e. Explains the methodology of Bioavailability/Bioequivalence (BA/BE) and clinical trial designs.

f. Monitors clinical trials and reviews, interprets, and documents clinical study reports.

g. Evaluates contractual obligations with Contract Research Organizations (CROs).

10. Pharmacovigilance:

a. Describes the established pharmacovigilance system and evaluates the Pharmacovigilance System Master File (PSMF).

b. Utilizes MedDRA terminology for the standardized classification of adverse drug reactions (ADRs).

c. Reviews corrective and preventive action (CAPA) plans.

d. Participates in internal/external pharmacovigilance trainings and maintains training logs.

e. Manages official correspondence with TITCK and TÜFAM and assists in drafting Risk Management Plans.