ACIBADEM MEHMET ALİ AYDINLAR UNIVERSITY

FACULTY OF PHARMACY

PHAR 593 REPORT

[redacted]

STUDENT'S

Name-Surname:

Student ID:

Academic Year:

Email:

Mobile Phone:

Address:

PHARMACY/INSTITUTION/HOSPITAL INFORMATION

Name:

Phone:

Address:

Pharmacist's Name-Surname:

Email:

Pharmacist's stamp and signature:

Start and end dates of the internship:

Total Internship Duration (Total Business Days): ... business days

PHAR 593 INTERNSHIP APPLICATION GUIDE

When doing your internship and filling out your report, please consider the following topics. Your report should be written in an understandable English with proper spelling and in a scientific language, using short and concise sentences. Your internship gains should be written to cover the following learning objectives. After completing your reports, they should be stamped and signed by the authorized pharmacist in the institution and delivered, along with the pharmacist evaluation forms, to the responsible faculty member within a week of completing the internship.

Production

- Knows the definition and function of Good Manufacturing Practices (GMP).
- Defines validation and manages industrial applications of production validation.
- Has knowledge of methods related to drug production, critical process steps, and production flowcharts.
- Knows the design, function, and control of the water system in the production site.
- Describes the HVAC system and has knowledge of its function.
- Classifies pharmaceutical production areas.
- Produces at laboratory scale and participates in industrial applications of pilot production.
- Applies methods related to drug raw material production and knows the flowchart.
- Prepares the necessary documents for pilot production, performs process validation reports and pilot production controls.
- Knows the process flow in packaging production areas and the label design for the final product.
- Participates in training processes for production personnel.
- Has knowledge of protective equipment and materials for production operators.
- Knows the cleaning of production areas and cleaning validation processes.

Licensing

- Knows regulations and guidelines in the pharmaceutical industry.
- Knows regulations and guidelines for non-pharmaceutical products (cosmetics, medical devices, food supplements, etc.).
- Has knowledge of pharmaceutical licensing authorities and structures in Turkey and worldwide.
- Has knowledge of non-pharmaceutical product (cosmetics, medical devices, food supplements, etc.) licensing authorities and structures in Turkey and worldwide.
- Knows the management structure of the industrial establishment and the responsibilities of its sections.
- Prepares documents required for drug licensing and knows the drug licensing process.

- Prepares documents required for non-pharmaceutical product (cosmetics, medical devices, food supplements, etc.) licensing and knows the licensing process.
- Has knowledge of the definition of Standard Operating Procedure (SOP) and its industrial importance.
- Knows the definition of the Common Technical Document (CTD), its modules, and contents.
- Knows drug recall levels and procedures.
- Has knowledge of the industrial audit mechanism, structure, and auditing process.

Quality Control and Quality Assurance

- Familiar with the duties and responsibilities of the quality control department.
- Aware of the duties and responsibilities of the quality assurance department.
- Knowledgeable about Good Laboratory Practices (GLP) and their role in the pharmaceutical industry.
- Familiar with quality-related guidelines and regulations.
- Knowledgeable about the definition of validation and the role of analytical method validation in the pharmaceutical industry.
- Involved in the analytical method development process.
- Conducts quality controls at different stages of the production of pharmaceutical or non-pharmaceutical products (in-process control, final product control, etc.).
- Involved in determining the analysis methods of active and excipient ingredients and performing their analysis.
- Participates in stability studies.
- Conducts packaging and labeling controls for the final product.
- Applies microbiological quality control methods for pharmaceutical and non-pharmaceutical products.
- Conducts water analysis used in the production facility.
- Familiar with the role of the quality assurance unit in industrial audit mechanisms.

Pharmacovigilance

- Defines pharmacovigilance.
- Familiar with the regulations and guidelines related to pharmacovigilance of national and international authorities.
- Defines adverse effects and evaluates drug interactions.
- Familiar with drug-drug, drug-food, and drug-herbal product interactions and reports them.
- Conducts drug adverse/ side effect notification, monitoring, and reporting activities.
- Plays a role in communication between pharmaceutical industry, hospital, pharmacy, and patient during the monitoring of drug adverse/side effects.
- Familiar with the duties and responsibilities of the National Poison Control Center (UZEM).

- Familiar with the functions and responsibilities of the Turkish Pharmacovigilance Center (TÜFAM).
- Familiar with the pharmacovigilance practices of the Turkish Medicines and Medical Devices Agency (TİTCK).

Research and Development (R&D)

- Has knowledge about industrial R&D studies (pharmaceuticals, cosmetics, medical devices, etc.) and the methods used.
- Knows the stages involved in developing a drug molecule (chemical, biotechnological, biological, etc.).
- Participates in pre-formulation studies, characterization processes, and formulation development (for drugs or cosmetic products).
- Has knowledge about the use of equipment in production, analysis, and characterization stages, and plays a role in determining the calibration of these devices and critical process parameters.
- Knows the original or generic product development process.
- Participates in scaling-up stages (from laboratory scale to large-scale production).
- Acquires knowledge by scanning scientific databases.
- Examines the bioavailability of the product.
- Has knowledge about the selection of appropriate packaging material for the product and calculates its shelf life.
- Participates in the preparation of the technical file for the product.

Sales & Marketing

- Has knowledge about the industrial structure and responsibilities of the Sales and Marketing department.
- Knows the duties and responsibilities of the Medical Sales Representative.
- Knows the duties and responsibilities of the Product Manager.
- Has knowledge about industrial market research and marketing strategies.
- Knows the segmentation definition in marketing and conducts situational analysis.
- Conducts positioning, targeting, and profiling.
- Participates in product life cycle and portfolio management.
- Participates in the procurement process for drugs or non-drug products and advertising processes.
- Has knowledge about corporate communication and sales promotions.
- Knows and applies ethical principles in marketing techniques.
- Has knowledge about IMS's definition, importance, and function in the pharmaceutical industry.

- Plays a role in the marketing of drugs and non-drug products from a business and commercial law perspective and knows sales channels for non-drug products (cosmetics, medical devices, food supplements, etc.).

Pricing (Pharmaco-economics)

- Understands the definition and function of pharmacoeconomics.
- Knows the drug pricing processes in Turkey and Europe.
- Is knowledgeable about drug pricing regulations, guidelines, and directives in Turkey.
- Participates in reference pricing, price list tracking and analysis processes.
- Plays a role in preparing and entering price applications into the system.
- Is involved in pricing of original and generic drugs.
- Understands drug reimbursement definition and system.
- Explains the importance of pricing in marketing.
- Conducts product cost-effectiveness research.
- Evaluates drugs used in rare diseases from a pharmacoeconomic perspective.

Medical and Clinical Research

- Has knowledge about the structure and functioning of the medical department.
- Understands the role and responsibilities of the Medical Director.
- Examines medical and clinical databases and is involved in data collection methods and processes.
- Uses regulations and guidelines for clinical research.
- Is knowledgeable about the methods and ethical considerations in clinical research.
- Knows the phases of clinical trials.
- Defines and applies Good Clinical Practice.
- Examines clinical situations such as drug-drug interactions, drug-food interactions, etc.
- Defines rare diseases and clinically evaluates drugs to be used in rare diseases.

Patent

- Has knowledge about patents and patent duration in the pharmaceutical industry.
- Understands intellectual and industrial property rights.
- Defines utility models.
- Knows the functions, duties, and responsibilities of the Turkish Patent Institute (TPE).
- Follows international patent boards.
- Gains information by searching databases used for patent searches.

Turkish Ministry of Health, Directorate General of Pharmaceuticals and Pharmacy

- Has knowledge about the role, duties, and responsibilities of pharmacists in the Turkish Ministry of Health, Directorate General of Pharmaceuticals and Pharmacy.
- Understands the functions and responsibilities of the Directorate General of Pharmaceuticals and Pharmacy.
- Knows the stages a drug license application file goes through until it receives a license.

Pharmacy & Hospital

- Familiar with areas of responsibility in the pharmacy profession
- Knowledgeable about medication storage and preservation processes
- Familiar with patient information and follow-up processes
- Familiar with self-treatment approaches and the support of pharmacists
- Aware of legal obligations
- Knowledgeable about patient rights
- Familiar with professional obligations and responsibilities
- Knowledgeable about early diagnosis, disease prevention, and healthy living practices
- Knowledgeable about smoking and substance addiction prevention and cessation efforts
- Familiar with medication side effect information, monitoring, and reporting efforts
- Knowledgeable about continuous medication education and lifelong learning efforts
- Familiar with chronic patient medication monitoring efforts
- Knowledgeable about sustainable, safe environmental health efforts in the absence of medication
- Knowledgeable about medication production, presentation, and monitoring processes.

ATTENTION TO OUR INTERNS

During your internship, spontaneous calls and visits will be made to the institution where you are interning in order to check your attendance. If you are not present during the visit, your internship will be extended for the number of days you were absent and this will reflect on your grade.

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Approval of Internship Supervisor (stamp and signature):