

#### ALTINBAŞ UNIVERSITY

#### FACULTY of PHARMACY

#### APPRENTICESHIP NOTEBOOK

**PHAR 576 - INDUSTRY PRACTICES II**

ISTANBUL-2018

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| Photo |

#### ALTINBAŞ UNIVERSITY

#### SCHOOL of PHARMACY

#### APPRENTICESHIP NOTEBOOK

##### Student's;

**Name and Surname:** **.............................................................**

**No:** **.............................................................**

**Type of Apprenticeship: ..............................................................**

**Signature: .............................................................**

**APPRENTICESHIP INFORMATION**

|  |
| --- |
| **Company’s;** |
| **Name**  |  |
| Telephone Number  |  |
| **Address** |  |
| **Name and Surname of the Responsible Manager** |  |
| **Apprenticeship Start Date** |  |
| **Apprenticeship End Date** |  |
| **Apprenticeship Period (Total Business Days)** |  |
| **Apprenticeship Attendance Status** | **Regularly attended to the apprenticeship ( )** |
| **Signature of the Responsible Manager ; Stamp and Date** |  |

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| --- | --- |
| **Course Coordinator :** | Assoc. Prof. Buket AKSU |
| **Instructors** | Asst. Prof. Kaan POLATOĞLUAsst. Prof. Genada SİNANİ |
| **Assistants** | Res. Asst. Gizem YEĞENRes. Asst. Efe Doğukan DİNCEL |
| **Goals** | The purpose of the Industrial Applications II course is making  |
| students see closely the processes that exist in medicine, cosmetics and other related industries and learn the processes from the development of a pharmaceutical product to the presentation of the market. |
| **Content** | Five-weeks, full-time (40 hours per week) industrial practice;  |
| total of 200 (5 x 40) hours. |

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| **LEARNING OUTCOMES****By the end of this apprenticeship students;** |
| * Define Pharmaceutical industry.
 |
| * Understand the place, duty and responsibilities of the Pharmacist in the Pharmaceutical industry.
 |
| * Describe the functions and responsibilities of administrative departments. (Licensing, marketing and sales, quality assurance, patent and data protection).
 |
| * Describe the functions and responsibilities of technical departments ( Research & development, quality control and production departments)
 |
| * Explain routine productions (process validations) and in-process test analysis.
 |
| * Define the responsibilities and apply activities of quality assurance;
	+ Activities in areas covered by quality assurance,
	+ Filing and documentation,
	+ Creation of databases and records,
	+ Complaints and remediation works,
	+ Drug control systems from raw Material to finished products,
	+ GMP applications
	+ Writing and control of standard operation procedures (SOP)
 |
| * Define and understand the scope of quality control and apply quality control activities;
	+ Quality control and documentation in drug raw materials and auxiliaries,
	+ Production stage and subsequent quality control procedures,
	+ In-process and finished product quality checks,
	+ Controls on finished products and packages,
	+ Finished product follow-up,
	+ Determination and validation of analytical methods,
	+ Dissolution rate analyzes,
	+ Quantitative determination methods,
	+ Impurity determinations,
 |
| * Define and understand the scope of licensing and apply licensing activities;
	+ Features related to finished product
	+ Preparation of SPI (Short Product Information) and UI(User Instruction)
	+ Preparation of CTD files
	+ Follow-up stability studies and transmission of necessary information to official centers
	+ Preparations of export files
	+ Pharmaceutical pricing rules, reimbursement systems
	+ Follow-up of clinical trials of bioavailability and bioequivalence tests.
 |
| * Define and understand the scope of Research & Development Studies and apply Research & Development Studies;
	+ Preformulation studies
	+ Formulation development
	+ Quantitative determination methods and quantitative analyzes
	+ The controls related to production.
	+ Purity Determinations
 |
| * Define and understand Pharmacovigilance Studies and apply Pharmacovigilance activities.
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**DAILY REPORT**

**Date:**

**Working Hours:**

**Daily Practices and Outcomes:**

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**Daily Approval of the Responsible Pharmacist**



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