

#### ALTINBAŞ UNIVERSITY

#### FACULTY of PHARMACY

#### APPRENTICESHIP NOTEBOOK

**PHAR 586 - INDUSTRY PRACTICES I**

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** | Assoc. Prof. Buket AKSU  Asst. Prof. Kaan POLATOĞLU  Asst. Prof. Genada SİNANİ |
| **Assistants** | Res. Asst. Gizem YEĞEN  Res. Asst. Efe Doğukan DİNCEL |
| **Goals** | The purpose of the Industrial Applications I 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** | Seven weeks, full-time (40 Hours per week) industry practices; |
| total of 280 (7 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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