Honored colleague;

We are writing to request your esteemed collaboration regarding the internship process of the students of Bahçeşehir University, Faculty of Pharmacy. Within the scope of the PHAR5997 Internship III course, our students are required to complete a compulsory industrial internship for a duration of 30 working days.

We would like to express our sincere gratitude for providing this invaluable opportunity to our students and for your continued support and collaboration with our Faculty.

Please be advised that our students are officially insured by the university strictly for the duration of their working days throughout the internship period. Consequently, students are required to be physically present at your establishment during the designated timeframe.

We kindly request that the internship program be structured in accordance with the guidelines provided below. Upon completion of the internship, we ask that you review the report prepared by the intern; if deemed satisfactory, each page of the report must be duly stamped and signed by the supervising pharmacist or authorized official.

Furthermore, we kindly ask you to complete the Internship Evaluation Form, place it in an envelope that is both sealed and stamped, and return it to the student for formal delivery to our department.

We thank you once again for your professional contribution to our students' clinical and industrial development and wish you continued success in your endeavors.

Addendum 1. Internship learning benchmarks.

Addendum 2. Internship Evaluation Report.

Bahçeşehir University
Faculty of Pharmacy
Internship Commission

Addendum 1. Internship learning outcomes

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.

Addendum 2

T.C. BAHÇEŞEHİR UNIVERSITY
SCHOOL OF PHARMACY
INTERNSHIP EVALUATION REPORT

I . Student and internship information

Student no:
Name:
Contact information for interned pharmacy:
Phone/Address:
Internship start date:
Internship end date:

II. Internship evaluation

	20 points inadequate	40 points below average	60 points average	80 points above average	100 points excellent
Daily attendance	☐	☐	☐	☐	☐
Punctuality regarding work times	☐	☐	☐	☐	☐
Obedience to work rules	☐	☐	☐	☐	☐
Interactions with patients/customers	☐	☐	☐	☐	☐
Ability to communicate and work in a group	☐	☐	☐	☐	☐
Desire for improving professional knowledge and skill	☐	☐	☐	☐	☐
Desire for self-improvement	☐	☐	☐	☐	☐
Sense of duty	☐	☐	☐	☐	☐
Professional skill	☐	☐	☐	☐	☐

III. Other observation and suggestions

IV. Overall evaluation of the intern

Success evaluation: ( ) Successful ( ) Unsuccessful
Date of evaluation:

Supervising pharmacist's

Name Stamp and signature

*** To be delivered to the office of the dean in a sealed envelope after signing and stamping.**