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 PHAR5998 Internship IV course, our students are required to complete a compulsory industrial internship for a duration of 40 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

PHAR5998 INTERNSHIP IV: 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.

Internship Learning Outcomes

A. Common Learning Outcomes

Upon completion of the internship, the student will be able to:

1. Explain the organizational structure, fields of activity and operations of the pharmaceutical industry and of drug-related research and development (R&D) centers.

2. Define the professional roles, duties and responsibilities of pharmacists working in the pharmaceutical industry and in R&D centers.

3. Explain the processes of drug research and development, manufacturing, quality control, quality assurance, marketing authorization and post-marketing surveillance, and the relationships between these processes.

4. Describe the activities of the institution or unit where the internship was completed, together with the main methods, technologies and work processes used.

5. Explain the legislation, quality standards, standard operating procedures (SOPs) and documentation processes related to the activities of the internship unit.

6. Evaluate the principles of professional ethics, occupational health and safety, data integrity, research ethics and confidentiality within the scope of professional practice.

7. Report, using scientific and technical terminology, the professional practices observed or participated in under supervision during the internship.

B. Unit-Specific Learning Outcomes

B1. Manufacturing

8. Explain pharmaceutical manufacturing processes, the equipment used and the stages of manufacturing.

9. Evaluate Good Manufacturing Practice (GMP), process validation and in-process controls performed during manufacturing.

10. Explain the SOPs, batch manufacturing records and documentation practices used in manufacturing processes.

B2. Quality Assurance

11. Explain the structure and main activities of the quality assurance system and its relationship with GMP.

12. Evaluate SOP, document management, deviation, change control and corrective and preventive action (CAPA) processes.

13. Explain the audit, records management and data integrity practices carried out within the scope of quality assurance.

B3. Quality Control

14. Explain the quality control processes for starting materials, intermediate products and finished products.

15. Explain the analytical methods used in quality control studies, method validation and the evaluation of test results.

16. Evaluate the processes of sampling, analysis, and the recording and reporting of results.

B4. Regulatory Affairs (Marketing Authorization)

17. Explain the marketing authorization processes for medicinal products for human use and the related national and international regulations.

18. Describe the content and preparation processes of marketing authorization documents such as the Common Technical Document (CTD), the Summary of Product Characteristics (SmPC) and the Patient Information Leaflet (PIL).

19. Evaluate the role of data on the quality, safety and efficacy of medicines in the marketing authorization process.

B5. Research and Development (R&D)

20. Explain the research and development activities carried out in drug and pharmaceutical product development processes.

21. Evaluate, depending on the field of activity of the center where the internship was completed, preformulation, formulation development, analytical method development or other experimental research processes.

22. Explain the basic laboratory techniques, instruments and experimental methods used in research studies.

23. Evaluate the properties of active substances, excipients or other components under investigation and their roles in the research process.

24. Explain the objectives, experimental designs and methods of the research conducted at the internship center.

25. Evaluate the processes of recording, analyzing, interpreting and scientifically reporting experimental data.

26. Discuss the potential contributions of the research conducted to drug development, pharmaceutical technology or other pharmacy-related fields.

B6. Medical Affairs / Clinical Research / Pharmacovigilance

27. Explain the duties of the medical affairs unit, scientific information management and scientific communication activities directed at healthcare professionals.

28. Evaluate the processes of planning, conducting, monitoring and reporting clinical trials.

29. Explain the ethical principles, Good Clinical Practice (GCP) and related legislation applicable to clinical trials.

30. Explain the structure, main activities and related legal regulations of the pharmacovigilance system.

31. Explain the processes of collecting, assessing, coding and reporting adverse drug reaction reports.

32. Describe the processes of risk management plans, periodic safety update reports (PSURs) and the evaluation of safety signals.

Addendum 2

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

I . Student and internship information

Student ID:
Name Surname:
Internship Code:
Internship Site Contact Information
Phone/Address:
Internship Start/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.**