GDAŃSK UNIVERSITY OF TECHNOLOGY

Subject card

Subject name and code	QUALITY MANAGEMENT IN FOOD AND PHARMACEUTICAL INDUSTRY, PG_00063464						
Field of study	ZARZĄDZANIE JAKOŚCIĄ PRZEMYSŁU SPOŻYWCZEGO I FARMACEUTYCZNEGO						
Date of commencement of studies	October 2025		Academic year of realisation of subject	2026/2027			
Education level	second-cycle studies		Subject group	Obligatory subject group in the field of study			
Mode of study	Full-time studies		Mode of delivery	at the university			
Year of study	2		Language of instruction	Polish			
Semester of study	3		ECTS credits	1.0			
Learning profile	general academic profile		Assessment form	assessment			
Conducting unit	Department of Chemistry Technology and Biotechnology of Food -> Faculty of Chemistry -> Faculties of Gdańsk University of Technology						
Name and surname of lecturer (lecturers)	Subject supervisor		dr hab. inż. Robert Tylingo				
	Teachers						
Lesson types	Lesson type	Lecture	Tutorial	Laboratory	Project	Seminar	SUM
	Number of study hours	15.0	0.0	0.0	0.0	0.0	15
	E-learning hours included: 0.0						
Learning activity and number of study hours	Learning activity	Participation in didactic classes included in study plan		Participation in consultation hours	Self-study	SUM	
	Number of study hours	15		2.0	8.0	25	
Subject objectives	The aim of this course is to deepen the knowledge and skills related to advanced quality management systems in the food and pharmaceutical industries, including regulatory frameworks, risk analysis, and continuous improvement practices. Students will learn about regulatory requirements (among others, mandatory HACCP systems in the food sector and Good Manufacturing Practice (GMP) standards in pharmaceuticals) as well as international quality standards. The course emphasizes an analytical and practical approach to quality management we cover real-world case studies from industry, analysis of quality documentation, internal and external audits, and Corrective and Preventive Actions (CAPA). Ensuring high product quality and safety in food and pharmaceutical production is critical for protecting public health; therefore, the course prepares students to effectively solve complex quality issues using up-to-date guidelines, standards, and best practices.						

Learning outcomes

Course outcome	Subject outcome	Method of verification
[K7_K101] acknowledges the importance of knowledge related to the field of study in solving cognitive and practical problems, critically assessing the information obtained	The student appreciates the importance of specialized knowledge in quality management for solving practical and theoretical problems in industrial biotechnology (food and pharmaceutical sectors) and is able to critically evaluate information obtained regarding quality and regulatory requirements	[SK2] Ocena postępów pracy [SK5] Ocena umiejętności rozwiązywania problemów występujących w praktyce
[K7_W101] is able to make an in-depth identification of key objects and phenomena related to the field of study, as well as theories that describe them and applicable analytical and design methods	The student identifies the key elements and phenomena related to quality assurance in the food and pharmaceutical industries, and understands the theories describing quality systems as well as the analytical and design methods applied in quality management in these sectors.	[SW1] Ocena wiedzy faktograficznej [SW3] Ocena wiedzy zawartej w opracowaniu tekstowym i projektowym
[K7_U07] evaluates the possibility of commercialization of a product or technology based on the analysis of scientific publications and patents	The student is capable of assessing the possibilities of commercializing a product or technology in the food or pharmaceutical sector based on an analysis of scientific literature, patents, and the quality standards and requirements applicable in the industry	[SU1] Ocena realizacji zadania [SU5] Ocena umiejętności zaprezentowania wyników realizacji zadania

Subject contents

Course content – lecture
The lecture series covers key aspects of quality management in the food and pharmaceutical industries. It introduces core concepts of product quality, safety, and the distinction between quality assurance and control, emphasizing the role of quality culture within organizations. It presents legal frameworks such as EU food law, the HACCP system, Good Hygiene and Manufacturing Practices (GHP/GMP), ISO 22000, BRC standards, and the oversight roles of GIS and EFSA. For the pharmaceutical sector, it discusses Good Manufacturing, Laboratory, and Clinical Practices (GMP, GLP, GCP), the Qualified Persons responsibilities, and the structure of a Pharmaceutical Quality System under ICH Q10. Topics include quality documentation, change control, supplier qualification, and data integrity. The course explores Quality Risk Management based on ICH Q9 and practical risk analysis tools (FMEA, FTA, Ishikawa diagram) used to assess consumer and patient safety. Students learn about internal and external audits, regulatory inspections, certification (ISO 22000), and laboratory accreditation (ISO/IEC 17025). The final part covers corrective and preventive actions (CAPA), root cause analysis, and monitoring of improvements. Selected case studies from food and pharmaceutical sectors illustrate real incidents and lessons learned. The lecture concludes with current trends, including digital transformation of quality systems (PAT, blockchain, LIMS) and recent regulatory updates influencing global quality management practices.

Prerequisites and co-requisites

Basic knowledge of biotechnology, food technology, and pharmaceutical science acquired during undergraduate studies. Familiarity with fundamental concepts of quality management (e.g. elements of ISO 9001 standards) as well as basic microbiology and chemistry will be useful. A specific prior course in quality management is not required, but any undergraduate experience related to quality control will be beneficial. In addition, the ability to read professional literature and documentation in English is required.

Assessment methods and criteria

Subject passing criteria	Passing threshold	Percentage of the final grade
Presentation of the problem	60.0%	100.0%

Recommended reading

Basic literature

1. **Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002** laying down the general principles and requirements of food law and establishing the European Food Safety Authority.
2. **Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004** on the hygiene of food stuffs.
3. **EudraLex, Volume 4 EU Guidelines for Good Manufacturing Practice (GMP) for Medicinal Products** (the EU GMP guide, in line with Directive 2003/94/EC).
4. **ICH Q10 Pharmaceutical Quality System** International Conference on Harmonisation guideline on pharmaceutical quality systems (adopted as FDA/EMA guidance, 2009).
5. **ISO 22000:2018** International standard *Food safety management systems Requirements for any organization in the food chain*.

Supplementary literature

1. **U.S. FDA.** *FSMA Final Rule for Preventive Controls for Human Food* requirements introduced by the Food Safety Modernization Act for proactive food safety management.
2. **ISO 9001:2015** *Quality Management Systems Requirements. (International standard outlining the fundamentals of quality management systems)*
3. **ICH Q9: Quality Risk Management** ICH guideline on quality risk management (in effect since 2006; updated version R1 2023).
4. **Codex Alimentarius General Principles of Food Hygiene (CXC 1-1969, Rev. 2020)** Codex Alimentarius Commission code: general food hygiene principles including HACCP guidelines.

eResources addresses

Example issues/ example questions/ tasks being completed	• Characterize the differences between quality management systems in the food industry and the pharmaceutical industry (refer to the different regulations and standards). • Using a selected example (from the food or pharmaceutical sector), describe the root cause analysis of a quality nonconformity and propose appropriate corrective and preventive actions (CAPA). • List and discuss the key elements of quality system documentation in a pharmaceutical manufacturing plant. Why is proper documentation critically important for meeting GMP requirements? • What steps are involved in implementing a HACCP system in a food production facility? Provide examples of critical control points (CCPs) and corresponding monitoring actions. Evaluate, based on available literature and patents, the commercialization potential of a new biotechnological technology, taking into account the regulatory requirements and quality standards in the given sector (food or pharmaceutical)
Practical activites within the subject	Not applicable

Document generated electronically. Does not require a seal or signature.