



Subject card

Subject name and code	Quality Management in Food and Pharmaceutical Industry, PG_00054731						
Field of study	Biotechnology						
Date of commencement of studies	October 2024		Academic year of realisation of subject		2027/2028		
Education level	first-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	4		Language of instruction		Polish		
Semester of study	7		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		1.0		9.0	25
Subject objectives	Introducing students to the philosophy of quality management, emphasizing its importance in the context of the food and pharmaceutical industries. Enabling an understanding of key concepts, norms, and standards that govern product quality in these sectors. Presenting historical and contemporary quality management methods and providing knowledge about procedures, tools, and practices used to monitor and enhance quality in the food and pharmaceutical industries. Additionally, the course aims to prepare students for obtaining an internal auditor certificate for the HACCP system.						
Learning outcomes	Course outcome		Subject outcome		Method of verification		
Subject contents	Course content – lecture General characteristics of quality management systems: Introduction to the fundamental concepts related to quality, quality assurance, and quality management. Overview of the evolution of quality management approaches in a historical context. Examination of the significance of quality management in a free-market economy and the advantages of promoting quality standards. Quality management in the food industry: In-depth analysis of quality standards such as GMP and GHP. Discussion on the EU legal requirements for food production and distribution. Case studies on the implementation and auditing of the HACCP system. Familiarization with international food industry quality management standards like ISO 22000, BRC, and IFS. Quality management in the pharmaceutical industry: Presentation of best manufacturing practices (cgmp) their legal foundations, system management, and auditing. Deep dive into the role and responsibilities of the Qualified Person (QP). Analysis of quality control procedures and process validation in the pharmaceutical context. Discussion on the CAPA system and its associated procedures.						
Prerequisites and co-requisites							
Assessment methods and criteria	Subject passing criteria		Passing threshold		Percentage of the final grade		
	Exam		60.0%		100.0%		

Recommended reading	Basic literature	Wiśniewska, M. Droga przedsiębiorstwa do uzyskania certyfikatu ISO 9000: praktyczny poradnik menedżera. Ośrodek Doradztwa i Doskonalenia Kadr, Gdańsk, 2000. 2. Kijowski J., Sikora T. Zarządzanie jakością i bezpieczeństwem żywności. WNT, Warszawa, 2003 3. Rozporządzenie Ministra Zdrowia w sprawie wymagań Dobrej Praktyki Wytwarzania podpisane przez Ministra Zdrowia (Dz.U. 06.194.1436) opublikowane 26 października 2006 roku
	Supplementary literature	Directives, and Regulations of the European Union.
	eResources addresses	
Example issues/ example questions/ tasks being completed	What is HACCP and why is it so important in the food industry?What are the key aspects of Good Manufacturing Practice (GMP) in the pharmaceutical industry?What procedures and controls are necessary to ensure the quality of a food product from production to distribution?	
Practical activities within the subject	Not applicable	

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