



## 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 2022	Academic year of realisation of subject			2023/2024		
Education level	second-cycle studies	Subject group			Obligatory subject group in the field of study Humanistic-social subject group		
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 Biochemistry of Food -> Faculty of Chemistry						
Name and surname of lecturer (lecturers)	Subject supervisor	dr hab. inż. Robert Tylingo					
	Teachers	dr hab. inż. Robert Tylingo					
Lesson types and methods of instruction	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	<p>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.</p> <p>Additionally, the course aims to prepare students for obtaining an internal Auditor certificate for the HACCP system.</p>						

Learning outcomes	Course outcome	Subject outcome	Method of verification
	[K7_W08] has a profound knowledge of methods of obtaining biotechnological products, possibilities and limitations related to the design of biotechnological processes, understands the specificity of the biotechnological industry, both in terms of organization, management and economic analysis	Capability to identify potential quality threats and ways to eliminate them. Skill in implementing and monitoring quality management systems in industrial organizations. Competencies in communication and collaboration within teams responsible for quality.	[SW3] Assessment of knowledge contained in written work and projects [SW1] Assessment of factual knowledge
	[K7_U08] can analyze patent documents, can make a preliminary assessment of the patentability of a product, process or substance, can use patent databases	The student possesses knowledge of key quality management concepts in the food and pharmaceutical industries.	[SU3] Assessment of ability to use knowledge gained from the subject [SU1] Assessment of task fulfilment
	[K7_U10] is able to use knowledge about possibilities, aims and limitations of biotechnology to develop, design and obtain products and biotechnological processes in the area of his/her specialization	Understanding of the norms, standards, and procedures ensuring quality in the food and pharmaceutical sectors.	[SU2] Assessment of ability to analyse information [SU4] Assessment of ability to use methods and tools
	[K7_K04] is aware of the need to solve problems and perform tasks, independently formulate questions to solve a given problem or task; is able to plan the execution of a larger task by dividing it into partial tasks and draw up an appropriate schedule	Ability to analyze and evaluate quality management systems in terms of their effectiveness and application in industrial practice.	[SK1] Assessment of group work skills [SK2] Assessment of progress of work
Subject contents	<p>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.</p> <p>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.</p> <p>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.</p>		
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	Adresy na platformie eNauczanie:	
Example issues/ example questions/ tasks being completed	<p>What is HACCP and why is it so important in the food industry?</p> <p>What are the key aspects of Good Manufacturing Practice (GMP) in the pharmaceutical industry?</p> <p>What procedures and controls are necessary to ensure the quality of a food product from production to distribution?</p>		

Work placement	Not applicable
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