# GDAŃSK UNIVERSITY OF TECHNOLOGY

## Subject card

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| Subject name and code | Quality Management in Food and Pharmaceutical Industry, PG_00054731 |
| Field of study | Biotechnology |

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| Date of commencement of studies | February 2024 | Academic year of realisation of subject | 2024/2025 |
| 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 | 1 | Language of instruction | Polish |
| Semester of study | 2 | ECTS credits | 1.0 |
| Learning profile | general academic profile | Assessment form | assessment |

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| 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 |
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| | Teachers | |

| Lesson types and methods of instruction | Lesson type | Lecture | Tutorial | Laboratory | Project | Seminar | SUM |
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| | 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 |
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| | 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. |
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| Learning outcomes | Course outcome | Subject outcome | Method of verification |
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| | [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<br>[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<br>[SU4] Assessment of ability to use methods and tools |
| | [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.<br>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<br>[SW1] Assessment of factual knowledge |
| | [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<br>[SK2] Assessment of progress of work |

| Subject contents | 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.<br><br>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.<br><br>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. |
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| Prerequisites and co-requisites | |
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| Assessment methods and criteria | Subject passing criteria | Passing threshold | Percentage of the final grade |
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| | 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 |
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| | Supplementary literature | Directives, and Regulations of the European Union. |
| | eResources addresses | Adresy na platformie eNauczanie: |

| 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? |
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| Work placement | Not applicable |
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