Zarqa University
Faculty of pharmacy

Document code	Course Description Curriculum (1)	Approval date	Revisions	
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Program:	Master in pharmaceutical Manufacturing	Department:	Pharmaceutics and pharmaceutical technology

Course No.	Course Name	Hrs.	Teaching method
1102701	Pharmaceutical Development and manufacturing (1)	3	Direct

Pharmaceutical development courses series is designed to enable the students to develop quality pharmaceutical dosage forms that meet international and regulators requirements. This course is divided into two parts. In the first part, the students will be introduced pre-formulation studies of drug candidate for development. In this part, the students will be able to conduct solid state characterization of drug substance, evaluate drug micrometrics characteristics, evaluate the solubility and dissolution properties of the drug, select the suitable form (salt, crystal form, prodrug, etc.) of the drug, evaluate drug stability characteristics and select the suitable additives for its formulation. The ultimate purpose of this part is to provide rational drug design into a pharmaceutical product in the future. In the second part, the students will study how to develop a solid dosage form for a drug. In this part, the students will know the ideal properties of solid dosage form, select the most appropriate additives for the drug, select the suitable methods to prepare the formulation and the final products and evaluation of the prepared pharmaceutical product.

1102702	Pharmaceutical Development and manufacturing (2)	3	Blended

Pharmaceutical Development courses series is designed to enable the students to develop quality pharmaceutical dosage forms that meet international and regulators requirements. In this course, the students will learn how to develop the drug substance into the following dosage forms: Solution dosage forms such as syrup, elixir, Otic, nasal ophthalmic and others preparation, Semisolid dosage forms such as ointments, pasts, cream, gel etc., aerosol dosage forms such as sprays, foam, MDI and others, modified release dosage forms, For each dosage form the student will learn its ideal properties, the used of suitable additives, method of preparation and quality control.

1102703	Pharmaceutical quality system	2	Direct

This introductory course provides a comprehensive overview of Good Manufacturing Practices (GMP) principles and regulations essential for ensuring the safety, quality, and efficacy of pharmaceutical products. Students will gain a thorough understanding of GMP frameworks, including those established by the FDA, EMA, and WHO. The course will cover key aspects such as quality management systems, manufacturing facilities and equipment requirements, raw material sourcing and control, production and packaging processes, quality control and testing procedures, documentation and record-keeping practices, and regulatory compliance and inspections.

1102705	**Good manufacturing practices**	**2**	**Online**

This advanced course builds upon the knowledge gained in pharmaceutical quality system, focusing on specific applications and specialized topics relevant to pharmaceutical manufacturing. Students will search deeper into areas such as aseptic processing techniques for sterile products, validation and qualification of processes and equipment, data integrity and regulatory compliance, continuous improvement and risk management, and case studies and practical examples of GMP implementation.

1102704	**Regulatory Affairs and intellectual property**	**2**	**Online**

This course provides a comprehensive overview of the regulatory aspects governing the pharmaceutical industry. Students will gain a thorough understanding of the principles, processes, and requirements for developing, registering, and marketing safe and effective pharmaceutical products. By analyzing key regulations and frameworks from the JFDA, FDA, EMA, and other global agencies, students will develop the skills and knowledge needed to navigate the complex regulatory environment and contribute to successful drug development and commercialization.

1102731	**Development and manufacturing of biological drugs**	**2**	**Online**

This course offers a comprehensive exploration of the dynamic fields of biotechnology and Biosimilars, focusing on their critical roles in advancing healthcare and therapeutic solutions. Students will go through into the principles of biotechnological processes, the development of innovative biopharmaceuticals, and the challenges and opportunities presented by Biosimilars.

1102730	**Practical applications in pharmaceutical manufacturing**	**1**	**Direct**

The Practical Applications in Pharmaceutical Manufacturing course is an intensive program designed to provide students with hands-on experience and in-depth knowledge of the practical aspects of pharmaceutical manufacturing. This course goes beyond theoretical concepts to immerse students in real-world pharmaceutical production settings, ensuring they are well-prepared for careers in pharmaceutical manufacturing, quality control, and regulatory affairs. students should train **at least 240 hours**.

1102706	**Quality control**	**3**	**Direct**

1102716	**Sterile product manufacturing**	**2**	**Blended**

This course deals with covers the fundamental principles, technologies, and regulatory requirements essential for the production of sterile pharmaceutical products. In this course the students will learn how to develop a drug into a parenteral dosage form. It includes product ideal properties and manufacturing considerations, suitable additives solvents, packaging systems, aseptic processing, methods of sterilization, and methods of getting rid of pyrogen. The course also discusses manufacturing of parenteral products and quality control. Due to the sensitivity of this dosage form special emphasis will be given to quality assurance aspects of it manufacturing including clean room design and its operation.

1102727	**Stability of pharmaceuticals**	**2**	**Blended**

This course deals with the extensive examination of pharmaceutical stability. Special emphasis is given to physical and chemical instability of pharmaceutical substances in the pharmaceutical dosage form. The course also covers the following topics: design of stability studies, kinetic evaluation of stability data, study of the factors that affect the rate of drug degradation, mechanism of drug degradation and prediction of shelf life. The course also discusses the design of stability protocol for pharmaceutical product according to regulatory guidelines.

1102720	**Pharmaceutical instrumental analysis**	**2**	**Blended**

This course provides students with a comprehensive understanding of advanced analytical techniques essential for quality control, research, and development. This course delves into a wide range of instrumental methods, including chromatography, spectroscopy, mass spectrometry, and electrophoresis, providing a comprehensive understanding of their applications in pharmaceutical analysis. Students will gain hands-on experience with state-of-the-art analytical instruments, learning to interpret complex data and troubleshoot analytical challenges. Emphasis is placed on the integration of instrumental analysis within regulatory frameworks, ensuring compliance with industry standards.

1102726	**Data management**	**2**	**Blended**

This course is designed to equip students with the skills necessary to handle and analyze large datasets generated throughout the pharmaceutical manufacturing process. Topics covered include data collection, storage, validation, integration, interpretation, and reporting using various software tools and platforms. Emphasis is placed on data integrity, security, and compliance with regulatory requirements. Students will also explore into emerging technologies such as data analytics, machine learning, and artificial intelligence, exploring their applications in optimizing manufacturing processes and decision-making.

1102715	**Pharmaceutical Microbiology**	**2**	**Blended**

The course is designed to provide specialized knowledge about the microorganisms and their critical role in the pharmaceutical industry. Throughout this course several topics will be covered such as: the impact of microorganisms on product quality and safety, latest advancements in microbial detection, contamination control, and relevant regulatory standards.

1102722	**Topics in pharmaceutical industry**	**2**	**Blended**

This course covers contemporary issues relevant to professionals in pharmaceutical production, emphasizing regulatory compliance, emerging technologies, market trends, and ethical considerations. The interdisciplinary nature of the course addresses diverse dosage form preparations, including solid, liquid, and semisolid formulations. Tailored for master's level students, the program fosters critical thinking and adaptability, preparing graduates to navigate the complexities of pharmaceutical manufacturing, contribute to the industry, and innovate in dosage form development.

1102711	**Pharmacovigilance and drug safety**	**2**	**Blended**

This course explores the critical role of pharmacovigilance in ensuring the safety of pharmaceutical products and its impact on public health. Students will learn about regulatory frameworks governing pharmacovigilance and practical strategies for implementing effective pharmacovigilance systems. Graduates will gain the expertise needed to navigate the complex interplay between drug safety and economic factors, making them valuable contributors to the pharmaceutical and healthcare sectors.

1102713	**Clinical Trials and Bioequivalence**	**2**	**Blended**

The course provides a comprehensive exploration of the essential principles and practices involved in designing, conducting, and evaluating clinical trials in the pharmaceutical industry. Students will gain a deep understanding of the regulatory framework, ethical considerations, and the various phases of clinical trials, from planning and recruitment to data analysis and reporting. Special emphasis is placed on bioequivalence studies, covering the critical aspects of demonstrating the equivalence of generic and innovator drugs.

1102714	**Pharmaceutical Supply Chain Management**	**2**	**Blended**

This course provides a thorough exploration of end-to-end processes in the pharmaceutical supply chain. Basic components of supply chain management system as procurement, logistics, inventory management, and distribution and their interrelationships will be covered. Emphasis is placed on the crucial role of supply chain strategies efficiency for drug availability, quality, and safety.