- **Program Study Plan**:

First Level:

#	Course Code	Name	No. of Study Units	Prerequisite
1	QCP 501	Pharmaceutical Statistics	2(2 + 0)	
2	QCP 502	Comprehensive Pharmaceutical Quality Control	2(2 + 0)	
3	QCP 503	Quality and Performance Audit Skills in Laboratories	2(2 + 0)	
4	QCP 504	Quality Control by Chemical Analytical Methods	3(2 + 2)	
5	QCP 505	Quality Control of Pharmaceutical Raw Material	2(2 + 0)	
Total			**14**	

Second Level:

#	Course Code	Name	No. of Study Units	Prerequisite
1	QCP 511	Quality Control by Advanced Analytical Methods	4(3+2)	
2	QCP 512	Principles, Procedures and Software in Validation	2(1+2)	
3	QCP 513	Good Manufacturing Practice (GMP)	2(2+0)	
4	QCP 514	Quality Control and Assurance in Hospital Pharmacy	2(2+0)	
5	QCP 515	Quality Control of Solid Dosage Forms	2(2+0)	
Total			**12**	

Third Level:

#	Course Code	Name	No. of Study Units	Prerequisite
1	QCP 521	Quality Control in Medication Use Management	2(2+0)	
2	QCP 522	Bioanalytical Techniques for Quality Control of Biopharmaceuticals	2(2+0)	
4	QCP 523	Quality Control of Liquid and Semisolid Dosage Form	2(2+0)	
5	QCP 524	Quality Control of Sterile Pharmaceutical Products	2(1+2)	
6	QCP 598	Research project (1)	3(3+0)	
Total			**11**	

Fourth Level:

#	Course Code	Name	No. of Study Units	Prerequisite
1	QCP 531	Stability-Indicating Methods for Pharmaceutical Products	2(1+2)	
2	QCP 532	Quality Control of Biological Products	2(2+0)	
3	QCP 533	Quality Control Testing of Stability and Packaging	2(2+0)	
4	QCP 534	Quality Control of Antimicrobial Preparations	3(2 + 2)	
4	QCP 599	Research project (2)	3(3+0)	QCP 598
Total			**9**	

- **Description of Courses**:

QCP 501	Pharmaceutical Statistics	2(2 + 0)
The course covers most of the statistical tools that quality control units applied to withdraw conclusions about pharmaceutical products and procedures. Course covers basic concepts such central tendency and dispersion. Also, more advanced frequently used statistical techniques such as ANOVA and the chi-squared test are illustrated. Sample size and selection of controls are also discussed. More emphasis on the course is toward writing statistical outcomes which are part of any official quality control reports.		

QCP 502	Comprehensive Pharmaceutical Quality Control	2(2 + 0)
The course is designed specifically to help student to learn the important of quality control units in pharmacist work. Also, it will help in learning the monitoring and adjusting processes that continuously improving pharmaceutical organization quality. This course is considered as introductory to application of quality control in pharmacist work. Focus will be linking directly to quality control units in institution such as hospital, FDA and industry. Many important topics will be covered including an introduction to quality, brief description of various quality topics, elements of a quality management system and project quality plan.		

QCP 503	Quality and Performance Audit Skills in Laboratories	2(2 + 0)
This course is an introductory for good (quality control) laboratory practices. It explores the fundamentals of quality systems in place within a regulated laboratory. It covers topics and concepts to successful implementation of quality within pharmaceutical laboratories. Topics include various quality management standards such as ISO 17025, ISO 15189, ISO 9000 and GLP. Focus is in implementing such standards and their requirements with respect to laboratory practices as well as the accreditation process through agencies such as the National Association of Testing Authorities. It provides students with knowledge and practical skills in auditing principles and practices. Course also gives students an advanced		

understanding of auditing practices and its relevant to quality unit.

QCP 504	Quality Control by Chemical Analytical Methods	3(2 + 2)
The course describes the basis and operations involved in chemical methods used for quality control of pharmaceuticals. It highlights the types of analytical tools, measures, standards, and standard operating procedures for preparing the reagents, standards and samples pretreatments as per the particular analytical techniques. In addition, the course describes chemical test for limits determination in pharmaceuticals for the purpose of quality control, good laboratory practice for quality assurance of analytical results, stoichiometric calculations in analytical chemistry, and general concepts of chemical equilibrium and kinetics. Furthermore, the course describes the electrochemical methods most commonly used in quality control laboratories in terms of their fundamentals, instrumentations and practical applications. These methods include potentiometry (analyte-selective electrode-based and potentiometric titrations).		

QCP 505	Quality Control of Pharmaceutical Raw Material	2(2 + 0)
The course deals with testing both active pharmaceutical ingredients and excipients as one of the main responsibilities of the quality control units in the pharmaceutical industry. Emphasis will be on the necessary tests which are going to be conducted on the incoming materials and released after satisfactory judgment. This course will provide the student with comprehensive overview skills of controlling of the received APIs and excipients. Many important topics will be covered including: Regulatory Requirements for APIs and Excipients (FDA and Pharmacopoeias), Current GMP Requirements for APIs, Sampling of incoming APIs and Excipients and Analytical Methods.		

QCP 511	**Quality Control by Advanced Analytical Methods**	**4(3+2)**
The course discusses the chemical principles and practice of both qualitative and quantitative analysis of samples for identifying their identities and determining the compositions by separation-based analytical techniques. These techniques include the most commonly employed in both industrial and academic research laboratories, spectrophotometry (ultraviolet and visible), spectroflurimetry, atomic absorption spectrometry, flame photometry, infrared spectroscopy, Raman spectrometry, nuclear magnetic resonance spectroscopy, and mass spectrometry, liquid chromatography, gas chromatography, capillary electrophoresis and their various hyphenated techniques. The course is devoated to describe the basis, instrument components, and operation of each technique. The course emphasizes hands-on experience in analyzing and quality control of real-life samples such as raw materials, pharmaceutical preparations, dietary supplements, medicinal herbs and cosmetics.		

QCP 512	**Principles, Procedures and Software in Validation**	**2(1+2)**
The course is devoted to discuss the integrated approaches conducted for validation necessary to control and assure the quality of pharmaceuticals. It highlights the guidelines recommended by authorities (International Conference on Harmonization, ICH; Food and Drug Administration, FDA; United States Pharmacopeia, USP) for validation of analytical operations and results, analytical instrument qualification, statistical aspects of analytical methods validation, use of statistics to support validation data, exploration of statistical techniques, planning, the sources of errors and uncertainties that happen during analysis procedures and the approaches for their minimizations and practical execution of validation parameters, preparing validation protocols/reports. In addition, it describes the documentation of validation, and validation software.		

QCP 513	**Good Manufacturing Practice (GMP)**	**2(2+0)**
The course provides an overview of the good manufacturing practice (GMP) guidance of manufacturing operations in the pharmaceutical industry with more emphasis on the role of quality control unit in the GMP compliance. Manufacturing environments and their application in order to optimize the GMP compliance will be discussed. This will include mainly the guidance to insure the quality of the active pharmaceutical ingredients (APIs), pharmaceutical excipients and more importantly pharmaceutical products especially products with special nature namely: sterile medicinal products; biological medicinal substances and products; herbal medicinal products		

QCP 514	**Quality Control and Assurance in Hospital Pharmacy**	**2(2+0)**
This course describes the standards, internal and international policies that regulate quality control and assurance processes at hospital pharmacy practice. Many topics is covered including: Define the concept of quality control on both organization and pharmacy levels, in addition understand the dimensions of quality control that provide the framework for proper quality management activities in healthcare settings. Understand the major organizational accreditations standards (e.g. Joint commission international (JCI), The Central Board of Accreditation for Healthcare Institutions (CBAHI)) that are used as tools to regulate the delivery and quality of healthcare services for healthcare institutions in general and hospital pharmacies in particular as a part of the whole institution. Discuss the major and specific hospital pharmacy standards requested for accreditation purpose that ensure proper quality control process (e.g. staff, committees, internal policies that regulate daily operations of the pharmacy). Describe the policies that regulate and ensure proper quality management of the different pharmacy sub-divisions (e.g. satellite pharmacies). Address challenges and concerns when applying quality control and assurance polices at hospital pharmacies.		

QCP 515	Quality Control of Solid Dosage Forms	2(2+0)
The course deals with testing solid dosage forms as one of the main responsibilities of the quality control units in the pharmaceutical industry. Emphasis is on the necessary tests which are conducted on the solid dosage forms including: tablets, capsules, granules, microspheres and mixed powders. This course provides student with comprehensive overview skills of controlling produced solid dosage forms. Many important topics are covered including: QC/R&D team working in solid dosage forms, chemical and physical testing of solids, dissolution and acceptance criteria.		

QCP 521	Quality control in Medication Use Management	2(2+0)
This course describes the principles, standards, activities and responsibilities required at hospital pharmacies for medication usage management to ensure that the medicine reaches the patient is safe, effective, and acceptable. Many topics is covered including: Define medicine usage management. Describe the complete drug flow process at hospital pharmacy starting from delivery until reaching the patient. Understand polices and common practice for quality assurance at each stage of drug flow process (e.g. selection, procurement, storage, transport, packaging, labeling, dispensing, monitoring, etc.). Describe the role of different hospital pharmacy departments that are involved in medication usage quality assurance process. Address quality challenges in medication usage management at hospital pharmacies.		

QCP 522	Bioanalytical Techniques for Quality Control of Biopharmaceuticals	2(2+0)
The course describes the basic science and practical methodologies involved in the development of critical bioanalytical methods for analysis of biopharmaceuticals (e.g. protein drugs, biological and biopharmaceutical products). These methods include ligand-binding assays, immunoassays, enzyme-based assays, biosensors and electrophoresis. The course gives detailed description for the required key critical reagents, assay formats, instrumentation, establishing the technical protocols for assays, and describes the specific validation parameters for these assays. The course emphasizes the applications of the techniques in quality control laboratories and pharmaceutical industries.		

QCP 523	**Quality Control of Liquid and Semisolid Dosage Form**	**2(2+0)**
The course deals with testing both liquid and semi-solid dosage forms as part of the main duties of the quality control units in the pharmaceutical industry. Emphasis is on the necessary tests which are conducted during and after manufacturing of liquid and semi-solid dosage forms in order to be released after satisfactory judgment. The prime objective of this course is to provide students with the basic information of quality control (QC) testing of liquid and semisolid pharmaceutical dosage forms as well as their in-process quality control (IPQC) testing.		

QCP 524	**Quality Control of Sterile Pharmaceutical Products**	**2(1+2)**
The course aims to introduce the principles and methods of preparation of pharmaceutical products from microbiological aspects in pharmacy practice. The course will focus also on sterilization, disinfection and preservation of biopharmaceuticals and immunological products.		

QCP 531	**Stability-Indicating Methods for Pharmaceutical Products**	**2(1+2)**
This course provides a comprehensive review of the considerations relevant to developing a stability-indicating analytical method. The course starts by anticipating likely degradation based on chemical structure. Consideration is then given to forced degradation (stress study) to produce likely degradants, followed by the selection of the proper method of analysis which is capable of simultaneous analysis of the intact drug entity and any degradants. Upon completion of this course, delegates will have learned what is necessary to develop a stability-indicating method for drug substance and drug product to comply with international regulatory guidelines.		

QCP 532	**Quality Control of Biological Products**	**2(2+0)**
The course describes the principles of Quality Assurance and Control measures taken for Biotechnology Products. Develop an effective risk management strategy for biotechnology products, address quality challenges in product development steps, demonstrate common guidance from regulatory arms nationally and internationally, and to appreciate the differences in managing quality for chemical drugs vs biotechnology products.		

QCP 533	**Quality Control Testing of Stability and Packaging**	**2(2+0)**
The course deals with testing the stability and packaging of pharmaceutical products as one of the main responsibilities of the quality control units in the pharmaceutical industry. Emphasis is on the necessary tests which are conducted to evaluate the product stability based on ICH guidelines. The test procedures for different dosage forms and interpretation of analytical stability date to withdraw the stability conclusions are the main backbone of the course. Moreover, various tests for determination of quality, integrity and compatibility of packaging materials are discussed. The packaging specification and requirements of quality testing depends on type of pharmaceutical materials also are highlighted.		

QCP 534	**Quality Control of Antimicrobial preparations**	3(2+2)
In this course the student identify the basic methods of sampling of pharmaceutical products and the identification micro-organisms with different methods include; traditional biochemical reaction, modern methods for automated identification based also on biochemical reactions. The student will be provided with methods of detection of pyrogen and different method of depryogenation either separation or inactivation. This course concerned with different method for antibiotics assay either in liquid medium or on solid medium.		

QCP 598		**Research project** (**1**)	**3**(**3+0**)
The aim of the course is to give the students an opportunity to perform a research project within the field of quality control under supervision according to student-research interest. Learning process starts by evaluating defined quality control problems, utilizing relevant scientific literature, applying experimental methods to solve a given scientific task.			

QCP 599		**Research project** (**2**)	**3**(**3+0**)
The aim of the course is to give the students an opportunity to perform a research project within the field of quality control under supervision according to student-research interest. Learning process starts by collecting data for evaluation, statistical treatment, summarizing the results in a research report and presenting the results of the project.			