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Original Research

Conceptualization, development, and evaluation of 'pharmaceutical product development' graduate program within pharmacy discipline

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Abstract

Objective: Designing a region's need-based programs can be an exceptional complement boosting the knowledge economy of the country. United Arab Emirates (UAE) is increasingly focusing on the pharma and biotech sectors. As a result, there have been increasing demands for qualifications in pharmacy education to fit into higher roles in pharmaceutical industries and multinational companies (MNCs) in the region. **Method:** This study is a case demonstration that details the design processes authors used for the graduate program 'Pharmaceutical Product Development'. **Results:** The three stages in program positioning; identifying the need for the new program, program design, and development, and program effectiveness are illustrated in this manuscript. **Conclusion:** The authors believe that this manuscript serves as a valuable resource for novice curriculum developers in the development of new educational programs.

Keywords: graduate program; program effectiveness; curriculum design; curriculum development; graduate competencies

INTRODUCTION

In the last decade, the Higher Education sector in the UAE has seen a vast transformation from traditional to responsive need-based program offerings. As the knowledge economy has started growing in UAE, Higher Education Institutions (HEIs) have also started evolving with new programs. The pharmacy profession has observed tremendous growth in the region. It is estimated that by the year 2025, drug expenditure in UAE will be worth AED21.74bn (USD5.92bn).[1]

Despite tremendous growth in the Pharma sector in the region, Pharmacy education has slowly evolved in the UAE and most skilled pharmacy professionals working in the region are expatriates. In the 1990s, the only college offering a Bachelor of Pharmacy program in UAE was the Dubai Pharmacy College was the sole key player.[2] The next program in pharmacy was started in 1996 by Ajman University. In 2010, Al Ain University, Gulf Medical University, Ras Al Khaimah, and University of Sharjah, Higher Colleges of Technology were also offering pharmacy education. With the addition of Fatema College of Health Sciences and City University College of Ajman at present, there are ten in the country.[2]

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Education and training that address the changing labor market needs will benefit not only the individuals but also contributes to the greater economic growth of the nation. With immerging trends in the pharmacy profession in the region, there was a strong need to introduce a new education program for meeting and preparing future task force needs of the nation. However, the growth story of bringing in new programs also has thrown up some challenges. As program development involves heavy finances, research, planning, and marketing strategy, the program development process needs to be on a firm foundation to avoid delays and losses.

There are three stages in the program positioning: identifying the need for a new program; program design and delivery, and finally, program effectiveness.[3] This paper examines all three aspects to give a complete overview of the new program development process for MPharm in "Pharmaceutical Product Development" (PPD) as a case study to help novice program developers and stakeholders in their decision-making.

STAGE 1: IDENTIFYING THE NEED FOR A NEW PROGRAM

An education needs assessment is a systematic exploration of a gap between the current level of educational services offered and the desired level of services. Through carefully evaluating the emerging markets and current situation, possible new directions can be identified.

Non-oil GDP in the UAE already accounts for more than 60 percent of total GDP, and Sheikh Mohammed bin Rashid, Vice-President, and Ruler of Dubai has set a goal to increase this figure to 80 percent of GDP by 2021.[4] The GCC pharmaceutical market is mainly dominated by patented drugs, with generics

having only about a 5%-6% market share.[5] Since the domestic manufacturers primarily focus is on generic drugs, they have managed to capture only a small portion of the overall market value; pharmaceutical products are outsourced and mainly operate through international scientific offices of multinational companies in the UAE.[1] Nowadays, the government is increasingly focusing on the pharma and biotech sector with enhanced regulations to support production and supply.[6] Dubai government has established 'Dubai Science Park' for pharmaceutical and biotechnology companies to establish their manufacturing and research units and is developing rapidly. It was projected that pharmaceutical factories and scientific offices are estimated reach to 34 and 75 respectively by year 2020 as suggested by Dr. Amin Hussain Al Amiri, Asst. Undersecretary for Public Health Policy & Licensing, Ministry of Health & Prevention, UAE.[1] In line with this, locally produced pharmacists with Industry-focus competencies are required generate locally produced graduates to meet the nation demands and lesser dependency on out of the country labor market. Overall, the development in the region supports the program implementation.

STAGE 2: PROGRAM DESIGN AND DEVELOPMENT

Once needs have been identified, they are sorted, prioritized, and translated into educational programs. A needs assessment will determine if the educational programs developed elsewhere can be adapted, saving considerable time, effort, and resources or if customized programs are needed to fulfill the needs. External benchmarking is an important tool for program development. Europe, the USA, and far eastern countries have well-established industrial sectors and the specialization programs offered in these countries are mainly developed to fit for industries. For example, colleges in these regions are mainly offering Masters in Pharmaceutics, Industrial Pharmaceutics, Quality Assurance, Regulatory Affairs, however, no specific program that meets all the requirements.[2] Therefore, designing a curriculum that fits both manufacturing industries' and multinational companies' requirements of the region was quite different from other parts of the world. Based on the market survey, key technical skills were identified and benchmarked against relevant programs (Table 1).[7]

The strength of any curriculum is determined by its content. Setting curriculum contents requires a comparison with a set of internal and external benchmarks and standards. The program specification is a description of the program that is required as part of the process of quality review in higher education. The *Qualifications Framework for the Emirates* known as the *QFEmirates* functioning under *National Qualification Authority* (NQA) serves as a single structure and reference point through which all qualifications in a country can be compared nationally and internationally.[8] It provides a framework of levels defined by learning outcomes to aid the design of fit-for-purpose

Table 1. Identified Key Competencies for a New Graduate Program Benchmarked against similar existing programs*

Area	Key competencies identified	Pharmaceutics	Industrial Pharmacy/ Industrial Pharmaceutics	Quality Assurance	Regulatory Affairs	Pharmaceutical Technology
Pharmaceutical Formulation Development	Knowledge and skills in pre-formulation, formulation development of a new chemical entity, or optimizing an existing drug delivery system or technology transfer process	√	√			√
Pharmaceutical Quality Assurance	Knowledge of Current good manufacturing guidelines, documentation including batch manufacturing reports and standard operating procedures.		√	√		
Regulatory affairs:	Knowledge of Regulatory guidelines and requirements, submission process.			√	√	
Pharmaceutical Quality Control	Knowledge and skills in in-process and finished products quality control procedures in compliance with various pharmacopeial and non-pharmacopeial requirements for different dosage forms and drug delivery systems.	√	√	√		√
Bioavailability and Bioequivalence studies:	Support Bioequivalence studies and endeavoring biowaiver applications based on BCS classification and in vitro-in vivo correlations.				√	
Intellectual Property Rights:	Conduct a patent search and look for infringement issues.				√	

*Authors' Disclosure: Benchmarking of competencies against similar existing programs is based on personal interpretation and available information only which may vary from case to case. Names of the Universities are not included due to conflict of interest. The authors have presented this information for illustrative purposes only.

qualifications and provide the basis for the comparison of UAE qualifications with other world-class national and international frameworks. Bachelor of Pharmacy and Master of Pharmacy qualifications fall at level 7 and level 9 respectively, in this qualification framework. Under this framework, learning outcome descriptors at each level are defined in statements of knowledge, skill, and competence that represent a hierarchy of relative difficulty, complexity, and depth particular to that level.

In alignment with *QFEmirates* and key employee competencies identified, a bottom-up approach was adopted to constitute the curriculum with proper constructive alignment and the courses were designed based on the model demonstrated in Figure 1 with internal and external stakeholders' involvement. After identification of different competencies, programs aim, outcomes and the detailed curriculum was drafted by the college faculty members in consultation with external stakeholders and with international benchmarking. As a result, the final program came out was of 36 credit hours requiring two years of study. Program aims and learning outcomes were designed in line with the vision, mission, and teaching-learning strategies that were aligned with program outcomes. The details are provided in Appendix 1. Once the program is structured, diversifying existing resources (human, financial, physical, and material) and procuring new resources need significant planning and budgeting.

STAGE 3: EVALUATION OF PROGRAM EFFECTIVENESS

The process does not end once a program has been planned; instead, the evaluation of the program's effectiveness should be done at the end to ensure that a new process is started; the evaluation process serves as a preliminary part of the subsequent needs analysis.

Successful program implementation depends heavily on the capacity of a college or university to support and sustain the curriculum being adopted. Process evaluation and program and performance monitoring are elements of program evaluation that can provide essential data in judging the program's effectiveness and providing critical feedback to curriculum designers on further program improvements.[9] The main factors that undermine the benefits of program effectiveness are the enormity of the data, diversity of the data, an overlap of data means duplication, lack of consistency, frequent additions leading to reformatting multiple times, and the report preparation itself becomes a tedious task. Since the data is exhaustive and unclear, there is less clarity among different strata. For this reason, there needs to be a practical framework or schema which can be easily understood. The authors created a framework to clarify the significant indicators on which the program's effectiveness relies heavily (Appendix 2). This framework identifies program effectiveness in eight different aspects, which include external environmental factors, faculty profiles and characteristics, student enrollment and success, core program learning outcomes assessment, clerkship assessment, student attitudes and perceptions related to college and library facilities, and lastly, quality of curriculum and student learning with a total of 42 indicators. The annual planning and assessment cycle has been created to take an inventory of the available data that may reveal the need for additional information. This cycle enables the development of a list of instruments and direct/indirect measures appropriate to the purpose.

CONCLUSIONS

In this manuscript, the authors have demonstrated the conception, design, and development of postgraduate specialization in pharmacy education to meet the nation's

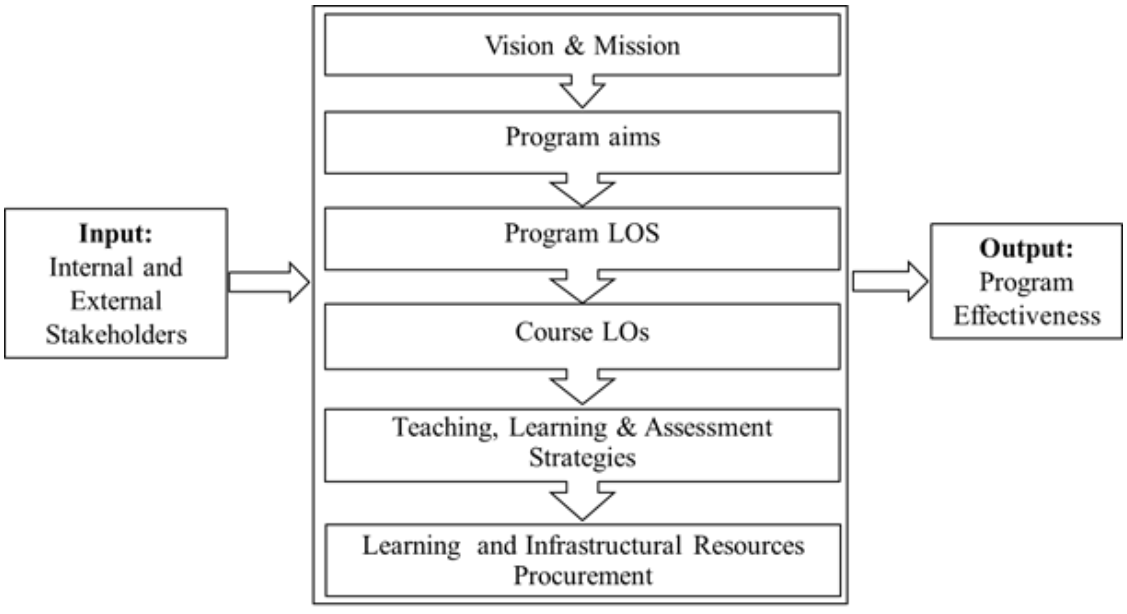

Figure 1. Curriculum development process

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growing needs. The program effectiveness evaluation helps the stakeholders to set further strategic directions for improvements. This study effectively demonstrates the curriculum planning and development process and discusses program effectiveness evaluation. The authors believe this manuscript serves as a valuable resource for curriculum developers in developing new educational programs.

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APPENDIX 1. PROGRAM AIMS AND LEARNING OUTCOMES

Program aims

The program is intended the graduates to:

To equip students with versatile skills in the theoretical understanding, practical execution and critical evaluation of pharmaceutical science principles to underpin their professional careers.

To provide with practical and hands-on skills applicable to the development of stable pharmaceutical products.

To develop within the context of Pharmaceutical Product Development, a comprehensive understanding of quality principles, regulations, intellectual properties, technology transfer and research methods.

To provide learning opportunities to enable to think critically and to further develop as an autonomous and lifelong learner.

To plan and execute major research project.

To enable students to develop knowledge and a range of interpersonal, transferable and employability skills.

Program Learning Outcomes and Teaching and Assessment Strategy

Knowledge and Understanding

Learning outcomes:

On completion of the M. Pharm. program, the graduates will be able to:

A1. Demonstrates specialist and comprehensive knowledge required in development and evaluation of pharmaceutical products

A2. Comprehend the ethical, legal and quality principles of professional practice in the field of specialization.

Teaching and assessment strategies for knowledge-based outcomes

The main method of providing information for knowledge is through lectures and the associated hand-outs and supporting material on the learning platform Desire2Learn.

Feedback on progress is given through tutorials, study groups, coursework and class tests, and students are expected to use this feedback to enhance and develop their learning. The coursework mark is derived from a series of assignments which assess your ability to synthesize information from various sources into reasoned reports. Coursework varies from course to course and comprises a mix of Practical write-ups, Patient profiles, written reports and essays, small group projects, oral presentations, quizzes etc. Coursework submission guidelines & grading criteria (usually in form of rubric) will be provided by course coordinator. Comprehensive exams usually combine MCQ section, short answers, and longer essay-type questions to evaluate LOs at different level of knowledge domain of bloom's taxonomy.

Skills

Learning outcomes:

On completion of the M. Pharm. program, the graduates will be able to:

B1. Formulate different pharmaceutical products based on sound physicochemical and pharmacokinetics aspects and evaluate them in vitro and in vivo.

B2. Communicate effectively orally and in writing and deploy a range of presentation techniques and strategies to present, explain and critique information within workplace settings.

Teaching and assessment strategies for skill based outcomes

Practical skills required are developed through objectively structured lab experiments. In order to equip DPC students with good communication skills which is a general skill required in both the field of pharmacy practice, various opportunities are provided and such as assignments, seminars, case discussion, written and oral communication through oral and written examinations. Practical skills are assessed through Objective Structured Practical Examination (OSPE) and written reports. Written and oral exams are used in different courses which provide opportunities for students to communicate in orally and in writing.

Assignments and seminars embedded in the courses are used to assess students' communications skills orally and in writing. Plagiarism check is used to assess the originality of students' submitted assignments and reports. Multidimensional sets of scoring guidelines (Rubrics) that clearly states criteria for evaluations are used to evaluate assignments and seminars to provide

performance expectations, feedback for improvement, and consistency in evaluating student work and to improve the teaching.

Competencies

Learning outcomes:

On completion of the MPharm program, the graduates will be able to:

Autonomy and responsibility

C1. Demonstrate self-direction and originality in tackling and solving problems, and act autonomously in planning and implementing tasks at a professional or equivalent level through executing major research project.

C2. Demonstrates ability to use skills to make decisions in complex situations where there are several factors that require analysis, interpretation and comparison.

Role in context

C3. Deal with complex issues both systematically and creatively, make sound judgments in the absence of complete data, and communicate their conclusions clearly to specialist and non-specialist audiences

C4. Undertake major product development project dealing with related ethical, quality, regulatory, intellectual property and stability related issues.

Self-development

C5. Practice self and continuing professional learning through reference books, published data, scientific publications and websites and attendance of seminars, workshop and conferences.

C6. Utilize and contribute to the available scientific literature in the field of pharmaceutical formulation development.

Teaching and assessment strategies for Competency based outcomes

Various competencies are instilled in the DPC students through different means. Throughout the courses of study, students are working independently as well as a part of a team. Opportunities are also provided to students to actively participate in various scientific and other events organized by the college. Opportunities for self-directed learning will be provided though out the program to develop self-learning skills. Probing questions posed by the instructors during various courses throughout enable the students to develop critical thinking abilities. Student presentations and reports are used to assess communication skills, reasoning (such as ability to answer questions on their work) and planning and management of complex individual tasks or of group tasks.

One-year long research project provides ample of opportunities to students to instill all the competencies and their assessments. Employers' surveys also provide useful tool for evaluate graduate competencies and are conducted.

APPENDIX 2. KEY PROGRAM EFFECTIVENESS INDICATORS

Component A: External Environmental Factors	
A.1.	Characteristics of Emerging Population and Economic Factors
A.2.	Characteristics of Emerging Educational Factors
Component B: Faculty Profiles and Characteristics	
B.1.	Faculty Qualifications (Full-Time & Part-Time)
B.2.	Faculty Profile
	B.2.1- Faculty Demographics
	B.2.2- Faculty Rank and Age Group
B.3.	Faculty Scholarship
B.4.	Faculty Workload (Full-Time/Part-Time)
B.5.	Faculty Turnover
B.6.	Percentage of courses taught by each faculty classification
B.7.	Student-Faculty Ratio
B.8.	Summary of Teaching Effectiveness
B.9.	Other Evidence of Faculty Effectiveness (Appraisal)

B.10.	Analysis Summary of Faculty Development
Component C: Student Enrollment and Success	
C.1.	Student Application and Registration
C.2.	M Pharm Student Enrollment pattern for the Program/s
C.3.	Student Enrollment by Emirate of Origin
C.4.	Enrollment Trend Analysis for undergraduate and graduate programs
C.5.	Student Age Profile
C.6.	Student Fit with Program Mission
C.7.	Student Scholarships
C.8.	Student Participation in Cocurricular/Organizations
C.9.	Student and Alumni Achievement
C.10.	CGPA Trend Analysis
C.11.	Student Attrition rate
C.12.	Graduate Success Indicators (Employment Status- Emiratis and Others)
Component D: Core Program Learning Outcomes Assessment	
D.1.	Program Aims and Learning Outcomes Alignment with QF Emirates Level 9
	· Knowledge of the discipline (What do students know?)
	· Skills (What can students do?)
	· Competencies (What are the abilities students need to do a job properly?)
	· Values (What do students care about?)
Component E: Student Attitude and Perceptions	
E.1.	Faculty Performance Appraisal includes Student Perceptions
E.2.	About Faculty (Teaching)
E.3.	Summary of Course Evaluation
E.4.	Survey Response Rate of Courses and Faculty Evaluation
E.5.	Helpfulness of Faculty (Office Hours)
E.6.	Satisfaction of Teaching Methods
E.7.	Mentoring and Advising
E.8.	Satisfaction of Classroom Facilities
E.9.	Satisfaction with Library
E.10	Satisfaction of IT Facilities
E.11.	Satisfaction of Student Services
E.12.	Course Scheduling
E.13.	Community Engagement activities
E.14.	New Student Orientation
E.15.	Exit Surveys
Component F: Clerkship (applicable for CP)	
F.1.	Clerkship Training Experience
Component G– Quality of Curriculum and Student Learning – Curriculum Structure, Assessment of Student Learning, Curriculum Map of Program Student Learning Outcomes, External Reviewers report criteria and rubrics (Provided in Program Handbook)	