Quality by Design: A Perspective of BS Pharmacy Students (2015 Curriculum) at the National University, Manila

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Abstract: Quality by Design (QbD) is a rigorous methodology for generating pharmaceutical goods that ensure established product quality through designing, formulating, and manufacturing practices. This study was constructed to measure students' perception under the 2015 curriculum at the National University-Manila towards the QbD as a course topic in Pharmaceutical Manufacturing. Forty-seven (N= 47) respondents were gathered using a descriptive, web-based cross-sectional research design. The validated survey questionnaire was employed to collect the necessary data. The frequency and percentages were included for demographic variables, and the population means were evaluated for the level of perception of the BS Pharmacy students towards QbD. The Mann-Whitney U-test was utilized to evaluate the significant differences in terms of gender. Data percentages showed that most respondents were female (85.1%), and the minority were males (14.9%). Data shows no significant differences between students' gender and age perception of QbD (p= 0.618). The respondents' demographic profile shows that 42 out of 47 (89.4%) respondents were 21-23 years old, and 5 (10.6%) were 24-26 years old. The Kruskal-Wallis H test was used to analyze the students' preferred Field of Pharmacy Practice. Statistical significance is defined as a p-value of less than 0.05. The data have highlighted that 27 (58.4%) and 14 (29.8%) of the respondents preferred Hospital Pharmacy and Manufacturing Pharmacy, respectively, as their field of course as a future Pharmacist. The data shows significant differences in several questions compared to the students' preferred area. Based on this study's results, the researchers accept the following null hypothesis: in terms of age, there was no significant difference in the respondents' perceptions of QbD; and there was no significant difference in the respondents' perception of QbD in terms of gender.

Keywords: Quality by Design; Pharmacy Students; Perspective; Curriculum

1. INTRODUCTION

1.1 Background

In this era of competition, quality has been given crucial magnitude, and failure to meet such quality resulted in massive shifts in the company in the share market. The International Conference on Harmonization (ICH, 2008) advocated the modernized approach in drug design development that was later termed Quality by Design (QbD), a comprehensive methodology in developing pharmaceutical products and constituents which emphasizes its manufacturing process. Using QbD in drug development allows the manufacturer to get the desired quality pharmaceutical product, minimize its resources, and know the impact of one factor over the desired process. However, despite its potential benefits and impressive success stories, the industry's fresh concept of QbD is not quickly embraced. This study measures the perception of the pharmacy students' knowledge about QbD as a

course topic in Manufacturing Pharmacy.

The extension of QbD as part of the course topic in Manufacturing Pharmacy can be considered a one-step approach to enhance the long run. Teaching QbD has the same context as building students' quality by teaching its process and principles. Today, it has become imperative that students aim for a solid foundation of knowledge where the course is up to date. Students want teachings that help them acclimate to the realities of the twenty-first century and are helpful in their chosen field of practice in the future, which is becoming competitive as time goes by. Incorporating QbD as a course topic in Manufacturing Pharmacy is evolutionary. It means that newer things should be introduced along with the traditional ones and not replaced. The data measured in this study can be utilized significantly for possible course enhancement and improve and prepare the future to work effectively in manufacturing and industrial settings, thus, the aim of this study.

1.2 Research Questions

This study aimed to answer the following questions:

1. What is the demographic profile of the respondents in terms of:
    a. Age;
    b. Gender; and
    c. Preferred Field of Pharmacy Practice
2. What are the perceptions of the respondents towards QbD?
3. Is there a significant difference in the respondents' perception of the QbD in terms of:
    a. Age;
    b. Gender; and
    c. Preferred Field of Pharmacy Practice?

2. METHODOLOGY

2.1 Study Design

To gather data, the researchers used a descriptive, web-based cross-sectional research design to determine BS Pharmacy students' perception of QbD.

2.2 Research Limitations and Delimitations

The study evaluates the BS Pharmacy students' perception of their knowledge regarding QbD as part of the Manufacturing Pharmacy course. The perception of students currently enrolled under the 2015 Curriculum or the Commission of Higher Education (CHED) Memorandum no.3 series of 2006 at the National University, Manila, was measured using validated online survey questionnaires via Google forms. The questions focused on their perception of the approach of Quality by Design in developing a pharmaceutical product and its reliability in enhancing the Manufacturing Pharmacy course. The level of perception was measured using a 5-point Likert scale. The study's respondents were chosen

based on the inclusion and exclusion criteria.

2.3 Respondents

The respondents were chosen from National University (NU) Manila: Department of Pharmacy using the following criteria:

- The student must be currently enrolled.
- The student must have taken the Manufacturing Pharmacy course.
- The student must be under the NU-BS Pharmacy 2015 curriculum or the Commission on Higher Education (CHED) Memorandum no.3 s. 2006 curriculum.

2.4 Instrumentations

A closed-ended survey questionnaire was thoroughly disseminated using Google Forms and Microsoft Forms web-based programs.

The tool is divided into the demographic profile and the level of perception about QbD. Each question on the questionnaire used a 5-point Likert scale ranging from one, where the respondents strongly disagreed with the statement, to a score of five, where the respondents strongly agreed with the statement.

The Likert scale is as follows:

5 - Strongly agree
4 – Agree
3 - Neutral
2 - Disagree
1- Strongly disagree

The means of the level of perception is interpreted as follows:

4.21-5.00 – Strongly agree
3.41-4.20 – Agree
2.61-3.40 – Neutral
1.81-2.60 – Disagree
1.00-1.80 – Strongly disagree

2.5 Ethics Review Approval

The research study was submitted to the Trinity University of Asia-Institutional Ethics Review Committee for approval. Reviewers' suggestions were addressed before conducting the survey.

2.6 Ethical Consideration

The researchers informed the students of the study's purpose, and general information w described and briefly explained to the students. Informed consent was uniformly given to each student before answering the survey questionnaire, and

they were requested to confirm their willingness to participate. Furthermore, the students' anonymity was protected in several ways, and the student's rights were explained.

2.7 Validity and Reliability

The researchers created the research instrument, which outside specialists validated. Upon validation, the questionnaire has undergone a series of revisions and modifications. Before conducting any data analysis, the research tool's reliability was analyzed using the statistical test Cronbach's Alpha.

2.8 Data Collection

The validated questionnaire was given to the respondents via Google forms and Microsoft forms. The approval of the dean, the program chair, and the Director of the NU-Student Affairs Office was sought before data collection. Students who confirmed their readiness to participate in the research were given a questionnaire. Students were given appropriate time to complete the survey.

2.9 Data Analysis

The Statistical Package for Social Sciences (SPSS) was used to analyze the data collected. The perception was assessed using descriptive statistics such as percentages for demographic variables and the population mean. The Mann-Whitney U-test compares samples without assuming that the data is normally distributed (Stangroon, 2021). According to Laake et al. (2015), the Mann- Whitney test only applies when the independent variable has two underlying populations with the same shape. Mann- Whitney Test is used to evaluate the significant difference in terms of gender. The statistical significance for the students' preferred Field of Pharmacy Practice was calculated using Kruskal-Wallis Method, also known as H Test. A non-parametric test does not require equal data distribution to compare the samples from two or more observations (Smalheiser, 2017). A p-value of less than 0.05 was considered statistically significant.

3. RESULTS

3.1 Reliability Test Result

The result of the reliability test of the research tool was 0.902. According to Taherdoost (2016), an exploratory or pilot study suggested that the reliability should be equal to or above 0.60. Thus, a value of ≥0.90 alpha shows excellent internal consistency.

3.2 Frequency and Percentage of the Respondents' Socio-Demographic Profile

Table 1. Demographic profile of the study respondents. (n=47)

	Frequency	***%***
Gender		
Male	7	14.9 %
Female	40	85.1 %
Age		
18-20	0	0%
21-23	42	89.4%
24-26	5	10.6 %
Preferred Field		
Community	6	12.8 %
Hospital	27	58.4 %
Manufacturing	14	29.8 %

The demographic characteristics of the 40 participants are displayed in Table 1, with 14.9 percent of females and 7 (14.9 percent) males. Data shows that 42 out of 47 (89.4%) of the respondents are from 21-23 years old, and 5 (10.6%) were 24-26 years old. About 27 (58.4%) of the respondents preferred Hospital Pharmacy as their chosen field of pharmacy practice, 14 (29.8%) also preferred Manufacturing Pharmacy, and 6 (12.8%) preferred Community Pharmacy as their field of pharmacy practice.

3.3 Result of the Questionnaire about BS Pharmacy Students' perception towards Quality by Design based on the 5-point Likert Scale

Table 2. Population Mean of the students' perception level towards Quality by Design

Statements	**Mean**	**Verbal interpretation**
1. QbD is relatively easy to study.	3.98	Agree
2. Learning QbD is beneficial in my field of study.	4.06	Agree
3. QbD will help better understand the research conducted in the field of study.	4.23	Strongly Agree
4. QbD highlighted technical areas in skills and knowledge.	4.00	Agree
5. Using QbD software makes me uneasy.	2.96	Undecided
6. QbD is too complicated for me to use effectively.	2.91	Undecided
7. QbD is practical and valuable.	4.00	Agree
8. QbD is an innovative way for process	3.93	Agree

validation.		
9. QbD should be included as a course topic in manufacturing pharmacy.	4.47	Strongly Agree
10. QbD has benefit/s in the Industrial Pharmaceutical Practice.	4.47	Strongly Agree
11. QbD is not helpful for most professionals.	2.83	Undecided
12. QbD will be useful as part of my future career practice.	4.19	Agree

*$p<0.05$

In Table 2, the population's mean was used to measure the BS Pharmacy students' level of perception towards Quality by Design. As shown in the table, several statements are Strongly Agreed (3), Agreed (6), and Undecided (3). The Mean score for each statement indicates the difference between different students, with all falling in the narrow range with the highest mean score of 4.27 (statements 9 and 10) and the lowest is 2.91 (statement 6).

3.4 Comparison of the significant difference of Gender, Age, and field of pharmacy practice to the approved questionnaire about the level of perception of BS Pharmacy Students towards QbD based on the 5-point Likert Scale.

Table 3. Respondents' significant difference between their gender and perception towards QbD.

Statements	**P-value**	**Decision**	**Remarks**
1. QbD is relatively easy to study.	0.65	Fail to reject Ho	No significant difference
2. Learning QbD is beneficial in my field of study.	0.849	Fail to reject Ho	No significant difference
3. QbD will help better understand the research that is being conducted in the field of study.	0.895	Fail to reject Ho	No significant difference
4. Quality by Design highlighted technical areas in skills and knowledge.	0.568	Fail to reject Ho	No significant difference
5. Using QbD software makes me uneasy.	0.188	Fail to reject Ho	No significant difference
6. QbD is too complicated for me to use effectively.	0.715	Fail to reject Ho	No significant difference
7. QbD is practical and useful.	0.548	Fail to reject Ho	No significant difference
8. QbD is an innovative way for process validation.	0.759	Fail to reject Ho	No significant difference
9. QbD should be included as a course topic in manufacturing pharmacy.	0.715	Fail to reject Ho	No significant difference

10. QbD has benefit/s in the Industrial Pharmaceutical Practice.	0.37	Fail to reject Ho	No significant difference
11. QbD is not useful for most professionals.	0.386	Fail to reject Ho	No significant difference
12. QbD will be useful as part of my future career practice.	0.781	Fail to reject Ho	No significant difference
OVERALL MEAN	0.619	Fail to reject Ho	No significant difference

*$p<0.05$

A Mann-Whitney U test was conducted to evaluate the research question of whether there was a significant difference between the level of perception of the BS Pharmacy undergraduates towards Quality by Design to the gender of students. At the level of significance ($\alpha= 0.05$), the researchers noted that there was no significant difference in BS Pharmacy students' attitudes toward Quality by Design based on their gender, with an overall p-value of 0.619.

Table 4. Respondents' significant difference between their age and perception towards Quality by Design

Statements	**P-value**	**Decision**	**Remarks**
1. QbD is relatively easy to study.	0.411	Fail to reject Ho	No significant difference
2. Learning QbD is beneficial in my field of study.	0.215	Fail to reject Ho	No significant difference
3. QbD will help better understand the research that is being conducted in the field of study.	0.538	Fail to reject Ho	No significant difference
4. QbD highlighted technical areas in skills and knowledge.	0.422	Fail to reject Ho	No significant difference
5. Using QbD software makes me uneasy.	0.599	Fail to reject Ho	No significant difference
6. QbD is too complicated for me to use effectively.	0.394	Fail to reject Ho	No significant difference
7. QbD is practical and useful.	0.354	Fail to reject Ho	No significant difference
8. QbD is an innovative way for process validation.	0.041	Reject Ho	There is a significant difference
9. QbD should be included as a course topic in manufacturing pharmacy.	0.625	Fail to reject Ho	No significant difference
10. QbD has benefit/s in the Industrial Pharmaceutical Practice.	0.145	Fail to reject Ho	No significant difference
11. QbD is not useful for most professionals.	0.475	Fail to reject Ho	No significant difference

12. QbD will be useful as part of my future career practice.	0.571	Fail to reject Ho	No significant difference
OVERALL MEAN	0.399167	Fail to reject Ho	No significant difference

*$p<0.05$

The researchers utilized the Kruskal– Wallis Test to see if there was a significant relationship between the students' perceptions of QbD and their age. As shown in Table 4, statement number 8 has a significant difference (p-value of 0.041). Still, overall, there is no significant difference between the respondents' age of the participants on their perception of QbD (p-value of 0.399).

Table 5. Respondents' significant difference between the preferred field of pharmacy practice and perception towards Quality by Design

Statements	**P-value**	**Decision**	**Remarks**
1. QbD is relatively easy to study.	0.018	Reject Ho	There is a significant difference
2. Learning QbD is beneficial in my field of study.	0.37	Fail to reject Ho	No significant difference
3. QbD will help better understand the research that is being conducted in the field of study.	0.379	Fail to reject Ho	No significant difference
4. QbD highlighted technical areas in skills and knowledge.	0.018	Reject Ho	There is a significant difference
5. Using QbD software makes me uneasy.	0.217	Fail to reject Ho	No significant difference
6. QbD is too complicated for me to use effectively.	0.139	Fail to reject Ho	No significant difference
7. QbD is practical and useful.	0.391	Fail to reject Ho	No significant difference
8. QbD is an innovative way for process validation.	0.398	Fail to reject Ho	There is a significant difference
9. QbD should be included as a course topic in manufacturing pharmacy.	0.038	Reject Ho	There is a significant difference
10. QbD has benefit/s in the Industrial Pharmaceutical Practice.	0.023	Reject Ho	There is a significant difference
11. QbD is not useful for most professionals.	0.265	Fail to reject Ho	No significant difference
12. QbD will be useful as part of my future career practice.	0.003	Reject Ho	There is a significant

			difference
OVERALL MEAN	0.18825	Fail to reject Ho	No significant difference

**p 0.05*

Kruskal Wallis test was utilized to evaluate the significant difference in BS Pharmacy students' perception of QbD and the preferred pharmacy practice field. As shown in Table 5, several statements have significant differences, which include: statements 1 and 4 (0.018), statement 9 (0.038), statement 10 (0.023), and statement 12 (0.003). Overall, there is no significant difference between the selected field (Community, Hospital, and Manufacturing) of the BS Pharmacy students under the 2015 curriculum and their perception towards QbD with a p-value of 0.188.

4. DISCUSSION

Quality by design is a new concept that recently sought to be implemented to develop pharmaceuticals amended by international regulatory agencies (Singh, 2016). QbD benefits the industry of Manufacturing Pharmacy by ensuring the product is at its highest rate during the process. The approach investigates the product's design to improve the quality. The product outcome's objective must be pre-determined so that the attributes are defined during the initial stages of the manufacturing process. QbD provides a robust framework for effective drug design implementation to include quality in the final product rather than depending on end-of-life testing (Singh, 2016). QbD focuses on the drug itself up to the manufacturing process to ensure its consistent quality, followed by identifying the specific parameters that may cause product variability during production that may influence its final grade. For this concern, QbD tools and risk management were used where the critical process and essential product parameters were placed.

Applying QbD in Manufacturing Pharmacy as part of the course topic have the same thought as building quality in the students through their education. At this age, an emerging drug design concept in drug manufacturing can influence education. According to Singh (2016), considering the QbD elements at micro and macro levels, part of teaching helps students acclimate to the realities of the twenty-first century, and the students' ambitions can be achieved comprehensively. Applying the QbD at micro levels will allow the students to know how QbD works in the Pharmaceutical Industry as a fresh concept in drug design strategies. It will let the students define their target profile and identify CQAs and process parameters during the product's manufacturing, followed by having controls on the QbD process variables and risk management approach. Applying QbD as a course topic in Manufacturing Pharmacy at the macro level will produce Pharmacy students with knowledge and skills for suitable jobs useful for entering active lifestyle and adaptable to the up-to-date world of work competitive day-by-day (Singh, 2016).

Conforming to the study results, successful implementation of QbD requires a deep comprehension of its principles and the process's unpredictability. Several

statements have significant differences in comparing the students' preferred field of Pharmacy practice and their perspective on QbD. Questions focus on the influence of the QbD in their preferred field and the understanding of its principles. By adding the QbD concept to education, the students can firmly educate and familiarize themselves with the principles and approach to drug design development. QbD can make a difference in pharmacy education through its principles and implementations. The industry must build quality for the students and close gaps between traditional and modern development. Pharmacy education must deliver the expectation and strive toward innovation. The outcomes will produce highly competitive pharmacy professionals who are up to date with industry realities (Torres, 2015).

5. CONCLUSIONS

Based on this study's results and discussion, the researchers accept the following null hypothesis; There is no significant difference in the respondents' perception of QbD regarding age. Second, there is no significant difference in the respondents' perception of QbD to gender. Lastly, there is no significant difference in the respondents' perception of their preferred pharmacy practice field.

According to the data obtained from the study, it can be deduced that the gender of most respondents comprises females, which is 85.1% or 40 respondents. Most responses are between the ages of 21 and 23. Also, most respondents prefer Hospital Pharmacy as their pharmacy practice field, followed by manufacturing pharmacy (29.8% or 14 respondents). Lastly, the community pharmacy practice accounts for 12.8%.

Based on the statistically analyzed results and discussion of the study, it is thereby concluded by the researchers that age and gender have no significant difference with the perception of BS Pharmacy participants of the National University of Manila under the 2015 curriculum. Besides, the Pharmacy field showed no significant difference in the respondents' general perception. However, specifically on the tabular presentation, it can be denoted that Q1, Q4, Q9, and Q12 focus on the relevance of the QbD and the chosen field. Have shown a significant difference in the perception of the BS Pharmacy Students of the National University of Manila under the 2015 curriculum. These questions look at the ease of studying (Q1), technical areas in skills and knowledge (Q4), inclusion as a course topic in manufacturing pharmacy (Q9), and usefulness in future career practice.

6. ACKNOWLEDGMENTS

The researchers acknowledge the BS Pharmacy respondents for their participation and the NU Department of Pharmacy faculty for their support.

7. REFERENCES

International Conference on Harmonization. (2005). ICH Q9: Quality Risk Management.

International Conference on Harmonization. (2008). ICH Q10: Pharmaceutical Quality System.

International Conference on Harmonization. (2009). ICH Q8 (R2): Pharmaceutical Development.

Laake, P., Benestad, H. B., & Olsen, B. R. (2015). Research in medical and biological sciences: from planning and preparation to grant application and publication. London: Elsevier/Academic Press.

Singh, S. (2016). Quality by Design in Education (QbDE)- A Possible Futuristic Approach to Improve Current Status of Pharmaceutical Education in India. Indian Journal of Pharmaceutical Education and Research, 39-44.

Smalheiser, N. (2017). Nonparametic Test. Data Literacy, 157-167.

Stangroon, J. (2021, February 12). socstatisctic.edu. Retrieved from Mann-Whitney U Test Calculator: https://www.socscistatistics.edu.com/tests/mannwhitney/

Taherdoost, H. (2016). Validity and Reliability of the Research Instrument; How to Test the Validation of a questionnaire/Survey in a Research. International Journal of Academic Research in Management, 28-36.

Torres, M. (2015). Challenges in Implementing Quality By Design: An Industry Perspective. BioProcess International.