**Project Proposal**

**QSRA mini project (BIO08041)**

**ATU Sligo**

*Please complete ALL sections*

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| **Project Title:**  **General Project Information: Use the following table to develop your Project Proposal** | A comparison of the traditional approach to pharmaceutical development to the Quality by Design (QbD) approach. |
| **Background:**  *Why are you researching this topic?* | To develop understanding of:  What are the fundamental principles and methodologies of the traditional and QbD approaches to pharmaceutical development?  How do the two approaches differ in terms of product design, process development, and quality assurance?  What are the potential advantages and disadvantages of each approach, considering factors such as development time, cost, and product quality?  How has the regulatory landscape influenced the adoption and implementation of QbD in the pharmaceutical industry?  What are the future trends and challenges in pharmaceutical development, and how might the QbD approach address these issues? |
| **Aims of the project:**  *What do you intend to achieve by completing this project?* | A deeper understanding of the key differences between traditional and QbD approaches.  A comprehensive evaluation of the advantages and disadvantages of each approach.  Identification of best practices for implementing QbD in pharmaceutical development.  Insights into the future trends and challenges in the pharmaceutical industry. |
| **Methods to be used:**  ***How*** *will you do it?*  ***Who*** *will you talk to etc.?*  ***What*** *will you need?* | **1. Literature Review:**  A review of articles, regulatory guidelines, and industry reports will be conducted to identify key concepts, methodologies, and best practices associated with traditional and QbD approaches.  The review will focus on areas such as drug product design, process development, quality assurance, and regulatory considerations.  **2. Case Study Analysis:**  In-depth case studies of specific pharmaceutical products will be analysed to illustrate the application of traditional and QbD approaches in real-world settings.  The case studies will examine factors such as development timelines, cost-effectiveness, product quality, and regulatory compliance. |
| ***Breakdown of project (by chapter)***  *Brief overview of how the project will be structured and chapter content.* | **Chapter 1**: **Introduction**  The scope of the project, including the purpose of comparing traditional and QbD approaches.  Importance of this comparison for the pharmaceutical industry, regulatory bodies, and patients.  **Chapter 2: Traditional Pharmaceutical Development**  Historical context: the evolution of traditional pharmaceutical development.  Key components: major steps involved in traditional development, including:  Preclinical research  Clinical trials  Regulatory submission  Manufacturing and quality control  Limitations and benefits associated with the traditional approach.  **Chapter 3: Quality by Design (QbD)**  Definition: the concept of QbD and its underlying principles.  Key components: the essential elements of QbD, such as:  Control strategy  Design space  Risk assessment  Quality target profile  Limitations and benefits of QbD, including improved efficiency, quality, and regulatory compliance.  **Chapter 4: Comparative Analysis**  Key differences between traditional and QbD approaches in terms of:  Process understanding  Control strategy  Risk management  Regulatory compliance  Case studies: analyses of real-world examples to illustrate the practical implications of each approach.  **Chapter 5: Impact and Future Trends**  Impact of QbD on Pharmaceutical Industry including:  Cost-effectiveness  Time-to-market  Product quality  Future trends and advancements in pharmaceutical development that may influence the adoption of QbD.  **Chapter 6: Conclusion**  Summary of Findings: the key findings from the comparison.  Recommendations based on the analysis, such as:  Strategies for implementing QbD  Areas for further research |
| ***Any other relevant information*** | This project will also include:  The role of regulatory agencies in promoting QbD adoption.  Ethical implications associated with QbD, such as patient safety and data privacy.  Use of data analytics and modelling in QbD. |