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MEDICAL DEVICES STUDY UNIT IN THE PHARMACEUTICAL TECHNOLOGY COURSE

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INTRODUCTION

Graduates of the three year programme leading to a degree of Bachelor of Science (Hons) in Pharmaceutical Technology join the pharmaceutical workforce equipped with knowledge and skills required in research and development, quality control and assessment, regulation and distribution. The inclusion of knowledge and competence development in approaching medical devices serves an example of how science is related to practice in pharmaceutical education.

AIM

To develop a study unit that supports students to acquire basic pharmaceutical regulatory competences in handling medical devices.

METHOD

During the first year of the course, students are introduced to medical terminology and specific terms related to medical devices. This is achieved as part of a study unit (6 ECTS) dedicated to principles of Health, Disease and Terminology in the use of medicinal products and medical devices. An interactive quiz is used to assess knowledge developed at the end of the medical devices terminology session.

During the second year of the course, students follow a 4 ECTS study unit focusing specifically on Medical Devices. This study unit provides an overview of the development, regulation, use, healthcare professionals collaboration and patient needs with respect to the evolving area of medical devices. The material within the study unit is delivered through a mix of active student learning sessions including reflections on practical examples, case discussions, flipped class through scientific articles selected for pre-reading and interactive quizzes to enhance student engagement.

RESULTS

The study unit is delivered by a team of academics together with specialists from medical devices regulatory sciences. In this way students are exposed to the scientific basis, regulatory processes and challenges in ensuring access to safe medical devices in the healthcare settings. During the workshops, clinical investigations, performance studies and application of artificial intelligence are discussed through the use of literature and publications to provide the opportunity for students to have a futuristic insight

Table 1: Medical device study unit course content

Area	Reflections
Historical reflections	Relevance of evolvement of regulation and legislation in the EU
Assessment	Designation, oversight and role of Notified Bodies
Quality	Quality Management systems, ISO standards, CE marking
Use	Product labelling, education, documentation
Vigilance	Surveillance procedures
Stakeholders	Regulators, economic operators, healthcare professionals, patients, healthcare settings
Applications	Good distribution practices, practical use of medical devices and point-of-care testing

CONCLUSION

The developed study unit incorporates general regulatory aspects related to medical devices procedures such as quality management systems, risk assessments, evaluations, and auditing processes. Throughout the study unit, the pharmaceutical technology students are guided to acquire basic knowledge and to achieve competencies required to work in the medical devices field. It further supports the students to identify, understand and discuss the ongoing challenges in the evolving area of medical devices.