TRAINING NEEDS IN QUALITY SYSTEMS:

A COURSE ON STANDARDS – ISO 17025:2017

A dissertation submitted in partial fulfilment

of the requirements for the Degree of

Doctorate in Pharmacy

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Dedication

To my parents, brothers, sisters, nieces, and nephews.

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ABSTRACT

Quality assurance is key to reliable laboratory functions and a fundamental step towards accreditation. The laboratories in Malta have been encouraged for high-quality laboratory standard practices and there is room for improvement. This study aims to identify the educational needs of laboratory personnel with regard to quality and to develop, implement, and evaluate a training course with a focus on ISO17025:2017 as a case example. A questionnaire to capture the training needs of laboratory personnel on quality standards was developed, validated by a focus group, and disseminated to laboratory personnel. A course on ISO 17025:2017 was developed, validated, and implemented. The training was evaluated by the participants. The respondents (N=50) of the questionnaire on training needs consisted of laboratory managers, pharmacists, and scientists from pharmaceutical & nutraceutical QC, medical & diagnostic, research & teaching, food & water, plant & veterinary, and forensic laboratories. Courses on ISO 17025:2017 (n=10), instrument use and quality control (n=9), measurement uncertainty (n=5), ISO 9001:2015 (n=3) and Good Laboratory Practices/Good Manufacturing Practice (n=3) were requested by 30 respondents. A two-day interactive training programme on ISO 17025:2017 *General requirements for the competence of testing and calibration laboratories* awareness course was developed for the laboratory professionals of a forensic science service. The programme of the course consists of learning objectives, outcomes, and description of the content scheduled over 14 hours delivered in a classroom mode. Out of 25 laboratory personnel working in the forensic field, 22 participated in the course delivered by qualified tutors. The course topics covered the individual requirements of the ISO 17025:2017, the basic understanding of quality management systems, and the practical aspect of the quality manager with a specific focus on forensic sciences. The training course was evaluated by 18 participants

(N=22). The majority of the respondents strongly agreed that the subject (n=11), content (n=12), tutors' knowledge (n=14), and logistics (n=12) met their expectations. This research has the potential to have a significant impact in improving the quality systems within laboratory operations by providing an academic platform for sharing the expertise between participants and experts. Addressing training needs on quality management systems through developing courses that are tailor-made for the end-users helps to sustain the quality requirements.

Keywords: Quality systems, educational needs, professional development, training design, laboratory, collaboration

TABLE OF CONTENTS

List of Tables

List of Figures

List of Appendices

List of Abbreviations

ACPE	Accreditation Council for Pharmacy Education
ASHP	American Society of Health System Pharmacists
CPD	Continuing Professional Development
EDQM	European Directorate for the Quality of Medicines
FDA	Food and Drug Administration
FSMA	Food Safety Modernisation Act
GPPQCL	Good Practices for Pharmaceutical Quality Control Laboratories
HPLC	High-Performance Liquid Chromatography
IEC	International Electrotechnical Commission
ILAC	International Laboratory Accreditation Cooperation
ISO	International Organisation for Standards
MCCAA	Malta Competition and Consumer Affairs Authority
MLN	Malta Laboratories Network
MPFSL	Malta Police Forensic Science Laboratory
NAB	National Accreditation Board
QA	Quality Assurance
QC	Quality Control
SOP	Standard Operating Procedure
WHO	World Health Organisation

Chapter 1

Introduction

1.1 Quality Revolution and International Standards

The landscape of science and technology has undergone a quality revolution in tandem with the dynamic evolvement and innovation within the scientific field (Sureshchander et al., 2001; De Silva, 2015). This resulted in a slew of processes, tools, essential dimensions, and other organisational requirements for the effective implementation of overall superior results (Sureshchander et al., 2002). Quality standards are well-established and eagerly pursued in organisations (Sureshchander et al., 2001). Exceptional service features give organisations a competitive edge. As a result, institutions, organisations, and scientific centres adopt a comprehensive system of international standards to assist them to continuously improve their services whilst attaining the highest quality service (Yang, 2006; Barradas & Sampaio, 2017).

There are various international standards which are technical standards developed by international organisations. Examples of these include standards put forward by the World Health Organisation (WHO), such as Good Practices for Pharmaceutical Quality Control Laboratories (GPPQCL), and the International Organisation for Standardisation (ISO) with specific standards applicable to the industries and commerce.[1,2] International standards serve as a lubricant for global harmony and trade (Heires, 2008). Barradas and Sampaio (2017) state that one of the differentiating factors in organisations for success in an increasingly globalized market is undoubtedly accreditation, and it can be accomplished through the implementation of standards.

[1] World Health Organisation (WHO). WHO guidelines approved by the Guidelines Review Committee [Internet]. Geneva: WHO; 2020 [cited 2020 Oct 11]; [about 2 screens]. Available from: https://www.who.int/publications/guidelines/en/

[2] International Organisation for Standardisation (ISO). ISOFOCUS Innovation Generation [Internet]. Geneva: ISO; [unknown date] [cited 2020 Oct 11]. Available From: https://www.iso.org/home.html

1.2 Impact of Quality Systems in Organisations

The international standards are a benchmark from which organisations and leaders base their decisions and processes. They govern the interplay of systems. A case in point is from antibody development against certain diseases, vaccine production, and testing, all the way to delivery and distribution. These standards ensure internal productivity, supply chain confidence, and reduce the costs and difficulties of incompatible or unsuitable products and processes sourced from different companies (Heires, 2008).

Studies recognise the critical role of implementing standards as a means of improving laboratory activities. Mao and Yang (2017) document that robust and comprehensive standard operating procedures (SOPs) in quality control (QC) and quality assurance (QA) activities facilitate uniform processes in the manufacturing process of safe and high-quality medicines. Küme et al. (2019) indicate that quality standardisation advances medical and pharmaceutical laboratory services. The utilisation of a laboratory-validated method that is accredited according to standards can expand laboratory services with high-quality results (Pantanowitz et al., 2013; Buchard et al., 2016; Lecointe et al., 2019). Compliance with standards improves the reliability and validity of test reports and enhances the laboratory quality system (Dijk, 2002; Homolka et al., 2019; Byrn et al., 2020; Wu et al., 2020). Standardisation as an organisational principle has spread beyond the realm of science and technology, from laboratory drug testing to a wide range of other areas of regulation (Heires, 2008).

1.3 Mandate on Quality Standardisation

International and national mandates are set in place to safeguard the public's consumption of goods and use of services. The United States Food and Drug Administration (US FDA) Food Safety Modernisation Act (FSMA) requires the testing of food by accredited laboratories.[3] Accordingly, this would ensure that the testing is carried out following relevant appropriate model standards, resulting in reliably accurate and valid test results. In the European setting, the European Parliament and the Council of European Union set out the requirements for accreditation of standardisation.[4] This is Regulation (EC) No 765/2008 which warrants that products that benefit from the free movement of goods within the European Union meet the standard requirement that provides a high degree of protection of public interests such as health and safety in general, as well as consumers, environment and security protection.[5] Article 7 of Directive 89/397/EEC states that laboratories are to comply with the criteria set out in European Standard EN 45000 series, which has since been replaced by International Organisation for Standardisation / International Electrotechnical Commission (ISO/IEC) 17025 *General requirements for the competence of testing and calibration laboratories*. The European Directorate for the Quality of Medicines (EDQM) exemplifies this by implementing a quality management system (QMS) based on ISO standards to sustain its vision and mission to provide consumers and stakeholders with the best goods and services possible.[6] The Consumer Affairs Act in Malta ensures that consumers shall be entitled to be protected against goods and production processes that are harmful to

[3] United States Food and Drug Administration (US FDA). Food Safety Modernisation Act [Internet]. Maryland: FDA; 2020 [cited 2020 Oct 29]. [About 5 screens]. Available from: https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-proposed-rule-laboratory-accreditation.

[4] European co-operation for Accreditation (AE) [Internet]. Paris: AE. European Accreditation Infrastructure; 2018 [cited 2020 Oct 11]. [About 10 screens]. Available from: https://european-accreditation.org/about-ea/relations-with-european-commission/

[5] REGULATION (EC) No 765/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

[6] European Directorate for the Quality of Medicines and Healthcare (EDQMH). Quality Management [Internet]. Strasbourg: EDQMH; 2020 [cited 2020 Nov 03]. Available from: https://www.edqm.eu/en/quality-management.

health.[7] This also includes services including laboratories that should be compliant with international standards to ensure that testing of various parameters like quality, efficacy, reliability, and other characteristics of products are checked before being made available to the public.[8]

1.4 Standards for Laboratories

There are numerous standards for laboratories on quality management systems. These are ISO 15189 *Medical laboratories – Requirements for quality and competence*, ISO 9001 *Quality management systems - Requirements*, ISO 17034 *General requirements for the competence of reference material producers*, ISO/IEC 17043 *Conformity assessment – General requirements for proficiency testing*, and ISO/IEC 17025 *General requirements for the competence of testing and calibration laboratories*. The ISO 15189 *Medical laboratories – Requirements for quality and competence* is an international standard that defines the standards for medical laboratories' quality management systems. These standards guide medical laboratory users on topics such as patient sample selection, test results interpretation, providing testing in a medical emergency, and the lab's role in health care personnel education and training. Although the standard is based on ISO/IEC 17025 and ISO 9001, it is a one-of-a-kind document that considers the unique requirements of the medical environment as well as the critical role of the medical laboratory inpatient care. It can also be used by laboratory clients, regulatory authorities, and accreditation bodies to validate or recognize the competence of medical laboratories.[9] The ISO/IEC 17043 *General requirements for the competence of*

[7] CONSUMER AFFAIRS ACT 1996 (MALTA)

[8] TestingXperts. Why Quality Assurance is Critical for Medical Device Testing? [Internet]. London: TestingXperts. 2020 Jan 14 [cited 2020 Oct 11]. Available from: https://www.testingxperts.com/blog/medical-device-testing.

[9] International Organisation for Standardisation (ISO). ISO 15189:2012 Medical laboratories — Requirements for quality and competence [Internet]. Geneva: ISO; [unknown date] [cited 2020 Oct 11]. Available From: https://www.iso.org/standard/56115.html

reference material producers specifies general standards for the competence of proficiency testing schemes providers and its development and operation. Proficiency testing companies are evaluated to ensure that they have a quality control system in place, as well as the staff and equipment necessary to create reference materials that are suitable for the tests or calibration in the scheme. Proficiency testing providers are often judged on how well they prepare, build, review, and report on sound, relevant schemes. These criteria are intended to be generic for all kinds of proficiency testing schemes and can be used as a starting point for developing specific technical requirements for specific fields of application.[10] The ISO 17034 *Conformity assessment – General requirements for proficiency testing* specifies general criteria for reference material producers' competence and consistency of operation. It is focused on reference standard producers, and it addresses not only the quality systems in use during production but also the determination of uncertainty levels for all values reported on a standard's certificate. It is designed to be used as part of the reference material producer's overall quality assurance processes.[11] The ISO 9001 *Quality management systems - Requirements* helps organizations to improve their overall performance by a sound basis for the system, and improve customer satisfaction.[12] The ISO 9001 can also develop excellent corporate culture, enforce standard operating procedures, and help in recruitment processes. The ISO/IEC 17025 *General requirements for the competence of testing and calibration laboratories* is the standard for which most laboratories must hold accreditation to be deemed technically competent.[13] It is used as a basis of other

[10] International Organisation for Standardisation (ISO). ISO/IEC 17043:2010 Conformity assessment — General requirements for proficiency testing [Internet]. Geneva: ISO; [unknown date] [cited 2020 Oct 15]. Available From: https://www.iso.org/standard/29366.html

[11] International Organisation for Standardisation (ISO). ISO 17034:2016 General requirements for the competence of reference material producers [Internet]. Geneva: ISO; [unknown date] [cited 2020 Oct 15]. Available From: https://www.iso.org/standard/29357.html

[12] International Organisation for Standardisation (ISO). ISO 9001 Quality management systems [Internet]. Geneva: ISO; [unknown date] [cited 2020 Oct 15]. Available From: https://www.iso.org/standard/62085.html

[13] International Organisation for Standardisation (ISO). ISO/IEC 17025 Testing and calibration laboratories [Internet]. Geneva: ISO; [unknown date] [cited 2020 Oct 15]. Available From: https://www.iso.org/ISO-IEC-17025-testing-and-calibration-laboratories.html

laboratory standards. It was first published in 1999 by the International Organization for Standardization as ISO/IEC Guide 25. Two editions were released: in 2005 and 2017. The most important differences between the 1999 and 2005 releases were a stronger focus on senior management's roles, improved customer communication, and explicit requirements for continuous improvement of the management system itself. Scope, terms and definitions, normative references, technical requirements, and management requirements are the five components of the 2005 version of the standard. General, structural, resource, and process requirements are the additional structures in the 2017 edition of ISO/IEC 17025.

As standards keep updating, concerned entities should also evolve. The laboratory practices change over time in terms of technical resources as well. Although such an occurrence is bound to happen, it should still be governed by an updated set of procedures. The simultaneous application of technological advances with the implementation of the standards in a laboratory can be made possible through continuous training, education, and communication.

1.5 Relevance of Training Laboratory Personnel

Training keeps staff updated on the skills required to meet business demands, address evolving industry trends, adopt changes within an organisation (e.g., meet new regulatory requirements), and use new technologies. It is a mission-critical component of every lab-based organisation.[14] The trained and qualified professionals are capable to check manufacturer’s statements on reagents and equipment they use in the course of their work because they understand quality management systems. Studies have recognized the need for laboratory professionals to be trained. In the study of Petti et al.

[14] Kridelbaugh D. Creating a Successful Laboratory Training Program. Lab Manager [Internet]. Lab Manager. 2018 [cited 2020 December 17]; Leadership and staffing: [about 7 screens]. Available from: https://www.labmanager.com/leadership-and-staffing/creating-a-successful-laboratory-training-program-2352.

(2006), among the identified obstacles in good laboratory operation were a limited number of skilled personnel, training programmes, and a lack of educators. Fernandez-García et al. (2014) identified training necessity and lack of expertise as barriers toward laboratory preparedness and response. Giménez et al.'s (2019) research revealed that laboratory professionals were dissatisfied with their current knowledge, had a strong desire to learn how to access standards, and expected to receive further training. Recent news articles in the United Kingdom have exposed poor working practices in a diagnostic laboratory carrying COVID-19 testing due to untrained staff.[15,16] It is crucial to understand that in the matters of competency, it is not only the individual who does the test that declares it but also the accreditation of the institution itself. And so, training through continuous professional development that addresses laboratory personnel's knowledge and skills towards the organisation's accreditation is a stepping stone (Guevara et al., 2014). How to best identify and provide training programmes requires a scientific method (Figure 1.1).

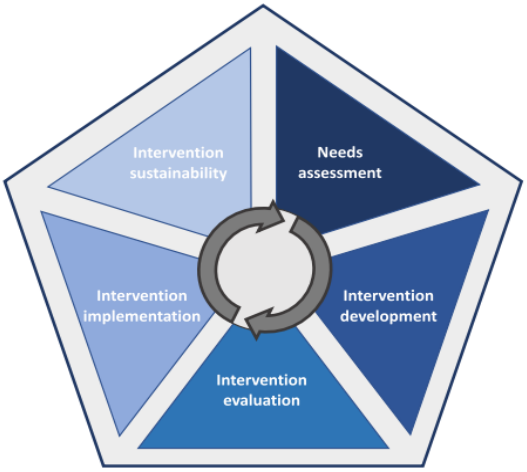

Figure 1.1 Key Strategic Model in Programme Intervention

(Adapted from Garcia-Cardenas V, Rossing CV, Fernandez-Llimos F, Schulz M, Tsuyuki R, Bugnon O, et al. Pharmacy practice research – A call to action. Res Social Adm Pharm. 2020;16(11):1602–1608.)

[15] Bloch-Budzier S. Coronavirus testing lab 'chaotic and dangerous', scientist claims [Internet]. 2020 Oct 16 [cited 2020 October 20]; Health: [about 4 p.]. Available from: https://www.bbc.com/news/health-54552620.

[16] Reporting team. Covid: Secret filming exposes contamination risk at test results lab [Internet]. 2021 Mar 29 [cited 2021 Mar 30]; UK:[about 8 p.]. Available from: https://www.bbc.com/news/uk-56556806.

1.6 Significance of Training Needs Assessment

Laboratory managers should identify required training needs and forecast future needs. Particularly, managers should conduct a knowledge and skill gap analysis with individuals regularly. Interestingly, in the study "Current American landscape in laboratory accreditation according to ISO/IEC 17025" by Grochau et al. (2017), a similar strategy of considering individual's needs to increase awareness and the number of accredited laboratories was proposed. Studies have used different techniques to assess the training needs of laboratory professionals. Among these were literature reviews, questionnaires, and focus group discussion (Mailoux, 1998). Published literature and internet sources enabled Shahangian and Snyder (2009) to assess the gaps with respect in the stages of the medical laboratory testing process, standard domains, and quality measures. An online survey such as that conducted by Bell et al. (2014) for veterinary laboratory personnel has revealed incompliances with guidelines, limitations of in-clinic laboratory equipment, regular quality control, repair and maintenance, as well as training of which illustrate the need for technical staff education. A focus group discussion has helped Alwahari et al. (2019) to recognise the need for professional training programmes for career enhancement. Combined use of comprehensive review of available websites, survey questionnaires, and personal communications allowed Li and Adeli (2009) to review the current status of laboratory quality and accreditation standards in Canada, whilst Goldsmith et al. (2020) used surveys, telephone interviews, and focus group sessions in identifying gaps which hindered the improvement of laboratory testing practices. Needs assessment studies guided the researchers to focus on the actual and future professional practice requirements, as well as related competence and skills, and corresponding learning and change requirements (Aherne et al., 2001). Through a systematic inquiry of educational

needs within an organization, one can determine priorities, make decisions, and allocate resources in a way that is consistent with an identified objective such as developing a continuing professional development (Kaufman & English, 1979; Triner et al., 1996; Kilduff et al., 1998; Lee et al., 2017). Through training needs assessment, Kasvosve et al. (2014) described the CPD training needs of medical laboratory personnel in Botswana, which included topics such as quality management systems, competence assessment, and customer service; whilst Boisvert and Shaikh (1998) were able to focus and develop training programmes that best meet the needs of the laboratorians. The development of CPD initiatives based on needs assessment will assist planners to concentrate on bridging gaps between existing knowledge or skills and needed competencies (Ulschak, 1988; Pearce, 1995; Gould et al., 2007).

1.7 Training Courses for Continuing Professional Development

Continuous professional development (CPD) captures learning outside of undergraduate and postgraduate training that helps an individual maintain and improve their performance.[17] It covers the development of knowledge, skills, attitudes, and behaviours across all areas of professional practice, and it includes both formal and informal learning activities.[18] The American Society of Health-System Pharmacists (ASHP) and Accreditation Council for Pharmacy Education (ACPE) laid down the strategic plan on standards for education and training programmes which must reflect its role within the community indicating long-term program goals, concrete measurable objectives, strategies for achieving the goals and objectives, a schedule for analysing and reviewing

[17] Royal College of Surgeons of England (RCS). Continuing professional development [Internet]. London: RCS; [unknown date] [cited 2020 Oct 17]. Available From: https://www.rcseng.ac.uk/standards-and-research/standards-and-guidance/revalidation/cpd/.

[18] Tumbwene M, Mbekenga CK, Isangula KG, Mwasha LK, Siaity E, Edwards G, et al. Validation of training need assessment questionnaire among health care workers in reproductive, maternal and newborn health care in low-income countries. BMC Health Serv Res. 2020

the plan, progress on the plan, and address programme outcomes.[19] CPD model resulted in personal development, rewards growth and competency, and sets high standards for all services and skills for laboratory professionals in the study conducted by Garza et al. (2012). Besides preparing for accreditation, continuing professional training and mentorship can increase and retain quality laboratory practice (Yao et al., 2010; Sayed et al., 2018; Gumma et al., 2019; Rusanganwa et al., 2019). Furthermore, a CPD that focuses on innovative tools can significantly increase the capacity for recognized learning, as well as enhance worker engagement and job satisfaction (Vanspronsen & McDonough, 2015).

1.8 Innovative Continuing Professional Training Programme

Studies have shown that the format of CPD is strongly related to competence improvement, with educational techniques that are centered on interaction and active participation (e.g., role-play, case discussion, hands-on practice sessions) being more effective than practice guidelines and formal instruction such as didactic lectures or seminars (Davis et al., 1999; Bloom, 2005; Yao et al., 2010). In the development of an effective continuing professional training programme, it is therefore important to understand both the specific needs of the target population and to investigate appropriate educational formats for training course delivery (Scholastak et al., 2010). Implementation of the training requires sound planning of programme content and instructional method. Understanding the context or system in which instructional design takes place should be viewed as a unique way to develop a framework allowing one to more clearly see the elements that influence the learning (Gardner, 2009). The study carried out by Karabiyik (2019) indicated that competencies in a standard are required

[19] American Society of Health-System Pharmacists (ASHP). Accreditation Standards for Pharmacy Technician Education and Training Programs [Internet]. Maryland: ASHP; [unknown date] [cited 2020 Oct 19]. Available From: https://www.ashp.org/Professional-Development/Technician-Program-Accreditation/Accreditation-Standards/Accreditation-Standards-for-Pharmacy-Technician-Education-and-Training-Programs?loginreturnUrl=SSOCheckOnly

to be addressed in a training programme where specific courses devoted to meet the objectives were considered in the programme development.

It is also vital to evaluate the implemented training to identify areas for improvement or develop a further series of topics (Karim et al., 2012). Ensuring that the design of the training event satisfied the trainees and addressing the organizational demands were few ways to improve effective training as detected by Granado (2019). The topic of assessment should be tackled in more depth, with fine-tuning made of the sessions' facilitation and timing. One study has incorporated recommended topics that are set at different levels for participants with varying levels of knowledge and skills.[20] Also, research on training effectiveness should be more aligned with the trainer's concerns if research findings are to be used by practitioners and, thus, they can help transform the culture and practices of employees.

1.9 Challenges in the Implementation of Training Programmes

Several factors should be considered when evaluating whether continuing professional training programmes can be accomplished or not. These factors include cost, quality of training, staff expertise, and many others. Access to CPD programmes is a significant challenge for laboratory personnel in developing countries, owing in part to their limited availability (Zapata-Garcia et al., 2007; Putri et al., 2019). Participation in CPD is also hampered by a lack of internet connectivity to access online CPD programmes, infrequent national professional meetings, lack of funding to attend regional and foreign conferences, and few to nonexistent national CPD providers that explicitly cater for laboratory professionals (Kasvosve et al., 2014). Another challenge in adopting CPD is

[20] Sammut MR, Abela G. Quality improvement through evaluation of GP trainers' continuing professional development in Malta. Malta College of Family Doctors; 2020.

the lack of continuous learning culture. Legislated revalidation and recertification of practitioners are moving the discipline towards mandatory professional development programmes, spanning a range of clinical, professional, and managerial activities around the world (Peck et al., 2000). Approaches vary greatly across the world, but the majority depends on professional self-regulation. In Malta, CPD is not a mandatory requirement for relicensing or continued registration of laboratory specialists. CPD activities are not therefore required to meet specific accreditation criteria associated with registration or licensing. Whatever scheme is implemented or legislated, every staff has a personal duty to participate in CPD and has a choice of a wide range of accredited educational activities to fulfil such responsibility. In laboratories, continuing professional training is of the utmost importance to scientists for maintaining professional recognition (Martin et al., 2014). Technical staff members are naturally interested and are self-motivated learners; it is important to foster the philosophy of lifelong learning in the workplace. In most cases, the only options available for CPD are the non-structured in-house training arranged by employers. Also, such factors should be studied to determine if new training should be delivered in-house or outsourced to a third party. A combination of both internal and external training sources is often needed to meet requirements. As Balchunas concludes in a recent article, companies can reduce costs and introduce outside perspectives, innovations, and subject matter expertise to move their practice forward by carefully leveraging a hybrid of internal and external learning and development partners to understand and solve learning challenges.[15] CPD is valued and is seen as effective when it addresses the needs of a person, the communities they serve, and the organisations within which they operate (Schostak et al., 2010).

1.10 Aim of the Study

The aim of this research is to establish and meet training needs on quality standardisation as tailored to the needs of laboratory personnel.

The objectives of the research are to:

i. identify the educational needs of laboratory personnel in relation to quality systems; and,
ii. develop, implement, and evaluate a training course on quality with a focus on ISO 17025:2017 as a case example.

Chapter 2

Methodology

This chapter presents the methodological framework adopted to fulfil the research objectives. It covers the research setting, research design, and procedures necessary for the accomplishment of the study.

2.1 RESEARCH SETTING

The study was conducted within the Malta Laboratories Network (MLN). The research was carried out at MLN, where I had the opportunity to work as a fellow as part of the Doctorate of Pharmacy programme. The MLN aims to sustain and develop laboratory services in Malta through the application of a unique model of cooperation based on fostering innovation, exchange of resources, and empowerment of stakeholders.[21] MLN acts as a coordinating body for various laboratories and scientific entities in Malta that are involved in archaeological testing, forensics, pharmaceutical, hospital-based laboratories, botanical, water, and food analysis. It also assists laboratories in applying for accreditation. The MLN works closely with the National Accreditation Board – Malta (NAB – Malta) and the Malta Competition and Consumer Affairs Authority (MCCAA) to promote quality standardisation and operate collaborative initiatives to support activities relating to the improvement of quality services in science and technology and within pharmaceutical processes through continuing professional training.

2.2 RESEARCH DESIGN

The study followed a qualitative research design set over two phases (Figure 2.1). Phase I was the identification of training needs concerning quality standardisation through a developed and validated questionnaire. Phase II focused on the development, implementation, and evaluation of a training course on quality.

[21] Malta Laboratories Network (MLN). MLN Home [Internet]. Malta: MLN; [unknown date] [cited 2020 Oct 11]. Available from: https://tourism.gov.mt/en/mln/Pages/default.aspx

Figure 2.1 Flowchart of the Study Design

2.3 PHASE I: IDENTIFICATION OF TRAINING NEEDS

Phase I focuses on the identification of training needs of laboratory personnel regarding quality standardisation. Figure 2.2 summarises the procedure undertaken within Phase 1 of the study.

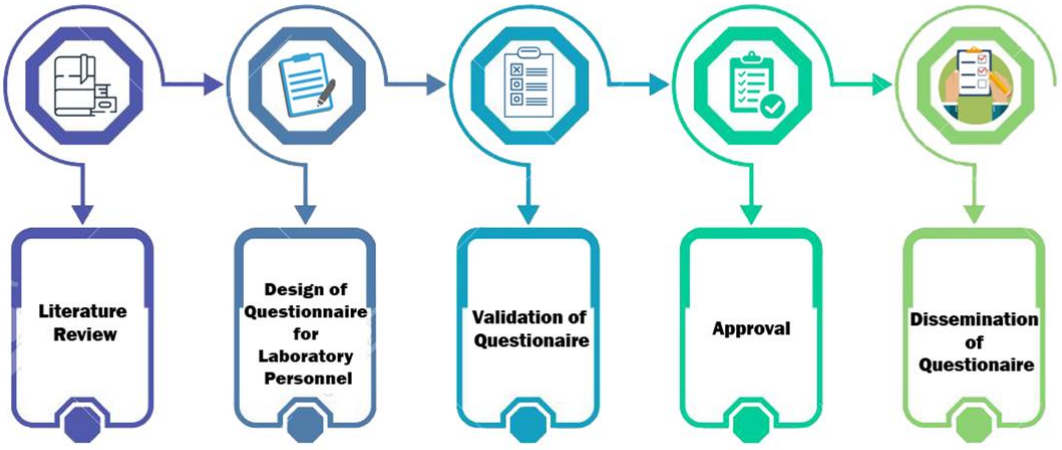

Figure 2.2 Flowchart for the Identification of Training Needs

2.3.1 Literature Review

A literature review was undertaken to highlight the basic aspects of professional development training courses for laboratory personnel on quality standardisation. The aim of the questionnaire was to capture the training needs of laboratory personnel in relation to standardisation, quality, and related areas targeting the specific needs of the national scenario. Literature was searched and taken from peer-reviewed journals and research papers. The major databases used were HyDi-Hybrid Discovery, MEDLINE/PubMed, and Google Scholar. The following keywords and phrases were used: educational needs, laboratory, professional development, quality control, quality standardi*, quality, training course, and training needs.

2.3.2 Development and Validation of the Questionnaire

The questionnaire was designed to capture the training needs on quality standardisation. A self-administered questionnaire entitled *Training needs assessment questionnaire* was developed. The questionnaire consisted of a combination of closed-ended and open-ended questions.[22] The closed-ended questions were yes or no and multiple-choice statements. The majority of the questions were open-ended to avoid potential bias and not to limit the respondents from providing ideas of their training needs and topics for training. The *Training needs assessment questionnaire* consists of seven sections capturing details of the laboratory, contact person, testing accreditation, laboratory accreditation, and equipment.

[22] Hicks C, Hennessy D. Hennessy-hicks training needs analysis questionnaire and manual [Internet]. Geneva: World Health Organisation; 2011 [cited 2020 May 21]. Available from: https://www.who.int/workforcealliance/knowledge/toolkit/19/en.

The *Training needs assessment questionnaire* was validated through a focus group discussion consisting of a quality manager pharmacist, an academic pharmacist, a scientist, and four international pharmacist-fellows working within MLN. A validation questionnaire (Appendix 2.1) was prepared to assist the focus group discussion. The focus group evaluated the content of the questionnaire using four criteria: relevance, clarity, simplicity, and the ability to elicit comments, opinions, and insights from the research participants. The focus group could tick “yes” or “no” and comment on each item. Recommendations put forward by the focus group were taken into consideration and the questionnaire was modified accordingly. The amended version was inputted using Google Forms (Appendix 2.2). Approval from the University of Malta Research Ethics Committee (UREC) and Malta Laboratories Network administration was sought prior to dissemination of the questionnaire (Appendix 2.3). Pilot testing was done to test the feasibility of the questionnaire. The pilot testing was completed by five stakeholders through Google Forms. The respondents were asked to complete the survey and give comments on the questionnaire after completion of the survey. The comments were considered, and the questionnaire was revised. The final version was disseminated to the personnel involved in quality standards.

2.3.3 Dissemination of the Questionnaire

The final version of the questionnaire was disseminated electronically to the 80 stakeholders of the Malta Laboratories Network. A follow-up telephone call to confirm if the staff received the questionnaire was undertaken.

2.4 PHASE II: DEVELOPMENT, IMPLEMENTATION, AND EVALUATION OF TRAINING COURSE

Phase II focused on the development, implementation, and evaluation of the training course for laboratory personnel regarding quality standardisation. The process involved the designing of the learning objectives, outcomes, description of the content, method of delivery, and choice of tutor. After the development of the training course, implementation took place. Finally, evaluation of the training course by participants completed this phase. Figure 2.3 summarises the steps involved in Phase II.

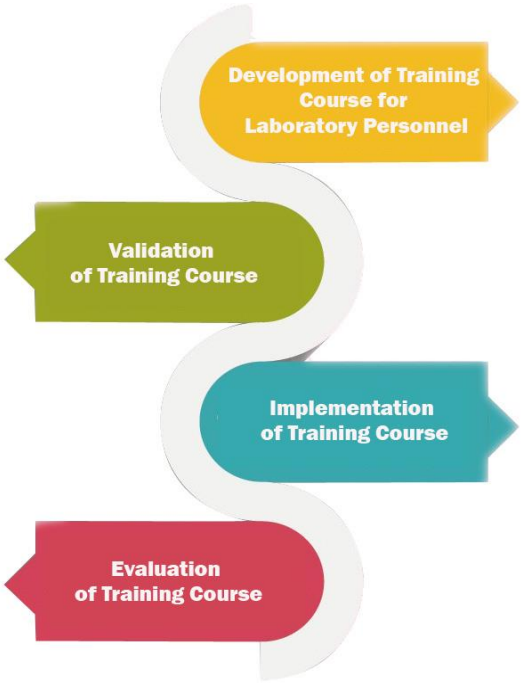

Figure 2.3 Development, Implementation, and Evaluation of Training Course

2.4.1 Development and Validation of Training Course - ISO 17025:2017

Study findings from Phase 1 were intended for the analysis to identify priority areas for training needs. Simultaneously, upon receiving and completing the *Training needs assessment questionnaire*, the Malta Police Forensic Science Laboratory directly contacted the MLN to provide a series of courses to assist the entity in enhancing

quality standards. A preliminary online meeting with the quality manager at the Malta Police Forensic Science Laboratory, the administration of the Malta Police Forensic Science Laboratory, the researcher, and the Malta Laboratories Network administration was held to identify target areas. The discussion highlighted the need for a course on ISO 17025:2017 *General requirement for the competence of testing and calibration laboratories awareness course for forensic professionals* specifically targeting the forensic professionals.

A training course was developed based on literature reviews looking at standards and guidelines issued by the World Health Organisation and the Academy of Royal Medical Colleges on training activities.[23,24,25] The ISO 17025:2017 *General requirements for the competence of testing and calibration laboratories awareness course for forensic professionals* was divided into course title, learning objectives, learning outcomes, description of the content, method of delivery, and choice of tutor. The course topics covered the individual requirements of the ISO 17025:2017, the basic understanding of quality management systems, and the practical aspect of the quality manager with a specific focus on forensic sciences laboratory operations. The guideline which was used as a reference for the topic was the ISO standard itself as put forward by the International Organization for Standardisation. The learning objectives, outcomes, and content of the course and the duration of the course were drafted. The delivery method chosen was face-to-face as this had been already agreed upon during the preliminary meeting held.

[23] World Health Organisation (WHO). Laboratory Quality Management System - Training toolkit [Internet]. Geneva: WHO; 2009 [cited 2020 September 10]. Available from: https://www.who.int/ihr/training/laboratory_quality/doc/en/

[24] World Health Organisation (WHO). Patient Safety Research: A guide for developing training programmes [Internet]. Geneva: WHO; 2012 [cited 2020 September 15]. Available from: https://www.who.int/patientsafety/topics/research/developing_research_training_ programmes/en/

[25] Academy of Royal Medical Colleges (AOMRC) [Internet]. London: AOMRC. Standards and Criteria for CPD Activities. A Framework of Accreditation; 2019 [cited 2020 Oct 11]. 1-11 p. Available from: https://www.rcoa.ac.uk/sites/default/files/documents/2020-06/Standards%20and%20Criteria%20for%20CPD%20Activities%2C%20AoMRC.pdf#:~:text=Guidance%20on%20the%20Standards%20and%20Criteria%20for%20CPD,that%20are%20needed%20to%20assisthe%20t%20accreditation%20process.

The design of the training course was validated through a focus group discussion consisting of an academic pharmacist, a pharmacist with a special interest in quality, an engineer who is responsible for accreditation in line with ISO 17025:2017 requirements, a scientist, two international pharmacists, and the quality manager of the Malta Police Forensic Science Laboratory. A validation questionnaire (Appendix 2.4) assessing training course design in terms of practicality for the implementation, feasibility, and target audience was prepared to lead the focus group discussion which was held online through Microsoft Teams. Recommendations put forward were taken into consideration. The final version was compiled (Appendix 2.5).

2.4.2 Implementation of the Training Course

The training was carried out following the standard operating procedure of MLN for the dissemination of course information, registration of participants, and logistic planning. Information on course material together with an invitation letter was compiled. An invitation message containing the training course description and registration link was sent to the quality manager at the Malta Police Forensic Science Laboratory who in turn circulated internally the information to forensic professionals. A list of interested participants was subsequently passed on to the MLN as the training course provider. The two-day interactive and face-to-face training course with a total of 14 hours was delivered in a classroom mode abiding by the current COVID-19 situation.[26,27]

Attendance to the two days was documented in the appropriate attendance sheet (Appendix 2.6) which was subsequently stored for record and auditing purposes of the

[26] Office of the Deputy Prime Minister. COVID-19 Transitioning - Standards for Gatherings and Events [Internet]. Valletta: Ministry of Health; 2020 August [cited 2020 October 02]. Available from: https://deputyprimeminister.gov.mt/en/health-promotion/covid-19/Documents/mitigation-conditions-and-guidances/Standards_Gatherings_And_Mass_Events.pdf

[27] Centers for Disease Control and Prevention (CDC). Guidance for organising large events and gathering [Internet]. Atlanta: CDC; 2020 [cited 2020 October 02]. Available from: https://www.cdc.gov/coronavirus/2019-ncov/community/large-events/considerations-for-events-gatherings.html

training course provider. The training course which was facilitated by qualified tutors included interactive exercises to increase discussion among participants and case scenarios to enhance practical and decision-making skills.

2.4.3 Development, Validation, and Distribution of the Evaluation Form

A literature review was undertaken to highlight the basic aspects of the formative evaluation form. The structure of the evaluation form includes trainees' reactions and satisfaction about the training course (Miles, 1965; Mann, 1996; Guskey, 2000; Tennant et al., 2002; Addy et al., 2004; Grohmann & Kauffeld, 2013; Ritzmann et al., 2014). The evaluation form aimed to capture the participants' views on the overall implementation of the training course as well as their perception of what to improve. The evaluation form was used as an evaluation tool and consisted of a combination of close-ended and open-ended question styles. Likert scale was used to measure the level of agreement on statements and questions pertaining to participant's reactions and satisfaction. Open-ended questions were also used to collect their opinions of the impact of the training on quality standardisation. The evaluation form was validated through a focus group discussion consisting of an academic pharmacist, a pharmacist with interest in quality, a scientist, and four fellows. Face and content validity was undertaken whereby the focus group evaluated the content of the questionnaire based on relevance, clarity, simplicity, and the ability to elicit comments, opinions, and insights from the research participants. Face and content validity of the evaluation form was undertaken through a validation questionnaire (Appendix 2.7) prepared prior to the focus group discussion which was held online through Microsoft Teams. Experts were then given the chance for discussion. The evaluation questionnaire was modified according to the suggested amendments by the focus group.

Following the training course, participants were invited to evaluate the training course by completing the evaluation form provided via a link through Google Forms (Appendix 2.8). It took three minutes to complete the evaluation questionnaire. Participants who attended the two-day training were awarded a certificate for completing the course. A template for the certificates was drafted and checked by the same focus group reviewing the evaluation form. No changes were put forward in the certificate template (Appendix 2.9).

Chapter 3

Results

The results chapter outlines the following:

- The result of the questionnaire validation
- The outcomes of the pilot test
- The dissemination of the *Training needs assessment questionnaire*
- The design of the training course
- The result of the training course design validation
- The result of validation for the questionnaire to evaluate the training
- The result of the training evaluation

3.1 PHASE 1: THE RESULT OF THE TRAINING NEEDS ASSESSMENT IN QUALITY SYSTEMS

The results in Phase 1 include the validation of the developed *Training needs assessment questionnaire* and its implementation.

3.1.1 Validation of the Questionnaire

All seven members who were invited to complete the validation process of the questionnaire through focus group discussion agreed to participate. All members agreed with the statements put forward in the questionnaire. However, 13 questions (33%) were modified following the comments and suggestions of the expert validation panel. Comments on the restructuring of order and layout were put forward for 13 out of 39 questions. Table 3.1 summarises the modifications put forward and the action taken.

3.1.2 Piloting of the Questionnaire

Five stakeholders from calibration and testing laboratories completed the pilot survey. The participating personnel originated from metrology calibration laboratory, teaching and research, plant, petroleum, and food and water testing laboratories (Table 3.2). The respondents were a director, a manager, a chief scientific officer, and two laboratory officers.

Table 3.1: Result of the *Training Needs Assessment Questionnaire* Validation

Question Section/ Number	***Original Question/ Statement and Suggestions***	***Action Taken***
Section A number 1	Change name of laboratory to type of laboratory.	Type of laboratory was used instead of name.
Section A number 3,4,5	Omit contact details.	Contact details were deleted.
Section B	Details of the contact person be changed to details of the respondent.	Details of the respondent are used.
Section B number 5	Omit contact details.	Contact details were removed from section B.
Section C	Subdivide the component of Section C: Laboratory and testing accreditation to general laboratory accreditation and testing accreditation.	Section C was subdivided. General laboratory accreditation was labelled "a" while the testing accreditation was labelled "b."
Section C	Entitled the questions as testing accreditation and labelled as "b."	Questions and statements of section C was retained, titled as testing accreditation and labelled as "b."
Section D	Move the questions to section C and labelled as "a. General laboratory accreditation."	Contents were transferred under section C and labelled as "a. General laboratory accreditation."
Section D	Include the statement "If no, please go to question 2" in number 1 and include statement "If no, please go to question 5" in number 4.	The suggested statement was included in question number 1 and 4.
Section E	Change the section title to "Section D: Equipment."	Section E was changed to Section D and titled as Equipment.
Section E	Convert the interrogative statement "What type of software is used in this lab?" to a declarative statement.	"What type of software is available within the laboratory?" was used instead of the question.
Section F Number 1	Include statement "If no, please go to section F."	Statement "If no, please go to section F" was included in number 1 of Section F.
Section F	Change the section title to "Section E: Specific HPLC Equipment questions."	Section F was changed to Section E and titled as Specific HPLC Equipment questions.
Section G	Change the section title to "Section F: Educational and Training needs."	Section G was changed to Section F and titled as Educational and Training Needs.

Table 3.2: Type and Classification of Laboratories Participating in the Pilot Study

Type of Laboratory	Classification of Laboratory
Realisation of SI units and Metrology	Calibration Laboratory
Teaching and Research Laboratory	Testing Laboratory
Plant Laboratory	Testing Laboratory
Petroleum Laboratory	Testing Laboratory
Food and Water Laboratory	Testing Laboratory

The bar graph in Figure 3.1 provides information on the accreditation status of the respondents. Among the respondents (n=5), only two laboratories were accredited. Two of the three unaccredited laboratories were interested in accreditation. All five respondents claimed that they were aware of the accreditation processes. Furthermore, data also revealed that four were unaware of the MLN Qual-Lab scheme grant and were interested.

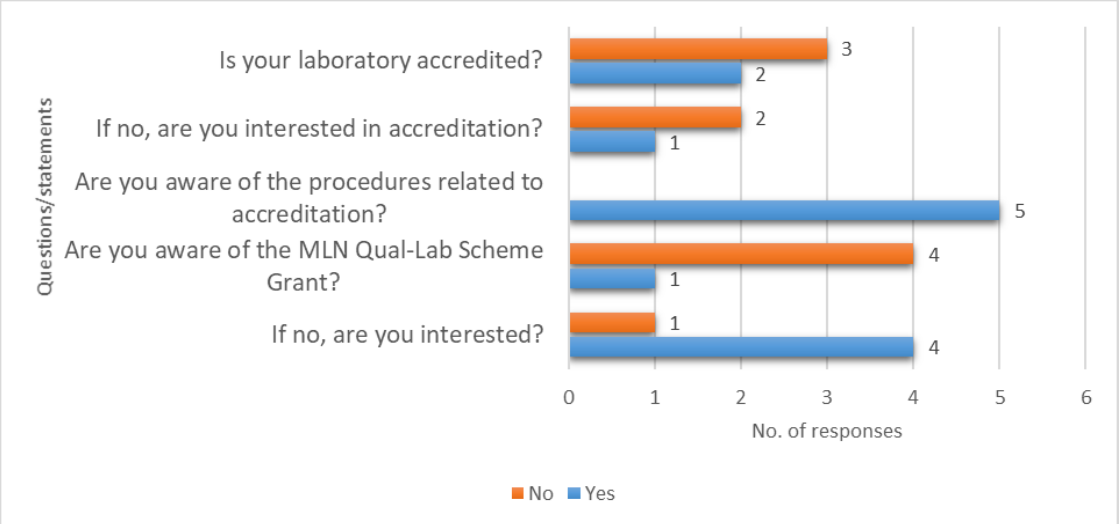

Figure 3.1: Accreditation Status (N=5)

Tests performed by the responding laboratories in the pilot study are in Table 3.3. Data revealed that the tests on the calibration of instruments and determination of petroleum properties were accredited by the National Accreditation Board of Malta (NAB-Malta). Tests that were not accredited but being offered include genetic, molecular, and microbiological testing.

Table 3.3: Test Services and Accreditation Status

Test Performed	Accreditation Status	Accrediting body
Calibration of electronic non-automatic weighing instruments	Yes	NAB-Malta
Genetic testing and Molecular Biology techniques	No	
No tests are done in the conventional way	No	
Determination of Kinematic viscosity, density, etc. for petroleum products	Yes	NAB-Malta
Microbiological testing for legionella	No	

Table 3.4 enumerates the available equipment in the laboratories and their usage status and frequency. The equipment includes membrane filtration, incubators, spectrometer, pH meter, and autoclaves, to name a few. Respondents declared that all equipment were always in use.

Table 3.4: Equipment Usage Status and Frequency

Available Equipment	Usage status	Usage frequency
Membrane Filtration, incubators, stomacher, spectrometer, pH meter, conductivity meter, autoclaves	All in use	Always in use
Autoclaves, growth room	All in use	Always in use

The study surveyed the use of high-performance liquid chromatography (HPLC). As can be seen in Figure 3.2, only one of the five respondents has it. The respondents were also asked if they have problem running the equipment or not. The result in Figure 3.3 showed that a respondent admitted to having such a challenge on the use of a deteriorating equipment.

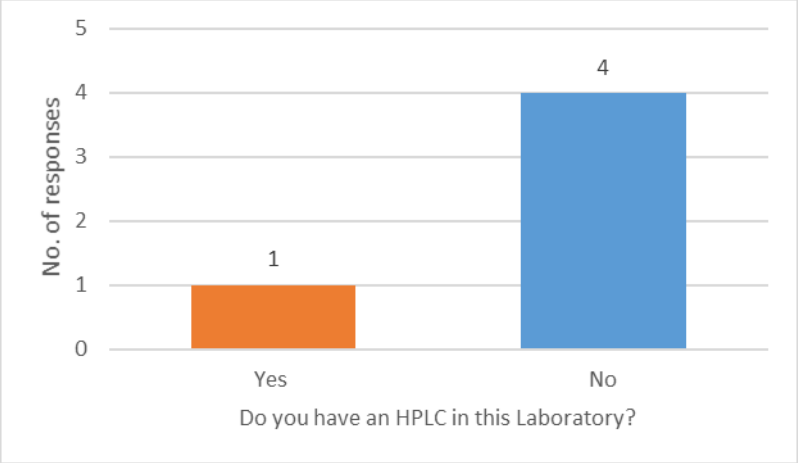

Figure 3.2: HPLC Availability in the Pilot Study (N=5)

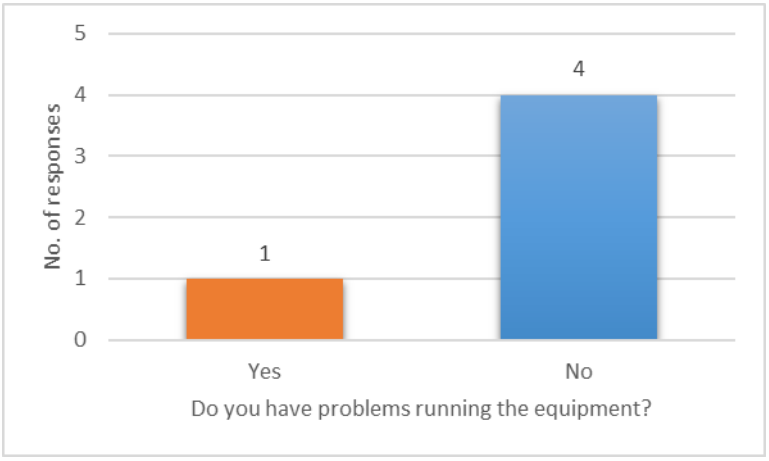

Figure 3.3: Equipment Use Problem (N=5)

Networking with other laboratories for equipment use and maintenance were also assessed. Figure 3.4 shows that two companies were aware of other laboratories having similar equipment being used. Also, two laboratories were in communication with other testing establishments. Three were not interested in meeting with other laboratories to discuss problems encountered, and only two were willing to share services.

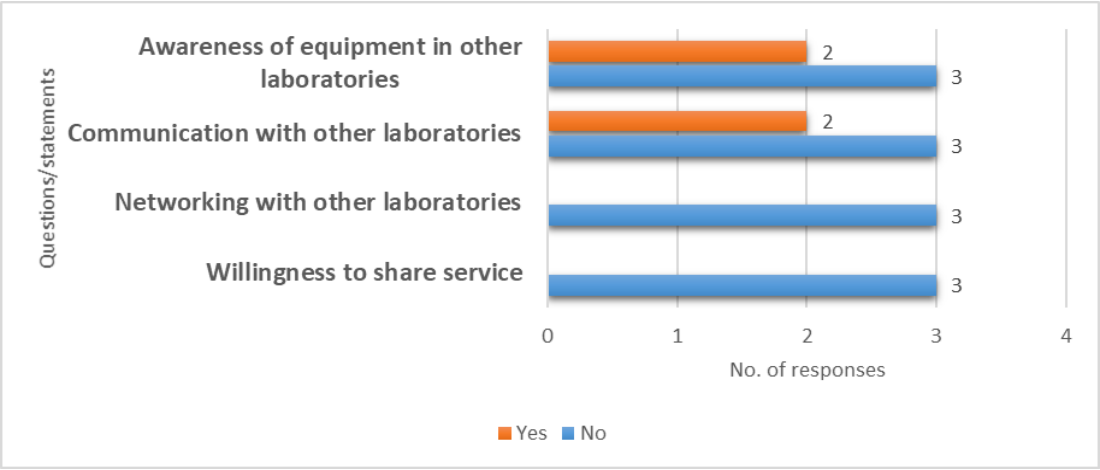

Figure 3.4: Collaboration on Equipment Use and Maintenance (N=5)

Plans to offer new tests requiring new equipment and the training services offered by Malta Laboratories Network (MLN) were evaluated and presented in Figure 3.5. Results revealed that two laboratories planned to offer new tests. From the respondents, there

was only one who has attended a training course offered by MLN and was satisfied with the course and its communication. As for the course delivery, three of five replied that they prefer attending online training programmes.

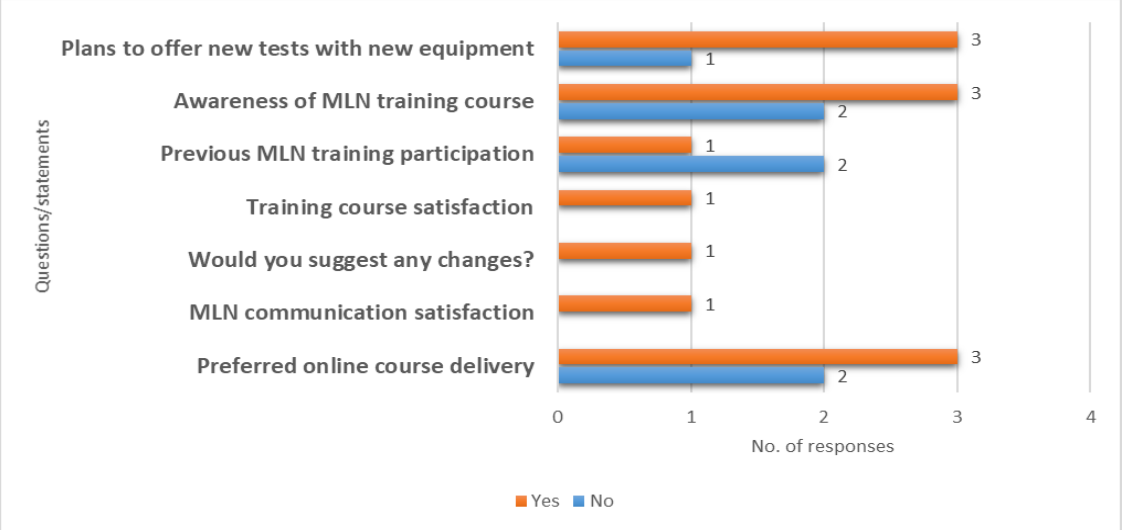

Figure 3.5: MLN Collaboration on Training Courses (N=5)

Table 3.5 provides the pilot study result of the training needs of the laboratory personnel for quality standardisation. Training on ISO 17025:2017 *General requirements for the competence of testing and calibration laboratories* and measurement uncertainty were suggested.

Table 3.5: Suggested Training Topics

ISO 17025:2017 *General requirements for the competence of testing and calibration laboratories*
Measurement uncertainty
Advanced courses on uncertainty of measurement

The respondents' feedback in the pilot survey was taken into account. These include the removal of duplicate questions due to erroneous inputting, the modification of the response status from mandatory to the optional setting, and the visibility of numbers in Google Forms.

3.1.3 Dissemination of the Training Needs Assessment Questionnaire

Out of the 113 Malta Laboratory Network stakeholders contacted, only 80 have laboratories. These laboratory staff were possible respondents, and the questionnaire was sent on to each of them. Sixty-three percent (n=50) of the contacts completed the questionnaire.

Out of a total of 50 respondents, 18 were laboratory managers, eight were laboratory directors, eight were laboratory officers, six were chief scientific officers, four clinical pharmacists, and the remaining six were professors, scientists, and veterinarians (Figure 3.6).

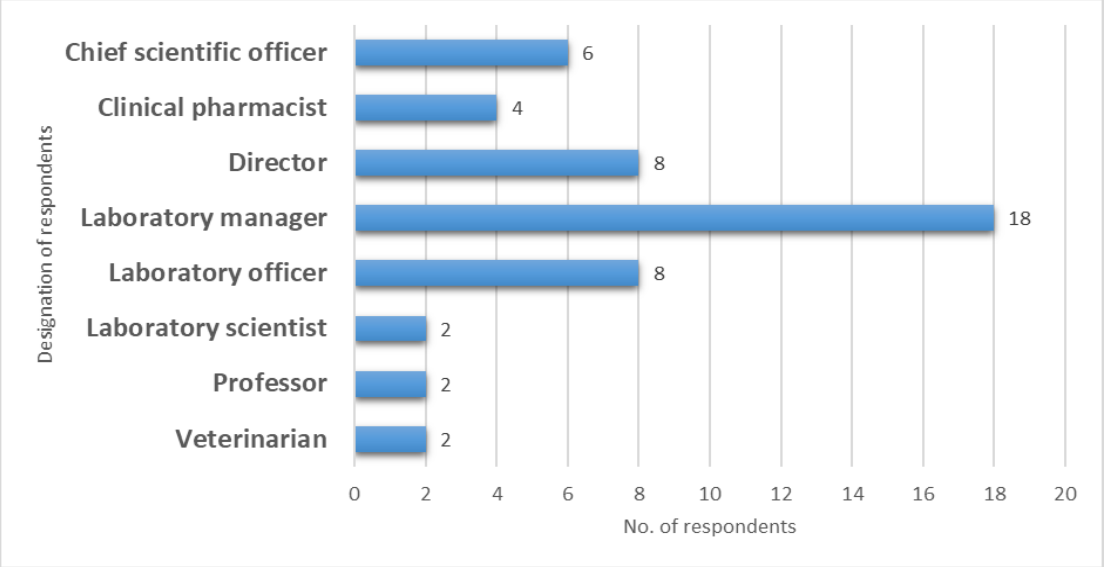

Figure 3.6: Designation of Respondents (N=50)

Types of Laboratories

Figure 3.7 presents the breakdown of the respondents according to the types of laboratory. Ten were from laboratories in pharmaceutical firms, six came from diagnostic companies, six were from food and water testing laboratories, five were from laboratories for research and teaching; plant research and building material testing

laboratories contribute four each, three were from calibration laboratory, and the same number is reflected by nutraceutical quality control and veterinary laboratories. The remaining six were comprised of environmental, petroleum, archaeological, and forensic laboratories. Of the 50 respondents, Figure 3.8 further classifies the companies as calibration laboratory (6%) or testing laboratory (94%).

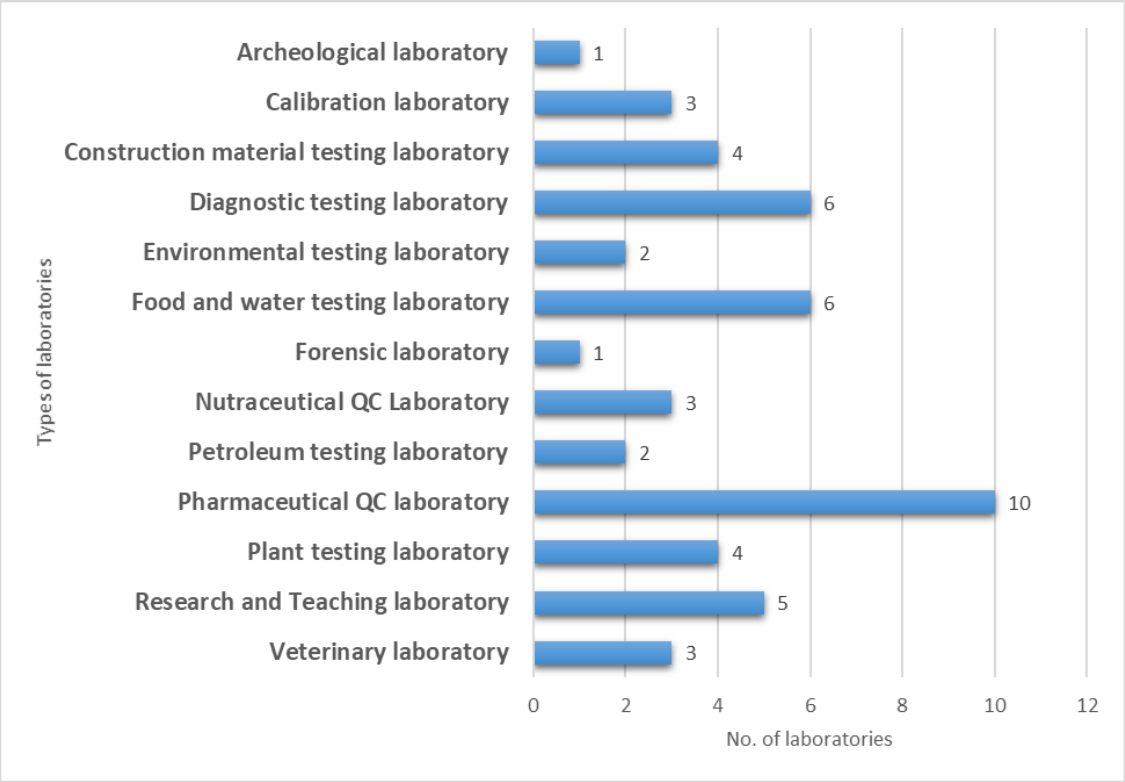

Figure 3.7: Types of Laboratories (N=50)

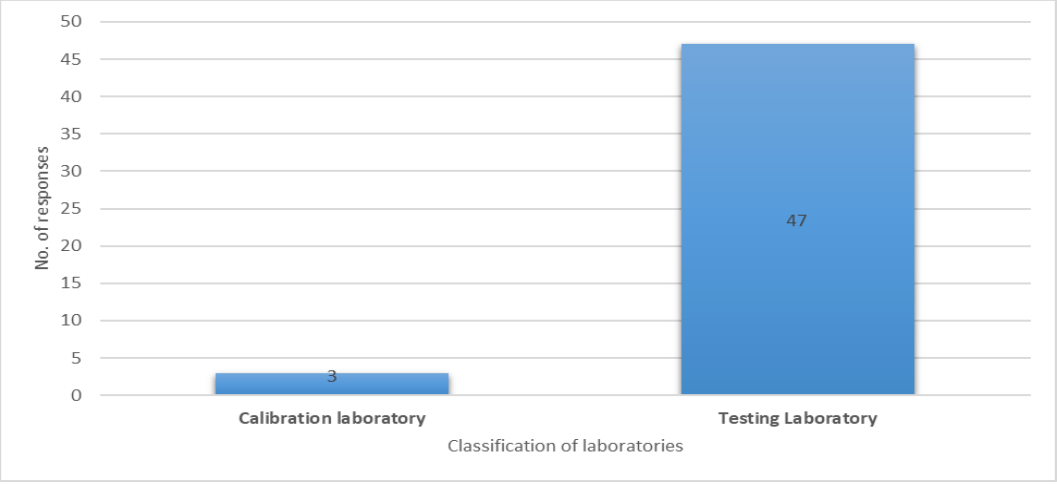

Figure 3.8: Classification of Laboratories (N=50)

Status of Accreditation

Results of the survey reflect that of the 50 laboratories that took part in this survey, only 45 answered and 42% (N=19) of which were fully accredited with ISO/IEC 17025. Meanwhile, of the non-accredited laboratories, 48% (N=12) demonstrate a willingness to be accredited with ISO/IEC 17025 (Table 3.6).

Table 3.6: Status of Accreditation and Future Plans for Certification of Various Laboratories in Malta

Parameters	N	Percentage (%) Distribution
No. of laboratories accredited to ISO/IEC 17025	19	42.2
Awareness on protocols of accreditation	36	80.0
Plans and willingness to be accredited	12	48.0
Awareness on MLN QUAL-LAB Scheme Grant	11	24.4
Interest for MLN QUAL-LAB Scheme Grant	25	73.5

Twenty-two accredited laboratories in Figure 3.9 enumerated 245 tests which were accredited by the National Accreditation Board of Malta (NAB-Malta), 40 tests were accredited by the European Union Good Manufacturing Practice - Malta Medicines Authority (EU GMP – MMA), and two tests were accredited by Ministry of Health – Malta. On the other hand, 118 unaccredited tests were enumerated by respondents.

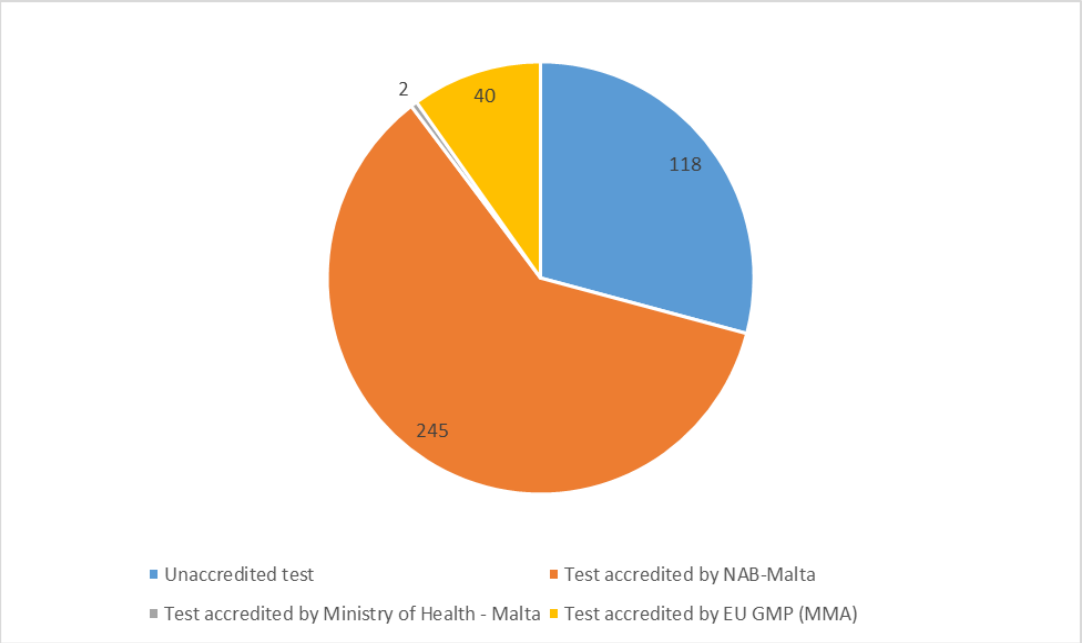

Figure 3.9: Test Accreditation

Suitability of Test Equipment

Table 3.7 summarizes the results in relation to the suitability of the test equipment. The study also investigated the utilisation of high-performance liquid chromatography (HPLC) in the laboratory. Fifteen were using it, as shown in Figure 3.10. The participants were also asked whether they had trouble operating the machinery or not. Figure 3.11 indicates that six personnel admitted to having such a problem. Also identified were the problems faced in the laboratory, and these were aging parts, maintenance costs, and training staff.

Table 3.7: Suitability of Test Equipment vis-à-vis with Operation

Parameters	Assessment
Availability of necessary equipment and software	Complied
Equipment and software suitable for achieving the required accuracy of testing	Complied
Establishment of calibration program	Complied
Equipment was operated by authorized personnel	Complied
Maintenance of equipment records in place	Complied
Procedures for safe handling, transport, storage use and planned maintenance are in place	Complied

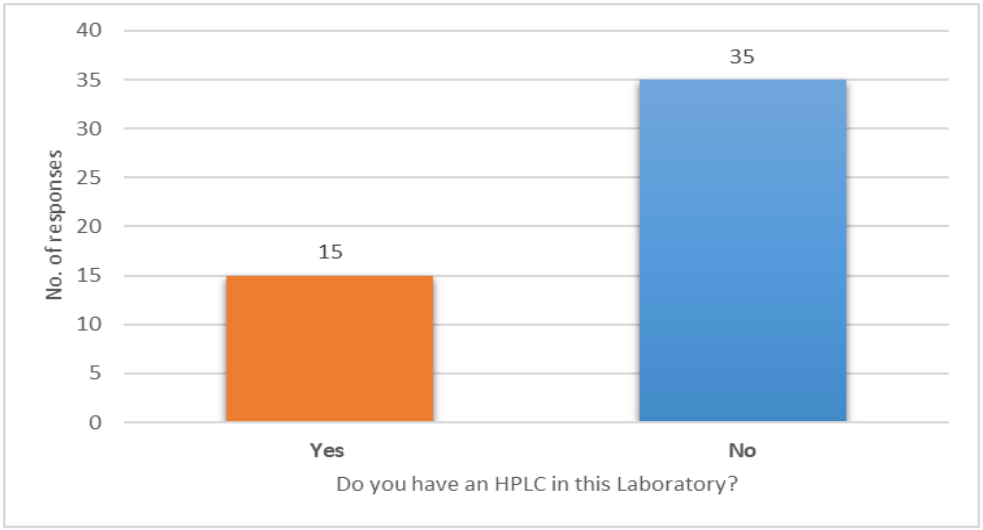

Figure 3.10: High-Performance Liquid Chromatography (HPLC) Availability among the Stakeholders (N=50)

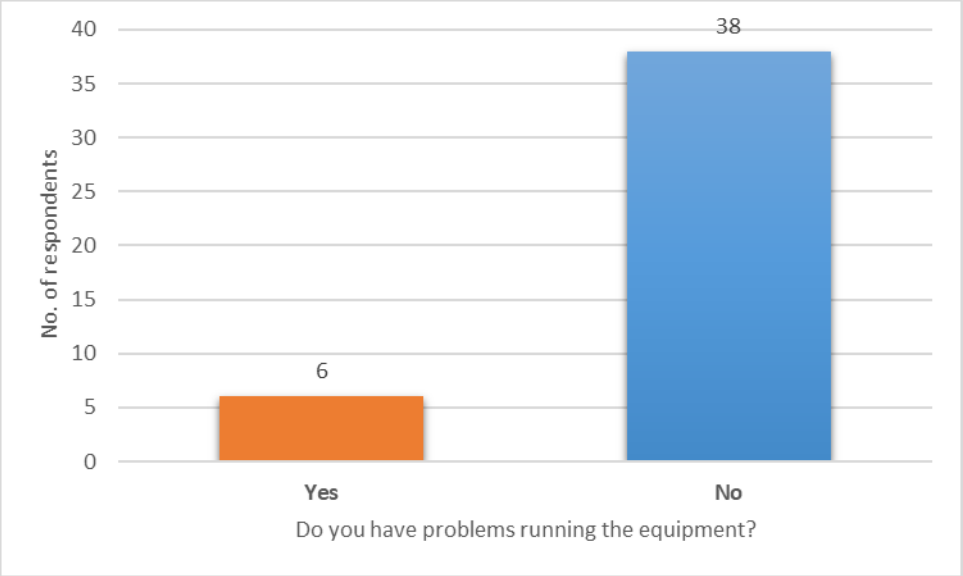

Figure 3.11: Problems Encountered in the Use of Equipment (n=50)

Technical Ability of Personnel

One important aspect of ISO/IEC accreditation is the technical ability of the personnel operating in the laboratory. The assessment of this stage is shown in Table 3.8. Assessment of the technical availability of personnel to conduct a specific testing for specific type of laboratory signifies current compliance of various laboratories.

Table 3.8: Technical Availability of Staff

Parameters	Assessment
Competent qualified appropriately trained personnel operate testing	Complied
There is a policy to identify training needs	Complied
There is a mechanism to identify training needs of personnel	Complied
Authorized specific staff is assigned to a specific work	Complied

Collaboration with other laboratories for the use and maintenance of similar equipment was also evaluated among the 50 participating individuals. Figure 3.12 shows that 24

firms were informed of finding the same equipment as theirs in other laboratories. Also, 14 staff are in contact with other research establishments. Fifteen respondents are not interested in meeting to address issues found with other laboratories. Moreover, 14 laboratory employees are willing to share resources.

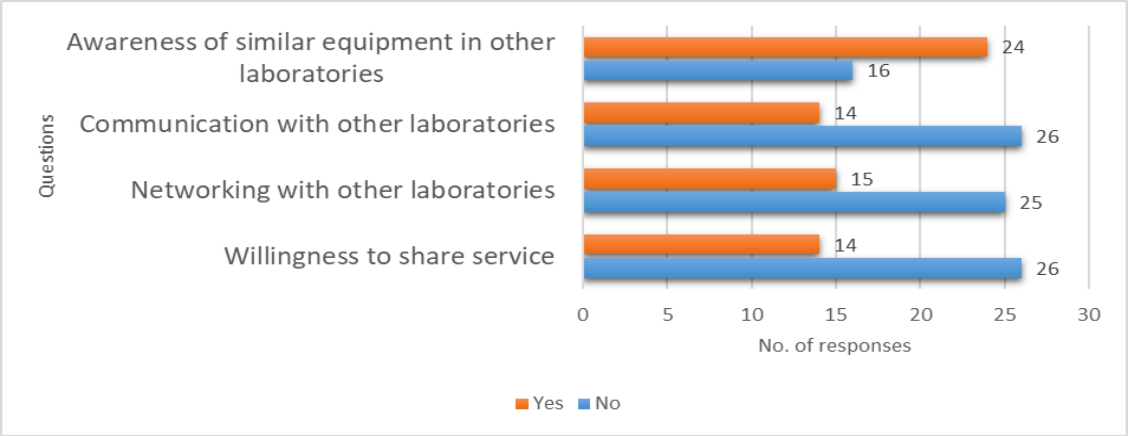

Figure 3.12: Collaboration on Equipment Use and Maintenance (N=50)

Laboratory Services Required from MLN

To continually support the laboratory towards accreditation and certifications, results indicated that several laboratories have assistance from MLN. Among these supports required are to facilitate proficiency testing, training on laboratory management, basic training for ISO, support to communicate with authorized government agencies, and networking and information.

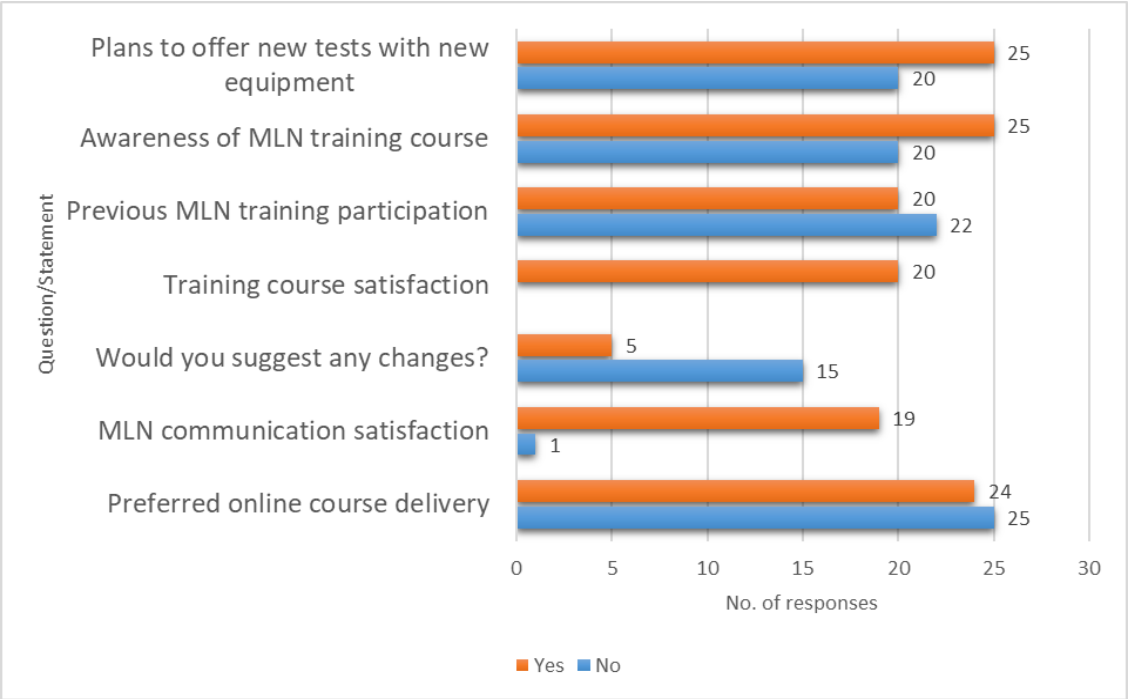

Figure 3.13: Malta Laboratories Network (MLN) Collaboration on Training Courses (N=50)

Plans for providing new tests requiring new equipment and training programmes provided by the Malta Laboratories Network (MLN) were assessed (Figure 3.13). The result showed that only 25 laboratories were planning to offer new tests. Of the 50 respondents, 25 were familiar with the MLN training course. Twenty have participated in the training course, or at least one of their peers has taken part in the training. These 20 respondents were satisfied with the course. Furthermore, 19 were pleased with the correspondence, while one did not respond to the question. Interestingly, the result has drawn even in the preference between taking the course online or face-to-face.

Training Needs of Technical Staff

Among the technical challenges in accreditation for ISO/IEC 17025 is the training requirements of the personnel. Continuous training of personnel in the laboratory is vital in quality laboratory management as it allows competence among personnel to do testing.

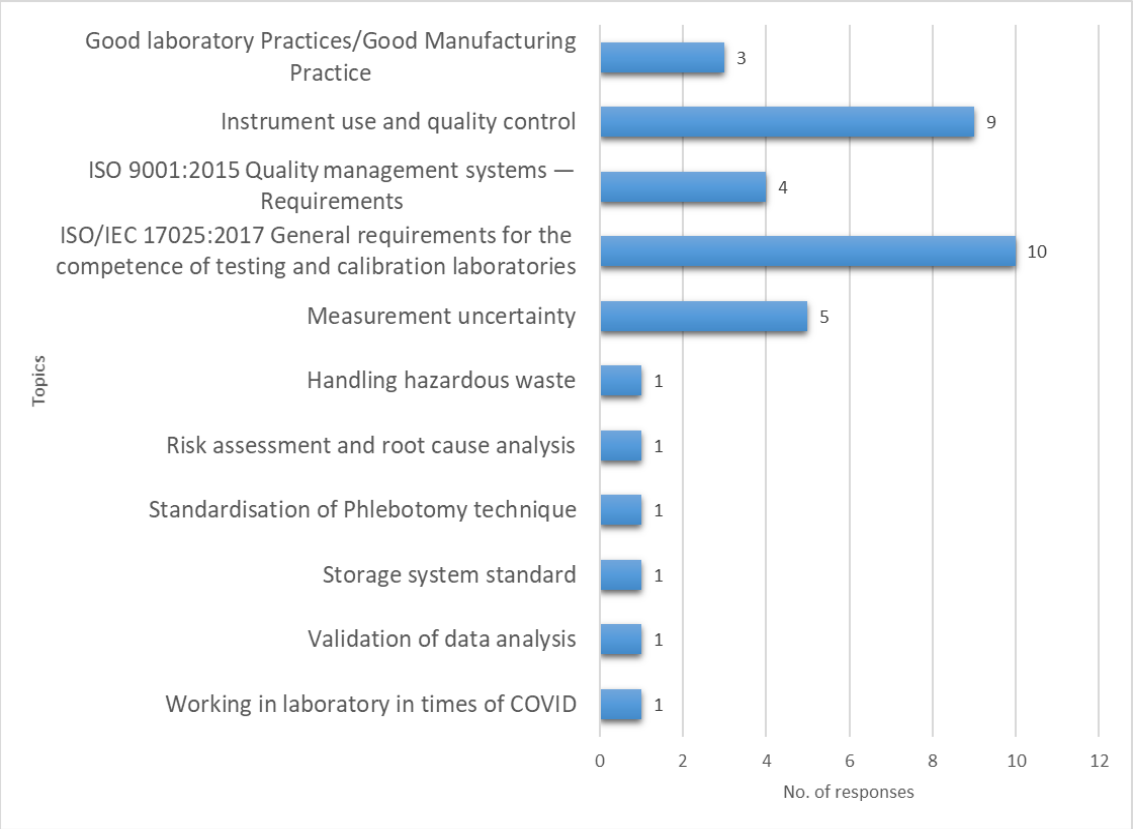

Figure 3.14: Training Needs Topics (N=50)

The topics found in the evaluation of laboratory staff training needs for quality standardization are presented in Figure 3.14. Training on ISO 17025:2017 *General requirements for the competence of testing and calibration laboratories* constitute 20% (n=10) of the responses. This was followed by nine responses on quality assurance (QA) and instrumentation (e.g., training on chromatography and microscopy). Five responses were training on the uncertainty of measurement, four suggested ISO 9001:2015 *Quality management system – Requirement*, and three for good laboratory and manufacturing practices. Other relevant answers were QA and handling hazardous waste, standards in the storage system, and phlebotomy standards. There were 13, to be accounted for, who did not respond.

3.2 PHASE 2: THE RESULT OF THE TRAINING COURSE DESIGN, IMPLEMENTATION, AND EVALUATION

The results in Phase 2 include the validation outcome of training course design, evaluation questionnaire, and the evaluation of the implemented training.

3.2.1 Result of Training Course Design Validation

Seven validating members completed the validation process of the training course design.

Four criteria were flagged for addition. These were the inclusion of address, contact details of the service provider, time, and venue of the training. One learning outcome was identified for revision (Table 3.9). Feedback from the expert validation panel was deemed necessary, and comments were incorporated.

A two-day interactive training programme on ISO 17025:2017 *General requirements for the competence of testing and calibration laboratories* awareness course was organised for forensic laboratory professionals. The training was made possible through a collaborative initiative among Malta Laboratories Network (MLN), the Malta Police Forensic Science Laboratory (MPFSL), and the National Accreditation Board of Malta (NAB-Malta). The event was held at Malta Police General headquarters, Floriana, Malta, last 22-23 October 2020 from 8:00 in the morning until 16:00 in the afternoon.

Table 3.9: Result of the Training Course Design Validation

Section	Remarks
Service provider	Include all the collaborators e.g. NAB-Malta
Contact details	Add contact details of the main service provider
Venue	Include venue in the final content
Learning objectives	Simplify the learning objectives below i. Describe the aim, objectives and elements of ISO 17025:2017 and all the components of a Laboratory Quality Management System (LQMS) ii. Design implementation plan to comply with the requirements of ISO 17025:2017 iii. Identify and prepare appropriate LQMS documentation iv. Develop pertinent performance monitoring parameters and strategies v. Discuss the critical role of internal audit, corrective, and preventive actions
Learning outcome.	Present a bullet type learning outcome
Content Structure	Structure it based on ISO Prepare a training agenda with timetable
Method of delivery	Specify the method of delivery

3.2.2 Result of the Training Course Implementation

All 25 personnel registered for the training. Twenty-four percent (n=6) of the participants were female, and 76% (n=19) were male. Out of 25, only 22 completed the two-day course with three participants dropping out due to personal reasons of leave and sick leave.

3.2.3 Result of the Post-training Evaluation Form

Seven validating members completed the validation process of the questionnaire through a focus group discussion. The direction of the questionnaire was modified whilst some of the contents were rephrased (Table 3.10). Feedback from the expert validation panel was deemed necessary, and comments were incorporated.

Table 3.10: Result of the Evaluation Questionnaire Validation

Section	*Remarks*
Direction	Describe the values instead of numbers
	Use check mark instead of encircling the number
Content	Formulate specific statements to assess the subject, speaker, relevant information, expectation, pace of the training, duration, learning, and objectives.
	Formulate open-ended questions to suggest other and future topics.

3.2.4 Training Course Evaluation Result

To facilitate the establishment of laboratory competence and quality, comprehensive training was provided to the personnel in Malta to relate to one of the salient features of ISO/IEC 17025. Of the 22 successful participants, 82% (n=18) filled the questionnaire on Google Forms to evaluate the training course on ISO 17025:2017 *General Requirements for the Competence of Testing and Calibration Laboratories Awareness Course for Forensic Professionals*.

Overall results on the quality, satisfaction and overall recommendation of the participants are shown below:

Table 3.11: Overall Level of Satisfaction of Respondents on the Training Conducted

Items	*Mean*	*Description*
The subject of the training was presented effectively.	4.59	Very high
The sessions delivered the relevant information.	4.65	Very high
The sessions met my expectations.	4.47	Very high
The speakers were knowledgeable about the subject.	4.76	Very high
The pace of the training was satisfactory	4.18	High
The duration of the training was sufficient.	3.94	Very high
The training was well led.	4.59	Very high
The training was well-organised.	4.65	Very high
I plan to apply what I learned in this training.	4.59	Very high
Training is an effective way for me to obtain information.	4.71	Very high
The presenters responded to the questions.	4.71	Very high
There was enough time allowed for question and discussion.	4.24	Very high
I am interested in attending future trainings offered.	4.41	Very high
Overall mean	**4.50**	**Very high**

Post-survey report showed that participants were very satisfied to the ISO 17025:2017 *General Requirements for the Competence of Testing and Calibration Laboratories Awareness Course for Forensic Professionals* with a mean value of 4.50. The satisfaction expressed by the participants was derived from the effective presentation of speakers, delivery of relevant information, expertise of speakers, duration of training, and the overall organisation of the training and training materials.

The interpretation matrix utilized in this study is shown below:

Table 3.12: Interpretation Matrix for the Level Satisfaction of Respondents on the Training Conducted (Alonazi et. al., 2019)

Mean level	Description	Interpretation
1.0 – 1.79	Very Low	The participants NEVER showed satisfaction on conducted training.
1.80 – 2.59	Low	The participants have SELDOM showed satisfaction on conducted training.
2.60 - 3.39	Moderate	The participants SOMETIMES showed satisfaction on conducted training.
3.40 – 4.19	High	The participants have USUALLY showed satisfaction on conducted training.
4.20 – 5.00	Very High	The participants ALWAYS showed satisfaction on conducted training.

Table 3.13: Mapping the Future Programs for Laboratory Personnel

Future Training Programs	N	Percentage (%) Distribution
External Audit	2	11.7
Biotechnology	1	5.9
Risk Assessment	1	5.9
Addressing nonconformity	1	5.9
Forensics	3	17.6
ILAC G19	1	5.9
Digital forensic	1	5.9
Occupational health and safety	1	5.9

A road map towards future training programs indicated that forensic science and external audit training top the lists of the priority with 17.6% and 11.7% of the

respondents expressing their intent to attend the training. These were followed on training related to biotechnology, risk assessment, addressing conformity, International Laboratory Accreditation Cooperation G19 (ILAC G19), digital forensic and occupational health and safety which received an equal percentage of response.

The current findings indicated the willingness of the respondents for any future training offered by the organization to help the laboratory personnel tackle the issues and challenges in the conformity of the laboratory towards internal consistency and quality.
A total of 18 participants put forward added comments of appreciation for the opportunity provided, all agreeing that such initiatives serve as a booster and motivation towards reaching accreditation and an appreciation of the work "behind the scenes in forensic science." All 18 participants commented that they were extremely satisfied with the course. Comments received in response to the question "What did you like most about this training?" included knowledge and practical application of the tutors, platform for discussion and sharing of ideas, and organisation of the course. Comments received in response to the question: "What did you like least about this training?" were related to the duration of the course. All participants who commented in reply to this question (n=13), indicated that they preferred to have shorter sessions over longer days or increased break times to allow for concentration and focus, a comment which is consistent with the question when asked to provide suggestion to improve the training. Further comments received were *Overall it was a very well organised course and very informative*, *Well done on the whole; I was very satisfied despite the COVID situation*, and *I was happy to participate and to learn. Thanks.*

Chapter 4

Discussion

This chapter brings to an end a study that set out at identifying training needs for laboratory personnel in the area of quality and standards. It attempted to address a priority area for developing in a scientific approach a training course. The ISO 17025: 2017 *General requirements for the competence of testing and calibration laboratories* training course for forensic professionals was highlighted as an immediate area of focus based on the need for assistance put forward by the Malta Police Forensic Science Laboratory to the Malta Laboratories Network. In this discussion, one attempt to reflect on what has been achieved and the way forward for training needs in quality systems.

4.1 Laboratories in Malta: A Pool of Diverse Fields

Laboratories are important in the health and safety of the public. They operate in the various fields of science and technology and quality systems, therefore need to be established. In this research, different laboratories participated in the survey on training needs assessment and were presented in Chapter 3. There was a very fascinating composition of laboratories involved. Its distribution ranges from pharmaceutical and medical testing laboratories to forensic and even archaeology laboratory. This reach of various laboratories shows an encompassing impact in Maltese society. The wider the types of laboratory in the society, the more they value the importance of industries for a quality operation through testing, and a worth mentioning, its degree of appreciation towards culture and heritage. The Pharmaceutical QC laboratory is crucial in determining the drug's disposition. It also ensures that all the products meet all specifications in terms of the life cycle of the products, safety, efficacy, and compliance. If the product is incorrectly tested, it may cause serious problems for the patient and/or the business. There is no doubt that the role of the pharmaceutical laboratory with quality standards in place plays a critical role.

In the medical realm, clinical laboratory tests provide information that helps doctors to deliver better and more effective care for their patients. Medical laboratory analyses specimens obtain information about a patient's health to help in disease detection, treatment, and prevention. It is often cited that laboratory results are an integral part of every medical decision. Furthermore, diagnostic centres also have played a proactive response in testing symptomatic and asymptomatic individuals on the COVID-19 pandemic which is recognised as a current public health emergency of international concern (Kiros et al., 2020).

Laboratory activities play a distinct and central role in the science curriculum, and there are many benefits to involving students in science laboratory activities. A well-designed laboratory experience will help a student improve problem-solving and critical-thinking skills while also exposing them to operations, materials, and equipment in a laboratory setting. Laboratory activities that adhere to international standards provide students with conceptual and analytical information to assist them in learning scientific principles and understanding the essence of science by scientific methods. It will also help inculcate to future scientists the culture of quality practices and produce reliable results for scientific discovery and publication, for example, the COVID-19 viral genome sequence and genomic surveillance of SARS-CoV-2 to detect, monitor, and assess virus variants.

A laboratory's role ranges from soil testing up to supporting decision-making and policy-making, as well as international standards. Plant pathology laboratories conduct tests to control threatening diseases which affect market quality. Plant laboratories also guide establishments for plant nutrient analysis. Moreover, laboratories engage in research to developing mineral and organic fertilizers, and new plant varieties to increase their production. Laboratories practicing quality standards provide critical

insight and innovative solutions to national and global agricultural development issues as well as critical scientific evidence to back up the solutions amidst the pandemic.

Participation from animal testing laboratories was identified in the survey. One of the principal roles of veterinary laboratories is to diagnose and confirm that an animal population is free from a defined infectious disease such as SARS-CoV-2 infected feline, bovine tuberculosis, avian flu, and swine fever (Truszczyński, 1998). This enables laboratories as an instrument in the control of infectious diseases. Supporting animal testing laboratories towards accreditation aids in better and faster management of health threats, thereby saving economic consequences and health challenges (Perry & Sones, 2007).

Laboratory testing of food and water is another important process which relies on scientific analysis to detect problems with products. It offers analytical data on the quality of a product or manufacturing process to aid in quality control. This will identify contaminants such as viruses and bacteria in raw materials, as well as contamination after a product has been produced and before it is brought to the market in order to protect public health and consumer's safety (Hennechart-Collette et al., 2015; de Castro Carvalho et al., 2020). Additionally, food testing is important for the research and development of new products, such as the selection of ingredients or components, design of food processing, and shelf-life studies of products (Mihafu et al., 2020; Skonberg et al., 2021). Another benefit of laboratory testing is that it ensures compliance with legislation for both the import and export of food products (Mahama, 2020). More importantly, laboratory testing that operates in high-quality standards safeguards the public consumption of goods against health risks.

Crime laboratories offer forensic science services to the justice system. Forensic collects, preserves, processes, and analyses evidence using scientific testing methods and cutting-edge technologies (Fraser, 2020). Forensic science laboratory is to provide an impartial scientific report to the investigating agencies, thereby assisting the judiciary system (Forry, 2019). Forensic science is a critical element of the criminal justice system (Sommers, 2018). Forensic scientists who follow international standards can review and analyse evidence from crime scenes and elsewhere to provide reliable, valid, and objective results that can aid in the investigation and prosecution of criminal suspects or absolve an innocent individual of suspicion (Page et al., 2019).

The ISO/IEC 17025 is a specific international accreditation for laboratory operations to be deemed technically competent (Sommer, 2018). In 2011, the European Council established the Vision for European Forensic Science (EFSA) 2020. The EFSA 2020[28] is based on the harmonisation of all the processes involved with forensic evidence or data in accordance with ISO 17025:2017 *General requirements for the competence of testing and calibration laboratories* and the ISO 17020:2012 *Conformity assessment: requirements for the operation of various types of bodies performing inspection* standards. This has contributed to the imminent assistance required by the national forensic science laboratory in requiring training within this area.

4.2 Re-training and Financial Aid Mobilisation: A Way to Accreditation

Accreditation based on international standards is a difficult, if not nearly impossible task for several laboratories in resource-constrained settings. However, the process of achieving accreditation brings considerable advantages (Olmsted et al., 2010). The

[28] European Union, Council conclusions on the vision for European Forensic Science 2020 including the creation of a European Forensic Science Area and the development of forensic science infrastructure in Europe. Brussels; December 2011. Available from: http://efic.pl/pliki/dokumenty/EU_Vision.pdf

findings on the status of laboratory accreditation signify the competence of the laboratories to conduct testing based on their respective operation. While this number is substantially lower 80% (n=36), the laboratory personnel were fully aware of the protocols of accreditation, yet engagement towards ISO/IEC 17025 accreditation is still to be materialized. The eagerness of non-accredited laboratories to be accredited shows that current laboratories require re-training on the importance of standardised testing and accreditation to ensure that they can produce precise and accurate test results. Based on the foregoing facts, the importance of accreditation as a tool to improve the management system in the laboratories must be integrated into testing facilities that offer varied services to ascertain standard quality of operation. Particularly, the need for re-training can assist. Such a strategy coupled with mentorship was observed to be successful in the study conducted by Ong et al. (2020).

The MLN provides a number of collaborative initiatives. Collaborative initiatives offer a reciprocal commitment joined by two or more organisations founded by a clear relationship that gives a beneficial effect to attain common goals like quality standardisation. Hence, this relationship is anchored according to the agreement of the objectives, collectively formulated structure, shared obligation, and dominance including resources, training, and future gains. The performance of training through this initiative produces intangible profits of high-level awareness and critical thinking, better communications as well as areas of self-management and leadership abilities.[29] Recently, investigators have examined the effects of collaborative initiatives among laboratories which include evolvement to a more holistic, bidirectional sharing of development resources information, strategies, technical resources, and training (Ned-

[29] Center for Teaching Innovation [Internet]. New York: Cornell University; 2020. Collaborative Learning; [unknown date] [cited 2021 Mar 11]; [about 5 screens]. Available from: https://teaching.cornell.edu/teaching-resources/engaging-students/collaborative-learning#:~:text=Why%20Use%20Collaborative%20 Learning%3F,%2Dmanagement%2C%20and%20leadership%20skills.

Sykes et al., 2021). Through collaborative initiatives by MLN with NAB-Malta and MCCAA, a continuing professional training programme can be developed.

Another collaborative initiative which has been provided by the MLN in the past years as a pilot test was the financial assistance for accreditation. According to the *Training needs assessment questionnaire* result, 11 laboratory personnel responded that they are aware of MLN QUAL-LAB Scheme Grant and they are interested to take part in the said grant. Study findings indicate that five have applied and one used this assistance. This could be due to a lack of communication between parties, necessary documents, or a bureaucratic tedious process. Remobilisation of this financial aid activity and subsequent active dissemination of this grant may be required in order to facilitate accreditation processes for laboratories.

4.3 Collaboration with Equipment Suppliers: Bridging the Gap

In Malta, besides being faced with the fact that the laboratory equipment is imported, new technologies have played and continue to have a key role in laboratories. The way laboratory staff perform their duties, as well as the way the entire laboratory operates, has changed considerably nowadays (Hajia et al., 2013; Karabiyik, 2019). A case in point in the forensic field, according to Kloosterman (2015), is that recent technological development is opening up new possibilities for performing rigorous scientific measurements and studies outside of the controlled laboratory environment. Such real-time, on-site forensic investigations offer diverse advantages and the technology has the potential to significantly hasten the criminal justice system. The advantages, however can only be realized if the quality is always ensured and findings can be used as forensic evidence in court. Study findings of this research indicate that the laboratory equipment assessment responses signify that most of the laboratories in Malta (regardless of the

type of operation) showed complete compliance on the availability of the type of equipment necessary for the operation. Respondents replied that there is equipment in place which is operated by competent personnel. Overall, the results signify that laboratory operations can be efficiently managed since equipment are vital and available for the operation and in good working condition. On the other hand, some have difficulty conducting maintenance of the equipment in place and seeks help from technical engineers to do preventive maintenance, calibration, and repair. A similar barrier was also observed by Rutebemberwa et al. (2020). Another logistical challenge that is related to this experience is the use of mentors based in different countries who were required to travel by air to provide on-site support. Thus, considerable funds needed to be invested and intervention may cause delay because of travel issues. Also, inviting technical experts or sending staff overseas is both costly and time-consuming. In the future, MLN's proactive involvement through a partnership with companies abroad could meet the needs of its minority stakeholders. From it, MLN can initiate training, communication between companies, and even purchases of wear and tear spare parts. Eventually, such a possible move may help build local capacity and reduce costs, particularly as the programme expands (Guevara et al., 2014).

4.4 Motivating Leaders for Change

The competence of staff is another technical requirement in most laboratory standards. In this dissertation, the assessment of the technical availability of personnel to conduct specific testing for a specific type of laboratory signifies the current compliance of various laboratories. It was indicated that professionals, competent and highly skilled personnel, were doing testing for a specific procedure using sophisticated instruments and technical procedures. In addition, most laboratories have the policy to identify the

training needs of their personnel which is an essential component in the ISO/IEC 17025 *General requirements for the competence of testing and calibration laboratories*. In this case, since there is no issue on technical competence, a consideration of attitude or behavioural factors can be studied to identify other barriers in the realisation of accreditation (Greenfield & Braithwaite, 2008; Teymourzadeh et al., 2016). This is an important issue for future research. Also, the MLN's previous training courses were mostly on professional and technical skills development.[30] Other types of training such as soft skills may be introduced to motivate leaders towards accreditation. The result on collaboration with other laboratories revealed that although the majority is aware of the availability of equipment with other laboratories, however they are unwilling to network and reluctant to share services. This could be due to poor communication among laboratories as reflected in the result. This result may be also explained by the fact that there is no organisation or association for laboratory professionals, an avenue that could move leaders, bring fellow laboratorians together, create a network, build a relationship, and enhance communication.

4.5 MLN Support

MLN has been assisting its stakeholders. The current study found out that although most of the respondents are aware of its training programme, more needs to be done to spread awareness of its activities. This may be done by boosting the current platform or utilising other forms of advertisement. This has been discussed with the MLN administration who recognised this issue and have sought technical competent assistance from the IT department to improve and ameliorate the MLN website, and

[30] Malta Laboratories Network (MLN). MLN Home [Internet]. Malta: MLN; [unknown date] [cited 2021 Apr 2]. Available from: https://tourism.gov.mt/en/mln/Pages/Training.aspx

social media platform for an easier, more user-friendly access.

The overall result on the respondents' satisfaction with the MLN training course indicates a positive view both in communication and implementation. Blended or distance learning delivery modes could be adopted given that the target audience can meet the required demands of the technical set up such as internet reliability, computer literacy, and instructional method compatibility amongst others.

4.6 Laboratory Personnel's Educational Needs

Topics for training courses identified through the *Training needs assessment questionnaire* include ISO 17025 *General requirements for the competence of testing and calibration laboratories*, instrument use and its quality control, ISO 9001 *Quality management systems - Requirements*, and measurement of uncertainty were top of the requirements. ISO/IEC 17025 is highly necessary as it will incorporate a quality system aimed at enhancing laboratories' ability to deliver reliable results on a consistent basis. Although a training course ISO17025 was offered by MLN, specifically to target forensic professionals, the training course could be retailored to meet other stakeholder's needs.

4.7 Limitation of the Study

One of the limitations of this study was the low number of respondents to the *Training needs assessment questionnaire*. Only the stakeholders on the MLN database were invited to participate. The study was carried out during the COVID-19 pandemic which in itself presented challenges such as the restricted face-to-face meetings which could have increased the response rate. One also needs to take into consideration that COVID-

19 disrupted the work routine, with people shifting to teleworking, and juggling other personal commitments and industry commitments which might have been deemed a priority by potential respondents over the questionnaire. Another limitation of the training course was the lack of pre- and post-training questions for knowledge since the participants have a prior understanding about the topic. The pre-training assessment was discussed in the preliminary meeting held between the MLN and the representatives of the Malta Police Forensic Science Laboratory who were concerned that such a questionnaire might put off the candidates from accepting to participate.

4.8 Recommendations

Research should be undertaken to investigate the attitude and aspects of the laboratory personnel towards accreditation. There is abundant room for further progress by evaluating the impact and result of the training on participants a year of post-training. Further, work is also required to establish a continuous professional training programme for laboratories to further align with the dynamic evolving quality requirements.

4.9 Conclusion

The study led to the identification of the educational needs of laboratory personnel with respect to quality systems. This research led to the scientific development of the ISO 17025:2017 *General requirements for the competence of testing and calibration laboratories awareness training course*. Subsequently, a total of three other courses on ISO 9001 *Quality management systems - Requirements*, internal auditing and ISO 17020 *Conformity assessment - Requirements for the operation of various types of bodies performing inspection* have already been designed and delivered in a similar

approach to target needs resulting from the *Training needs assessment questionnaire*. A further three separate courses on risk management, quality management systems, and internal auditing targeting specifically the entire Malta Police Force are being designed during the completion of this research. Furthermore, the MLN is currently completing the process of accreditation as an institution for higher education to further support its courses. Addressing training needs on QMS through courses that are tailor-made for the end-users helps to sustain the quality requirements whilst providing an academic platform.

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APPENDICES

Appendix 2.1:

Guide Questions for the Validation of Questionnaire

Adopted from:
University of the Immaculate Conception
Graduate School, A Bonifacio St. 8000 Davao City, Philippines

Validation Form for the Questionnaire

Introduction and Instructions:

You are invited to participate in the **validation** of a questionnaire entitled "**Training needs in Quality Systems**" developed as part of a project being undertaken by Doctorate in Pharmacy student Rogelio L. Rivera Jr.

You are kindly requested to determine the validity of the presented instrument in relation to the purpose of the study; specifically with regard to the research objective. The question items must be evaluated in terms of their relevance, clarity, simplicity, and the ability to elicit comments, opinions, and insights from the research participants.

Your feedback will be considered to revise the questionnaire.

Section	Items	Evaluation		
		Yes	No	Remarks
Introduction Key Components	1. Is there an opening statement expressing gratitude to the research participants for his or her willingness to join session?			
	2. Does this section of the questionnaire reveal the name of the researcher? (i.e. the researcher introducing himself or herself?			
	3. Is the purpose explicitly stated?			
	4. Is the duration of the session clearly stipulated?			
	5. Is there a statement assuring the research participants of the confidentiality of his or her responses?			
	6. Does this section explain how the survey be conducted?			
	7. Does this section include a statement assuring the research participants of his or her opportunity to be clarified further before proceeding to the intended activity?			
	8. Does this section provide spaces for the consent of the research participants?			

Questions	9. Are there no more than 15 questions (i.e. no more than 3 research questions with no more than 5 probing questions each)?			
	10. Are factual questions asked first before probing questions?			
	11. Are there questions requiring the participants to describe his or her experiences?			
	12. Are the vocabulary level and language structure of the questions appropriate to the age and capability of the research participants?			
	13. Are the questions clear and understandable?			
	14. Do the questions possess the ability to elicit qualitative data relevant to the attainment of the objectives of the study?			

Closing Key Components	15. Does this section guarantee the participant of his or her chance to give additional comments?			
	16. Does this section inform the research participant of the researcher's plan regarding the data being collected, its analysis, and the corresponding report and what the researcher would do next?			
	17. Does this section of the questionnaire express gratitude to the research participants?			

Appendix 2.2:

Training Needs Assessment Questionnaire

TRAINING NEEDS ASSESSMENT QUESTIONNAIRE

I am Rogelio Rivera Jr, and I am currently a 3rd Year PharmD Student. As part of the Doctorate in Pharmacy degree at the Department of Pharmacy (University of Malta), I am conducting a study entitled "Training Needs in Quality Systems: A course on standards – ISO 17025:2017".

I am kindly requesting your participation in a survey designed to identify the training needs of laboratory workforce with regard to quality. For the purpose of this questionnaire, the researcher will be able to identify topics for trainings on quality standardisation.

The survey is an anonymous and confidential questionnaire; no one will be able to identify you or your answers. The results will be reported in aggregate form, and no one respondent will be identifiable. It will remain open for three months.

Please follow the directions and answer all questions. This questionnaire should take no more than 15 minutes of your time. All contributions are highly valued, and we appreciate your time and effort.

This research has been approved by the Faculty of Medicine and Surgery Research Ethics Committee and Malta Laboratories Network administration. The information collected in this questionnaire will be used in my PharmD dissertation and in scientific, research and/or policy publications.

Your participation is entirely voluntary. You may refuse to take part in the research or exit the survey at any time. You are free to skip any question you do not wish to answer for any reason.

For further information or if you have any enquiries about this questionnaire, please contact me at: rogelio.rivera.18@um.edu.mt

Many thanks for your contribution.

Sincerely,

Rogelio L. Rivera Jr
PharmD student
Department of Pharmacy
University of Malta

If you are happy to continue, please select the option below to confirm that you consented (if you do not consent then please close this browser to exit the survey). *

- ◯ I give my consent for my responses to this questionnaire to be used strictly as described in the Privacy Statement and for the anonymised data to be archived at the University of Bristol Research Data Repository.

Page 1 of 8

Next

TRAINING NEEDS ASSESSMENT QUESTIONNAIRE

*Required

Section A: Details of the Laboratory

Type of Laboratory: *

Your answer

Description of service:

Your answer

Number of employees:

Your answer

Section B: Detail of the respondent

Position in the organisation:

Your answer

Section C: Laboratory and Testing Accreditation:

a. General Laboratory Accreditation
Tick YES or No where applicable

Accreditation/certification

	YES	NO
1. Is the laboratory accredited? If no, please go to question 2.	☐	☐
2. If no, are you interested in accreditation?	☐	☐
3. Are you aware of the procedures related to accreditation?	☐	☐
4. Are you aware of the MLN QUAL-LAB Scheme Grant? If no, please go question 5	☐	☐
5. If no, are you interested?	☐	☐

b. Testing Accreditation

Kindly list the tests performed indicating whether each test is accredited and if yes who is the accrediting body?

Tests performed

Your answer

Section D: Equipment

a. Name the different equipment in your laboratory. Indicate if it is still used and the frequency of use.

Details should include the following details as shown below:

Name of Equipment	Used (U) or Not used (NU)	Usage Frequency (1) Always (2) Sometimes (3) Seldom (4) Very Seldom	Comments *(If not in use, please specify reason/s why)*

Your answer

Equipment (continuation)

Your answer

b. Indicate what type of software is available within the lab

Your answer

Section E: Specific Equipment questions

1, Do you have an HPLC in this Lab?

- ◯ Yes
- ◯ No

2. Specify the HPLC Type:

Your answer

3. Specify the Brand:

Your answer

4. Identify and list down tests carried out using HPLC:

Your answer

5. Name and contact number of Person responsible for this equipment:

Your answer

6. Do you have problems running the equipment?

- ◯ Yes
- ◯ No

If yes, what type of problems do you have? (Qualified trained personnel, spare parts, maintenance, technical, etc.) Please specify:

Your answer

Tick where applicable

	YES	NO
7. Are you aware of other labs that have this type of equipment?	☐	☐
8. Are you in communication with them?	☐	☐
9. Are you interested in meeting other labs having the same equipment to discuss and share experiences in its usage and problem solving?	☐	☐

10. Are you willing to share services if need be?	☐	☐

Additional information or comments:

Your answer

Section F: Education and training needs

Tick where applicable

	YES	NO
1. Are you planning to offer new tests that may require additional equipment?	☐	☐
2. Are you aware of the training courses organised by MLN?	☐	☐
3. Did you or your colleagues attend courses organized by MLN	☐	☐
4. Were you satisfied with the courses?	☐	☐
5. Would you suggest any changes?	☐	☐
6. would you prefer attending online course?	☐	☐
7. Are you satisfied with MLN communication? If NO how can this be improved?	☐	☐

If your answer in number 6 is NO, how can this be improved? Please specify:

Your answer

8. Please suggest training courses required: *

Your answer

9. Recommendations/Additional comments *

Your answer

Thank you

You've arrived at the end of the survey. In the space below, feel free to recommend or provide additional comments regarding your training needs.

Your answer

Please click the 'Submit' button for your answers to be recorded.

Back Submit Page 8 of 8

Appendix 2.3: UREC Approval

FRECMDS_2021_061 - 7614_12012021_Rogelio L. Rivera Jr. - for records

FACULTY RESEARCH ETHICS COMMITTEE <research-ethics.ms@um.edu.mt>
to me, Anthony, Louise

Dear Rogelio Jr Rivera,

Since your self-assessment resulted in no issues being identified, FREC will file your application for record and audit purposes but will not review it.

Any ethical and legal issues including data protection issues are your responsibility and that of your supervisor.

Kindly confirm that you sent all the documents which you attached to the UREC form and also other documents related to your study for audit purposes.

Regards,

L-Università ta' Malta

Ruth Stivala | Secretary
B.A.(Hons)(Melit.),M.A.(Melit.)

Faculty Research Ethics Committee
Faculty of Medicine and Surgery
Medical School, Mater Dei Hospital
+356 2340 1214
https://www.um.edu.mt/ms/students/researchethics

Appendix 2.4: Guide Questions for the Validation of Training Course

Adopted from:
University of South Africa AND *Mathematics, Science, and Technology Academy*
Preller Street, Muckleneuk Ridge, Pretoria, South Africa

VALIDATION FORM FOR TRAINING COURSE

Validation of the training course development result

Section	Items	Evaluation		
		Yes	No	Remarks
Service Provider	Is there a name of the service provider stated?			
	Is there a logo?			
	Is there an address?			
	Is there a contact details?			

Section	Items	Evaluation		
		Yes	No	Remarks
Training Course Title	Is there a subject?			
	Is there a title?			
	Is there a clearly defined target audience?			
	Is there a date?			
	Is there a time?			
	Is there a venue?			

Section	Items	Evaluation	
		Yes	No
Learning objective and outcomes	***Learning objectives:*** Is there a clear statement of what a participant is expected to learn and of how the learning is to be demonstrated?		
	Are the learning aims specifically defined to indicate what knowledge or skills the participants are expected to obtain?		
	Remarks: Explain if they are aligned to the topic as well as to the standards.		
	Learning outcomes: Are the learning outcomes measurable?		
	Are learning outcomes indicate knowledge or skills the attendees are expected to obtain?		
	Remarks: Explain if they are aligned to the objectives.		

Section	Items	Evaluation		
		Yes	No	Remarks
Description of the Content and Structure	Comment on the quality			Comment on the quality
	Is the concept well explained?			
	Is the context well presented?			
	Is the flow in logical order?			
	Is the duration of the session clearly stipulated?			
	Are the topics listed together with any materials/products/technologies to be used?			
	Is the educational content aim to be authoritative, accurate, based on balanced evidence and free from unjustifiable claims or bias?			
	Is the course structured with appropriate breaks for delegates?			
	Does the course award a certificate?			

Section	Items	Evaluation		
		Yes	No	Remarks
Method of Delivery	***Teaching Activities:*** Is there a clear statement about what delivery methods are used (Lectures, presentations, discussions, etc.)?			
	Is the subject information up-to-date and accurate, with appropriate language, style and pace?			
	Remarks: Comment on the planned teaching activities.			
	Learning Activities Does the activity provide a scientific or educational purpose only?			
	Is the teaching method used is relevant to the defined learning aims?			
	Are there processes in place to encourage self-reflective learning?			
	Remarks:			
	Presentation			
	Remarks: Comment on the quality of presentation and relevance of the illustrations in the presentation.			
	Materials: Are there supporting information and materials used?			
	Are the supporting materials up-to-date and accurate?			
	If the content is shown, is the name and contact details of the publisher/copyright owner of the content, the country of publication and the date of the activity or production clearly identifiable?			
	If there is a sponsoring company, is it acknowledged on supporting material having provided sponsorship?			
	Remarks: Comment on the planned teaching and learning support materials (suitability to the topics to be covered, planned usability, include educational technology, etc.).			
	Venue			
	Remarks:			

Section	Items	Evaluation		
		Yes	No	Remarks
Choice of Tutor	Is the tutor an expert in the field?			
	Does the tutor has the knowledge to deliver the education programme within the specific subject(s) identified?			
	Does the tutor has the skills to deliver the education programme within the specific subject(s) identified?			

Rate of the training course LAYOUT.

|_____|_____|_____|_____|_____| =

1 2 3 4 5

_____

Evaluator's name and signature

References:

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Appendix 2.5: Developed ISO 17025:2017 General Requirements for the Competence of Testing and Calibration Laboratories Awareness Course for Forensic Professionals

AWARENESS COURSE FOR FORENSIC PROFESSIONALS

22 – 23 October 2020

A two day interective training course organised through a collaboretive initiative between the Malta Laboratories Network, the Malta Police Forensic Science Laboratory and the National Accreditation Board.

Learning objectives:

Quality is a science that is essential in the running of laboratories. The ISO/IEC 17025:2017 is the standard specifying the requirement for competence and impartiality of laboratories performing testing and calibration. Through this course, the participants will be able to:

- Enhance competence skills;
- Generate valid and reliable results;
- Boost professional confidence;
- Promote credibility in the laboratory team
- Share ideas and network with experts in the field.

The course is led through an interactive approach encouraging active participation and discussion between the course participants and course tutors.

Learning outcome:

By the end of the course, the participants will be able to:

i. Appreciate the principle behind quality in laboratory services
ii. Sustain a culture based on robust quality management systems
iii. Describe the aim, structure and contents of ISO/IEC 17025: 2017
iv. Discuss the relevance and benefits of ISO/IEC 17025:2017
v. Understand the entire requirements of ISO/IEC 17025:2017
vi. Design implementation plans to comply with the requirements of ISO 17025:2017
vii. Incorporate ISO/IEC 17025: 2017 in daily practice
viii. Understand the relevance of the accreditation process
ix. Establish a networking contact with experts in the field.

Method of delivery:

An interactive face-to-face training course.

Duration:

Two days

Content:

- Philosophy and Science
- Introduction
- Resource Requirements
- Quality Management System
- General requirements
- Structural requirements
- Process Requirements
- Internal Audit and Accreditation

Teaching strategy:

Teaching, lecture, large group, problem-based learning, case studies, and work-based learning.

Choice of Tutor:

Claudio Boffa

Franklin Balzan

Venue:

Malta Police General Headquarters

San Kalcidonju, Il-Furjana

Agenda:

22 October 2020: Day 1

8.30 – 9.00	Registration
9.00 – 9.15	Opening
SESSION ONE: INTRODUCTION	
9.15 – 9.30	The relevance of quality within an accreditation era
9.30 – 9.45	Achieving excellence through leadership and commitment
9.45 – 10.00	Quality: Philosophy and science
10.00 – 10.30	Introduction to ISO/IEC 17025
10.30 – 10.45	**Coffee break**
SESSION TWO: GENERAL, STRUCTURAL, RESOURCE AND PROCESS REQUIREMENTS	
10.45 – 11.00	General requirements
11.00 – 11.15	Structural requirements
11.15 – 13.00	Resource requirements part I
13.00 – 14.00	**Lunch break**
14.00 – 14.30	Resource requirements part II
14.30 – 16.00	Process requirements part I
16.00 – 16.30	**Wrap up discussion**

23 October 2020: Day 2

8.45 – 9.00	Attendance
SESSION THREE: QUALITY MANAGEMENT SYSTEM REQUIREMENTS	
9.00 – 10.00	Process requirement part II
10.00 – 10.15	**Coffee break**
10.15 – 10.30	Quality Management Systems: Philosophy and science
10.30 – 10.45	In practice session: Quality Management Systems and the role of Quality Manager in Forensic Science
10.45 – 12.30	Management system requirements
12.30-13.30	**Lunch break**
SESSION FOUR: INTERNAL AUDIT AND ACCREDITATION	
13.30 – 15.00	Internal Audit and Accreditation
CLOSING	
15.00 – 15.30	**Wrap up discussion**
15.30 – 16.00	**Course Evaluation and Closing Remarks**

Resources:

International Organisation for Standardisation

Registration process:

Course registration: https://forms.gle/3pvnod86aKV2BLLK8

For enquiries please call +356 22477610 or e-mail Rogelio.rivera.18@um.edu.mt / info.mln@gov.mt

Certificate of attendance will be awarded to successful participants.

Collaborators:

Malta Laboratories Network (MLN)

National Accreditation Board of Malta (NAB-Malta)

Malta Police Forensic Science Laboratory

Malta Laboratories Network

NAB-MALTA

Appendix 2.6: Attendance Sheet

ISO 17025:2017 Awareness Course for Forensic Professionals
October 22, 2020

** I consent that this personal data will be used for attendance purposes as well as for the basis of issuing the certificate of participation only.*

	Participants*	***Company****	***Signature****	***Telephone number****	***Email Address****
1.					
2.					
3.					
4.					
5.					
6.					
7.					
8.					
9.					
10.					

Appendix 2.7: Guide Questions for the Validation of Evaluation Questionnaire

VALIDATION FORM FOR EVALUATION FORM

Introduction and Instructions:

You are invited to participate in the validation of an evaluation questionnaire for the training course on ISO/IEC 17025:2017 "General requirements for the competence of testing and calibration laboratories" - Awareness Course for Forensic Professionals developed as part of a project being undertaken by Doctorate in Pharmacy student Rogelio L. Rivera Jr.

You are kindly requested to determine the validity of the presented instrument in relation to the purpose of the study. The question items must be evaluated in terms of their relevance, clarity, simplicity, and the ability to elicit reaction from the research participants.

Your feedback will be considered to revise the questionnaire.

Section	Items	Evaluation		
		Yes	No	Remarks
Introduction Key Components	1. Is there an opening statement expressing gratitude to the research participants for his or her willingness to join session?			
	2. Does this section of the questionnaire reveal the name of the researcher? (i.e. the researcher introducing himself or herself?			
	3. Is the purpose explicitly stated?			
	4. Is the duration of the session clearly stipulated?			
	5. Is there a statement assuring the research participants of the confidentiality of his or her responses?			
	6. Does this section explain how the survey be conducted?			
	7. Does this section include a statement assuring the research participants of his or her opportunity to be clarified further before proceeding to the intended activity?			
	8. Does this section provide spaces for the consent of the research participants?			

Section	Items:	Evaluation		
		Yes	No	Remarks
Reaction	9. Does it measure the participants' reaction if you like it?			
	10. Does it measure the participants' initial reaction to valuable insights into material quality?			
	11. Does it measure the participants' reaction on its usefulness?			
	12. Does it measure the participants' reaction on the tutor's knowledge?			
	13. Does it measure the participants' reaction on the refreshment and meal?			
	14. Does it measure the participants' reaction on room's right temperature?			
	15. Does it measure the participants' reaction if the chairs were comfortable?			
	16. Does it measure the participants' reaction on the acquisition of the intended knowledge and skills?			
	Comments:			

Closing Key Components	17. Does this section guarantee the participant of his or her chance to give additional comments?			
	18. Does this section inform the research participant of the researcher's plan regarding the data being collected, its analysis, and the corresponding report and what the researcher would do next?			
	19. Does this section of the questionnaire express gratitude to the research participants?			

_____

Evaluator's Name and Signature

Appendix 2.8 Validated Evaluation Questionnaire on Google Forms

COURSE EVALUATION

ISO 17025 AWARENESS COURSE FOR FORENSIC PROFESSIONALS (22 - 23 October 2020)

Dear Participant,
Your esteemed opinion will be appreciated in order to enable us improve the quality of our training courses and seminars. We kindly ask you to spend a few minutes to give us your evaluation.

*Required

1. Please rate your satisfaction with the content of the training by indicating your level of agreement or disagreement with each of the following statements below. *

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
The subject of the training was presented effectively.	☐	☐	☐	☐	☐
The sessions delivered the relevant information.	☐	☐	☐	☐	☐
The sessions met my expectations.	☐	☐	☐	☐	☐
The speakers were knowledgeable about the subject.	☐	☐	☐	☐	☐
The pace of the training was satisfactory.	☐	☐	☐	☐	☐

The duration of the training was sufficient.	☐	☐	☐	☐	☐
The training was well led.	☐	☐	☐	☐	☐
The training was well organised.	☐	☐	☐	☐	☐
I plan to apply what I learned in this training.	☐	☐	☐	☐	☐

2. Are you satisfied with the topic? *

- ◯ YES
- ◯ NO

3. If 'NO' please state reason(s): *

Your answer

4. What other topics or future topics would you suggest? *

Your answer

5. Please rate your satisfaction with the delivery method of the training by indicating your level of agreement or disagreement with each of the following statements. Please put a check mark (✓) in the corresponding box. *

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
Training is an effective way for me to obtain information.	☐	☐	☐	☐	☐
The presenters responded to the questions.	☐	☐	☐	☐	☐
There was enough time allowed for question and discussion.	☐	☐	☐	☐	☐
I am interested in attending future trainings offered.	☐	☐	☐	☐	☐

6. What did you like MOST about this training? *

Your answer

7. What did you like LEAST about this training? *

Your answer

8. Suggest ways we could improve our trainings. *

Your answer

Other comments *

Your answer

Appendix 2.9 Certificate of Participation

Malta Laboratories Network

NAB-MALTA

Certificate of Participation

This is to certify that

Participated in the
ISO 17025:2017 Awareness Course for Forensic Professionals
on 22 and 23 October 2020.

Prof. Anthony Serracino Inglott
Chairperson, Malta Laboratories Network

Ing. Claudio Boffa
Director, National Accreditation Board

Ref No. 03/2020