2023

NSF GUIDELINES

ON

QUALITY ASSURANCE: APPLICABLE TO RESEARCH PROJECTS LEADING TO COMMERCIALIZATION AND STARTUPS

This document is a report prepared by the working group on Quality Assurance. The report gives an outline on Quality Assurance, selection of quality standards for research projects leading to commercialization and startups based on the quality standards available under the Sri Lanka Accreditation Board (SLAB) and the Sri Lanka Standards Institute (SLSI)

National Science Foundation, Sri Lanka
NSF Working Group on Quality Assurance

Working Group on Quality Assurance

- **Dr A. Dharshan De Silva (Chairperson)**
- **Mr L. H. D. Bandusoma**
- **Mr Rasika Waduge**
- **Ms Rashika Tennekoon**
- **Dr Mahesha Nadugala**

Experts Providing Guidance for the report

- **Dr Jaanaki Gooneratne**
- **Mr Gamini Thilakarathna**
- **Dr Gowry Moorthy**

Contents

About NSF

The National Science Foundation, mandated to serve and strengthen the Science and Technology sectors in Sri Lanka, performs its tasks in accordance with the functions set out in the enabling Science and Technology Development Act, no 11 of 1994 and its activities conform to the National Science & Technology Policy. Accordingly, the National Science Foundation facilitates research, development and innovation to create a knowledge economy. It also facilitates capacity building, infrastructure development, technology transfer, knowledge creation and sharing in all fields of science & technology to improve the quality of life of the people.

Among other things, NSF has several research grant schemes such as Competitive Research grants which are expected to facilitate and support basic and applied scientific research for the advancement of knowledge and socio-economic development of the country while promoting capacity building of S&T personnel. Laboratories with modern infrastructure facilities are needed for research to be in par with the global S & T research. The laboratory equipment grant scheme intends to assist the acquisition of equipment for research that is generally too costly to be purchased by the Research Institutions and Universities.

The purpose and scope of the document

This guidance document prepared by working group on Quality Assurance of the NSF and aims to provide guideline for research and development community and laboratories to develop their research proposals and goals incorporating aspects of quality assurance in relation to research processes and laboratory activities. Additionally, this will provide guidance in selection of the correct quality standards for projects leading to commercialization /startups and the quality standards available under the Sri Lanka Accreditation Board (SLAB) and the Sri Lanka Standards Institute (SLSI)

1. Introduction to Quality Assurance

Quality assurance (QA) is a way of preventing mistakes and defects in manufactured products and avoiding problems when delivering products or services to customers. The key to quality assurance is being able to measure and evaluate this aspect. Most research projects funded by the NSF involve basic R&D and experiments, which undergo a trial-and-error process. However, some projects funded by the NSF (particularly the Technology Development & Innovation arm) are for scaling up of the manufacturing process and the focus of this report will remain on products.

Source of image: https://www.sofeast.com/glossary/what-is-quality-assurance/

Products are checked and tested to verify whether they meet the specific requirements or performance of the product specification. As shown in the figure it is important to monitor and control the process (**stage 1**), identify issues in the process or product (**stage 2**) and then generate corrective actions after studying the issue (**stage 3**). This is followed up by verification and implementing the corrective action (**stage 4 & 5**).

The Sri Lanka Accreditation Board (SLAB) and the National Medicines Regulatory Authority (NMRA) currently play a critical role in assuring quality control of products manufactured in Sri Lanka and those that are imported. This relates to the **stage 1** of the process and in the current context items produced in Sri Lanka are mainly evaluated based on the manufacturing process and the setup of the plant. However, there has been less emphasis on QA or testing of the product by third parties after manufacturing starts.

A number of institutions in Sri Lanka are involved in testing products and have the ability to analyze the components of a biological or chemical product. This is important for **stages 1 & 2** to identify possible problems in the manufacturing process.

Once an issue/problem is identified it is up to the manufacturer to generate corrective actions, verify and implement a solution (**Stages 3,4 & 5**). For many manufacturers this may pose a challenge since they may lack the necessary expertise to think deeply and analyze the problem.

In such a situation the manufacturer can approach the NSF to utilize their STIMS database to find the necessary expertise or the testing institutes to solve the problems that may come up and connect them with the proper expertise from outside their institute.

The main institutes for such testing are the Industrial Technology Institute (ITI), Laboratories of the Bureau Veritas Consumer Products Services Lanka (Pvt) Ltd, Bamber& Bruce (Pvt) Limited among others. Several universities have the capabilities, but few such university labs have the necessary accreditation and tight quality controls, but the knowledge and the expertise exist.

In recent times as the government has emphasized increasing the local manufacturing of pharmaceuticals and with this the QA of the finished products has become an especially important factor. The National Medicines Regulatory Authority (NMRA) recently started seeking expertise in universities to test the quality of locally manufactured drugs by mandating Bioequivalence and other relevant studies. The universities are expected to serve as independent testing labs carrying out the trials with NMRA oversight. The capacity to carry out such testing is being developed by the University of Colombo and Kotelawala Defence University, among others.

It is difficult to design a common proposal to use as a pathway for all possible testing of products that maybe developed by Sri Lankan scientists for small- or large-scale manufacturing. Instead, it is suggested that a pathway be developed by NSF to obtain advice and to proceed on a case-by-case basis as a product is brought forward for evaluation.

Pathway to find projects and the application of the QA process:

1. Identify several projects that have been funded by NSF in the past and inquire as to which individuals/companies require such QA services and following evaluation pick a project that can be implemented swiftly.
2. Once a project requiring the Quality Assurance process has been identified, a meeting should be arranged with the TDIA committee to develop a roadmap to provide the necessary services.
3. Connect the necessary resource persons using the STIMS database and arrange in-person or online meetings to carry out the necessary services.
4. Contact the relevant regulatory agencies (and Ministries) for advice on developing the most efficient pathway to provide the service.
5. Allow the QA procedure to be carried out for the product and NSF should assist the individual/company during all the stages.
6. After completion prepare a report that can be used as a case study for future reference.

Suggestions for improvement of the above-mentioned process:

1. Most universities are mandated to setup a Technology transfer office with the ability to offer commercial services to outside parties. Utilizing the expertise in the academic staff to setup the necessary protocols to carry out testing using the advanced equipment that is already available in the universities. This can be linked to the NSF (and STIMS) for their capabilities to be known and to be advertised to Sri Lankan companies via the NSF.
2. Assist the existing private laboratories to build up their capacity by hiring university academic staff as consultants to provide the necessary expertise. NSF can utilize their STIMS database to connect the proper expertise with the outside institutes. A proper mechanism whereby the universities and NSF benefit by receiving a percentage of the consulting fees could be implemented.
3. Almost all testing services for QA require a payment even when carried out by the government institutes. It is not practical to expect these services to be carried out free of charge. When such a proposal is sent to the NSF requiring such services if the party requiring the QA services is not able to pay for the services, NSF can consider covering the cost of the analysis to assist with the QA for the production process as a component of the grant.

Components of Quality in Research projects and commercialization

Source of Image: https://psr.iq.harvard.edu/files/psr/files/Lars_Lyberg_Quality_Assurance_and_Control.pdf

NSF's future approach of QA for R & D

In the process of evaluating proposals and requests for research and equipment grants, it is required to ensure maximum use of grants to generate intended results from the research or laboratory equipment. The demand from stakeholders has arisen to ensure the research processes and maximum use of equipment through proper planning, execution of research correctly with time frames /maximum use of equipment, continuous monitoring and evaluations and introduction of corrective measures to minimize deviations and continual improvement to research processes and laboratories.

This guidance document prepared by the working group on Quality Assurance of the NSF aims to provide guidelines for the research and development community and laboratories to develop their research proposals and goals incorporating aspects of quality assurance in relation to research processes and laboratory activities. Additionally, this will also guide to set up selection criteria for NSF grant schemes and evaluation/monitoring of progress of grants.

In the process of developing the documents, due attention was paid on the use of existing requirements /standards and processes and different certification and accreditation schemes operated in Sri Lanka in order to prevent the duplication of work by other institutions. Therefore, as and when required direct reference or link to relevant institutions/publications was given to direct the users of this document.

2. Process Approach

This document adopts a process approach when designing and developing a research study and ensuring its compliance with set procedures and objectives of the research study. Similarly, development of laboratory facilities with high end equipment acquired through NSF equipment grants. Understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its intended results. The process approach involves the systematic definition and management of processes, and their interactions, so as to achieve the intended results in accordance with the research design and objectives/ expected testing targets and strategic direction of the organization. Management of the processes and the system as a whole can be achieved using the PDCA cycle, with an overall focus on validity/credibility and recognition aimed at taking advantage of opportunities and preventing undesirable results through implementation of effective quality assurance programme into research studies and R & D laboratories.

Plan: establish the objectives of the system and its processes, provide the resources needed to deliver the results, and identify and address risks and opportunities;

Do: implement what was planned;

Check: monitor and (where relevant) measure processes and the resulting products and services, analyse and evaluate information and data from monitoring, measuring and verification activities, and report the results;

Act: take actions to improve performance, as necessary.

In this document, as illustrated in Figures 1 & 2, the process approach used in research projects and laboratories is shown

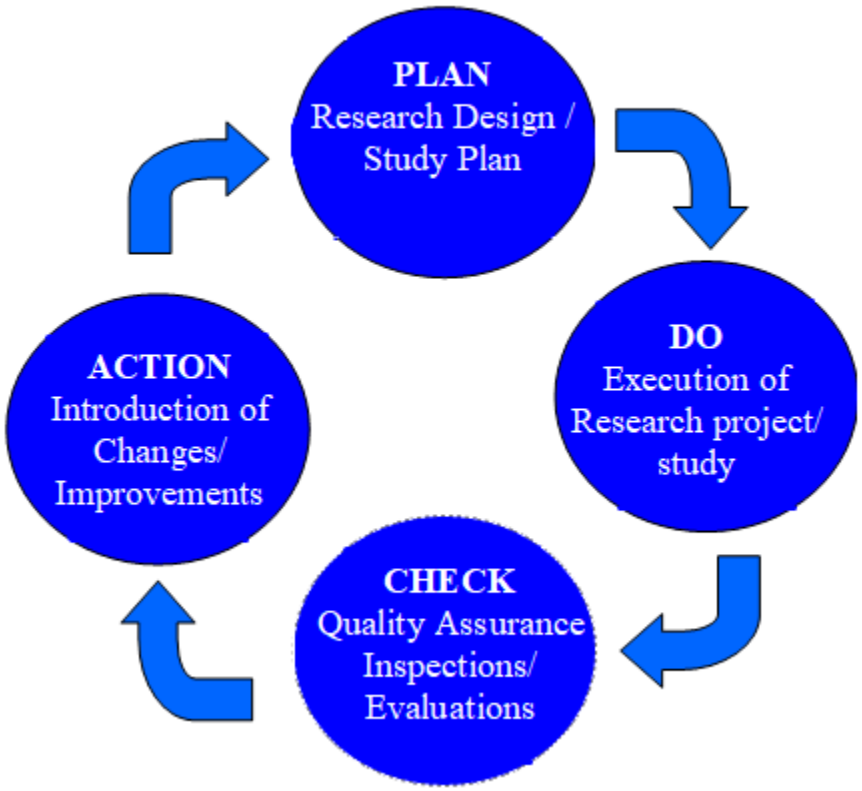

Figure 01: P-D-C-A in Research Projects

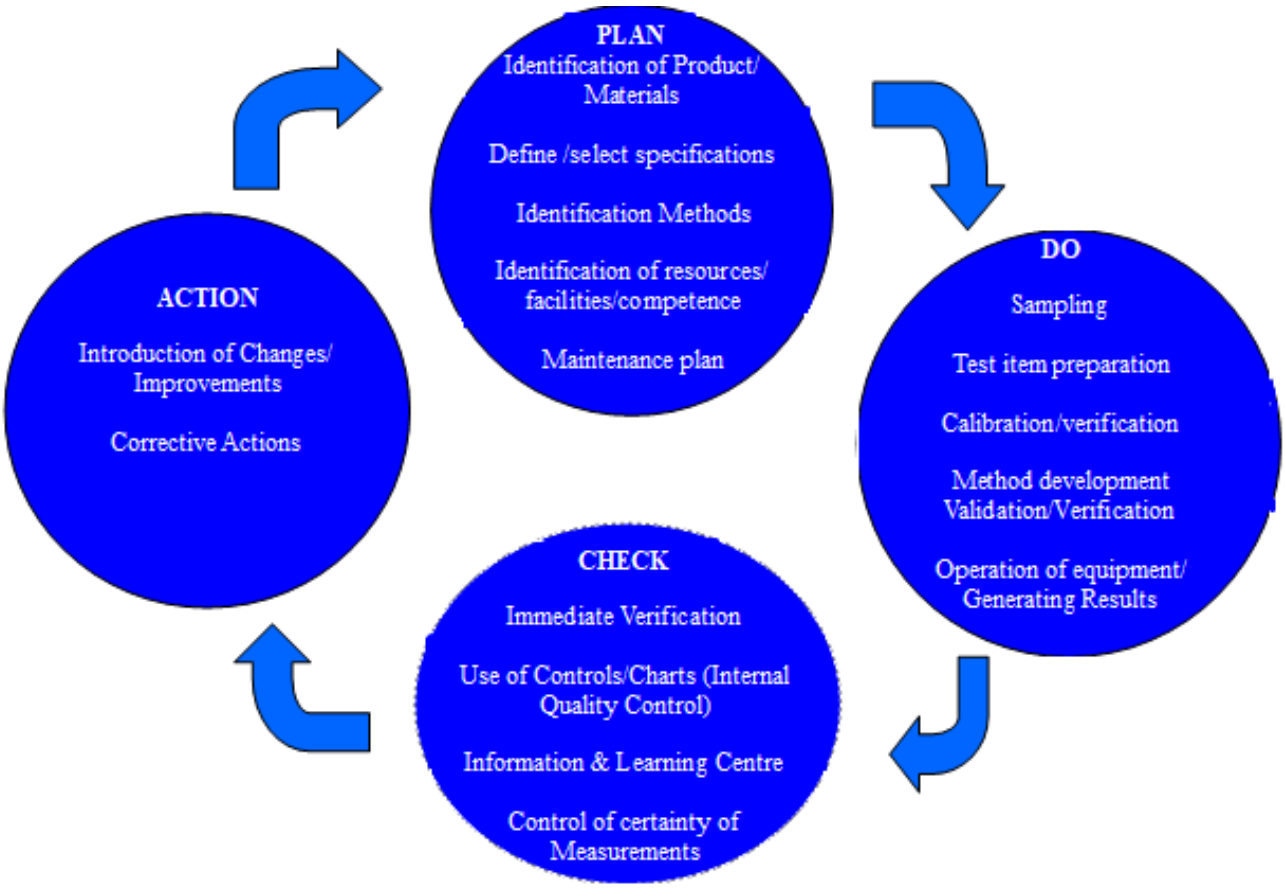

Figure 2: PCDA in R & D Laboratories

3. Terms and Definitions

Quality Management System

Quality management system (QMS) is defined as a formalized system that documents processes, procedures, and responsibilities for achieving quality policies and objectives.

Quality Assurance

Quality assurance can be defined as "part of *quality management* focused on providing confidence that *quality requirements* will be fulfilled." The confidence provided by quality assurance is twofold—internally to management and externally to customers, government agencies, regulators, certifiers, and third parties. An alternate definition is "all the planned and systematic activities implemented within the quality system that can be demonstrated to provide confidence that a product or service will fulfill requirements for quality.

Quality Control

Quality control can be defined as "part of *quality management* focused on fulfilling *quality requirements*." While quality assurance relates to how a process is performed or how a product is made, quality control is more the inspection aspect of quality management. An alternate definition is "the operational techniques and activities used to fulfill requirements for quality.

4. The context of research projects leading to commercialization and startups

In the development stage of research proposals or request for equipment grants, the requester should understand the context of the research area/laboratory. Internal and external issues, views of interested parties, relevant industries, regulatory bodies etc should be considered when determining the context and how this can be extended for commercialization.

It is required to declare the contribution from the research to the knowledge generation/commercialization/startups and the relevant stakeholders as well as the national economy.

Common areas considered in establishing Quality Assurance

Quality assurance is a critical component of laboratory operations, particularly in the areas of research, development, and production. Quality assurance refers to the systematic process of ensuring that all laboratory activities are conducted in a manner that meets established quality standards and complies with applicable regulations. In this report, we will discuss the key quality assurance practices that can be applied in release and development laboratories, as well as start-up companies.

Document Control: Effective document control is essential to ensuring that laboratory procedures are followed consistently and accurately. A document control system should be established to manage all laboratory documentation, including standard operating procedures (SOPs), work instructions, test methods, and validation protocols. The system should include procedures for document creation, revision, approval, distribution, and archiving. Document control ensures that laboratory personnel have access to the most up-to-date procedures and instructions, reducing the likelihood of errors and inconsistencies.

Equipment Calibration and Maintenance: All laboratory equipment must be properly calibrated and maintained to ensure accurate and reliable results. A program for equipment calibration and maintenance should be established, including scheduled preventive maintenance, repair, and replacement of equipment. Calibration and maintenance records should be kept and reviewed regularly to ensure that equipment is functioning correctly. Properly calibrated equipment ensures that laboratory results are accurate and reliable, reducing the likelihood of errors and inconsistencies.

Employee Training and Qualification: All personnel must be properly trained and qualified for their roles. Training should include procedures, safety, and equipment usage. Training records should be maintained and reviewed regularly to ensure that personnel are up-to-date on current procedures and techniques. Properly trained personnel ensure that project activities are

conducted in a consistent and accurate manner, reducing the likelihood of errors and inconsistencies.

Quality Control Testing: A comprehensive quality control testing program should be established to ensure that all products meet established quality standards. This should include product testing, raw material testing, and environmental monitoring. Quality control records should be maintained and reviewed regularly to ensure that project activities are in compliance with applicable regulations. Quality control testing ensures that products meet established quality standards, reducing the likelihood of defects and nonconformities.

Risk Assessment: A risk assessment should be performed to identify potential hazards in the laboratory/work place and implement appropriate controls to mitigate those risks. This should include regular safety audits and inspections. Risk assessment records should be maintained and reviewed regularly to ensure that project activities are conducted in a safe and secure manner. Properly identified risks and controls ensure that project activities are conducted in a safe and secure manner, reducing the likelihood of accidents and incidents.

Validation and Verification: All methods and procedures must be validated and verified to ensure that they are accurate and reliable. This should include validation of analytical methods, cleaning methods, and process validation. Validation and verification records should be maintained and reviewed regularly to ensure that project activities are in compliance with applicable regulations. Properly validated and verified methods and procedures ensure that project results are accurate and reliable, reducing the likelihood of errors and inconsistencies.

Change Control: A change control process should be established to manage changes to project procedures, equipment, or products. This should include a review and approval process for any changes made. Change control records should be maintained and reviewed regularly to ensure that project activities are in compliance with applicable regulations. Properly managed changes ensure that project activities are conducted in a consistent and accurate manner, reducing the likelihood of errors and inconsistencies.

Auditing and Monitoring: Regular internal audits and monitoring should be conducted to ensure that all quality assurance practices are being followed and that the process is in compliance with applicable regulations. Audit and monitoring records should be maintained and reviewed regularly to ensure that project activities are in compliance with applicable regulations. Regular audits and monitoring ensure that project activities are conducted in a consistent and accurate manner, reducing the likelihood of errors and inconsistencies

Repeatability: Repeatability is important in quality assurance because it ensures that products and processes are consistent and reliable over time. Without repeatability, there is no way to ensure that a product will perform as expected or that a process will produce consistent results. This can lead to a range of problems, including poor product quality, increased production costs, and decreased customer satisfaction. To ensure repeatability, it is important to develop standardized procedures and protocols for testing and analysis. These procedures should be

clearly defined and communicated to all employees involved in the quality assurance process. Additionally, equipment and tools used in testing and analysis should be regularly calibrated to ensure accuracy.

Statistical Analysis: Statistical analysis is important in quality assurance because it provides a way to analyze data and identify patterns or trends. By analyzing data, it is possible to identify areas where improvements can be made and make data-driven decisions. Statistical analysis can also be used to predict future trends and identify potential problems before they occur. To implement statistical analysis in quality assurance, it is important to collect and record data in a standardized way. This can be done using software or other tools that allow for easy data collection and analysis. Once data has been collected, statistical analysis can be used to identify patterns or trends and make data-driven decisions.

Study personnel/Research Group/Laboratory Staff

Leaders / Principal Investigators

Members / Research Assistants/Technicians

Quality Assurance Team/Auditors/Evaluators

Competence requirements

Selection, recruitment, training, evaluation, authorization

Note: Search STIMS database (https://stmis.nsf.gov.lk) for potential resource personal

Planning of research / Laboratory development / Plan of Study flow

Study Plan -OECD requirements

Resources/Facilities

Availability and suitability with justification

Define required conditions

Define procedures for purchasing services and supplies and specifications

Receipt, installation, verification /calibration

Metrological traceability

Execution of research /use of equipment

Understanding the testing requirements

Proper sampling

Handling of test items

SOPs /WIs

Generation of results

Reporting and achieving results

Quality control and assurance

Improvement

5. Examples on execution of research projects leading to commercialization and startups

The plan of execution should be clearly designed from doing research to implementation as knowledge dissemination or commercialization of a product. Two projects which completed the research part with commercial value have been taken as examples.

1. Manufacturing of virgin coconut oil
2. Manufacturing a PCR Kit

Manufacturing of Virgin Coconut oil

Pre-requests - The site shall maintain environmental and operational procedures to ensure safe and legal food production (e.g., Pest control, cleaning and sanitizing, testing for allergens etc). Equipment maintained at working standards and trained personnel with safety equipment and maintaining personal hygiene.

Step No.	Step	Points of Quality check
1	Receiving seasonal coconut & Inspection	Origin of material, composition (raw materials, ingredients, allergens)
2	Storing	Required storing standards and conditions
3	Sorting & loading to hatcheting tanks	Required standards for storage
5	Hatcheting	Clean equipment to remove contaminants
6	Paring, Splitting and Washing	Removing contaminants
9	Transfer to cutting	Clean equipment
10	Pre cutting	Any size standards if required
12	Transfer to inspection table &White kernel inspection (OPRP 1)	Quality of material
13	Transfer to crushing machine and crushing	Clean and timely maintained and working equipment
14	Transfer to dryer	Clean and timely maintained and working equipment
15	Dehydration (55-60 ^{0}C for 45 min) (CCP 1)	Temperature and time control
16	Cooling	Temperature control
17	Packaging & palleting (Temporary storage)	Standard packaging material
18	Transfer to expeller section	
19	Extraction of oil (below 60 ^{0}C) (CCP 2)	Temperature and time control
20	Transfer to temporary storage tank	Clean and timely maintained and working equipment, temperature control
21	Transfer to Sedimentation tanks and sedimentation	Clean and timely maintained and working equipment, temperature control
22	Temporary storage tank 01	Clean and timely maintained and working equipment, temperature control
23	Filtering 01(below 2.5 bar)	Clean and timely maintained equipment, maintaining correct standards
24	Temporary storage tank 02	Clean and timely maintained and working equipment, temperature control
25	Filtering 02 (below 2 bar)(OPRP)	
26	Temporary storage tank 03	Clean and timely maintained and working equipment, temperature control

27	Transfer to storage tanks	Clean and timely maintained and working equipment, temperature control
28	Dehydration tank 01 (1st circle, below 40 ^{0} C)	Temperature and time control
29	A Sample drawing & testing	Detection of high FFA and high moisture
30	Dehydration tank 02(2nd circle, below 40 ^{0} C)	Increase dehydration time in Step above
31	Jars receiving from the store	Cleaned
32	Feeding jars	Cleaned
33	Storing	Temperature, humidity etc
34	Washing	Contaminants
35	Drying & Sterilizing (below 120 ^{0} C for 20 min)	Temperature and time control
36	Filling	Standard procedure
37	Capping	Standard procedure
38	Secondary packaging	Standard of packing material, packing process
39	Dispatching	Standard transportation conditions(temperature variations, packing for transport and method of delivery)

Manufacturing a PCR kit

Kit developed in a laboratory with ISO 15189 and BSL-2 standards, with Health Ministry/NMRA approval for manufacture.

Step No.	Steps	Quality Assurance Check Points
1	Development of primers	PCR hoods and PCR machines maintained in working order. Contamination checks. Standard molecular laboratory practices should be followed.
2	Other reagents for the PCR kit	PCR hoods maintained in working order. Storage conditions and temperature maintained. Contamination checks. Standard molecular laboratory practices should be followed.
3	Packing material	Sterile, Contamination checks.
4	Packing	Sterile conditions and standard procedures maintained
5	Storing and transportation	Necessary temperature and humidity conditions maintained.

Assessing the specific required QA for a manufacturing procedure or any process is difficult and will be highly customized as the two above examples show. Hence, it is difficult to have a generic document prepared for QA. Therefore, the table below highlights the various institutions in Sri Lanka that provides information on QA.

6. Guide to identify the QA standard for individual projects

Categorize the project into one of the following areas (section 1) and further breakdown into a necessary sub-category as the area of specialization requires. Then use the table (section 3) to find the relevant institute to obtain the required standards.

1. Main Area of Research /Commercial value
    a) Biotechnology
    b) Electrical Engineering
    c) Construction

    OR

    a. Ornamental fish industry
    b. Electricity board
    c. Health
    d. Milk product industry
    e. Virgin coconut oil industry

2. Sub categories as required according to the specialization.

3. ISO standards that could be followed (Use the table below as a reference)

Links for further information on ISO standards to connect Research Activities/ Laboratory activities with relevant institutions/service providers

Type of Project/Service required for testing /research	Main requirements/specifications	Institute relevant to dissemination of information	Links /contact information	QA purposes
1. Use of diagnostic kit (Research purpose)	ISO 17034	SLAB	List of accredited reference materials manufactures	Internal quality control Method validation/ Method verification
		NMRA	List of approved medical devices	
		SLSI	List of companies certified under ISO 13485 for medical devices	
2. Equipment calibration /verification	ISO/IEC 17025 Calibration methods Equipment operational manual	MUSSD (Measure-ment Units, Standards & Services Dept)	https://www.measurementsdept.gov.lk/index.php?lang=en	
3. Commercial production of diagnostic (diagnostic purpose)		NMRA	https://nmra.gov.lk/index.php?lang=en	
4. Calibration/Testing of equipment		SLAB	ISO/IEC 17025 https://www.slab.lk/service/testing-and-calibration-laboratories/	
5. Research projects that QA can be applied		SLAB	Good Laboratory Practice (GLP) https://www.slab.lk/service/laboratories-practicing-good-laboratory-practices/	
6. Emission of green house gases		SLAB	ISO/IEC 14065 https://www.slab.lk/service/green-house-validation-and-verification-bodies/	
7. Commercial manufacturing/system certification		SLSI	ISO 9001:2015 http://www.slsi.lk/index.php?option=com_content&view=article&id=59&Itemid=302&lang=en#quality-systems-certification-scheme-iso-9001	

8. Projects that may impact the environment		SLSI	http://www.slsi.lk/index.php?option=com_content&view=article&id=59&Itemid=302&lang=en#environmental-management-system-iso-1400	
9. Research projects that QA can be applied at the managerial level of manufacture		SLSI	Good Management Practice http://www.slsi.lk/index.php?option=com_content&view=article&id=59&Itemid=302&lang=en#good-manufacturing-practices-scheme-gmp	
10. Research projects that impose health and safety		SLSI	http://www.slsi.lk/index.php?option=com_content&view=article&id=59&Itemid=302&lang=en#occupational-health-safety-scheme-iso-45001	
11. Resulting product verification		SLSI	SLS Mark scheme- Local/Overseas http://www.slsi.lk/index.php?option=com_content&view=article&id=63&Itemid=267&lang=en	

7. References

- ISO 9000 ASQ/ANSI/ISO 9000:2015: Quality Management Systems - Fundamentals and Vocabulary, published 2015.
- ISO 9001:2015: Quality systems-requirements, last reviewed and confirmed in 2021.
- ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories, published 2017.
- ISO 15189:2012: Medical Laboratories-Requirements for quality and competence, revised 2022.
- ISO 21500:2021: Project Programme and portfolio management- Context and concepts, published 2021.
- ISO/IEC 17034:2016: General requirements for the competence of reference material producers, published 2016.
- ISO/IEC 17043: 2010: Conformity assessment — General requirements for proficiency testing, published 2015.
- OECD GLP Principles
- ISO 21500:2021 : Project, programme and portfolio management, published 2021.