DMSc Quality Assurance Scheme in Chemical Analysis

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Abstract

Quality policy of the Department of Medical sciences (DMSc), Ministry of Public Health stated to implement and maintain quality system and intend to conduct the testing accurately, valid and comply to the related law, ISO/IEC 17025 and other relevant standards e.g. WHO Guideline for National Laboratories : 2005. One of the responsibilities of the DMSc is the laboratory services and confirmation for registration, monitoring and post-market surveillance of health products. Laboratories in the Division/Bureau/Institute/Regional Center under the DMSc are national reference laboratories in many fields. The DMSc quality assurance (QA) scheme in chemical analysis has been established and the first chemical test was accredited for ISO/IEC Guide 25 by the National Association of Testing Authorities (NATA), Australia in 1995. The QA scheme of the DMSc was implemented, according to the ISO/IEC 17025, throughout the laboratories under the DMSc. Thousands of chemical tests have been extended to be accredited since then by accreditation bodies both national and international.

The essential elements of QA scheme have been implemented i.e. management structure and responsibilities, documentation, records (validation, calibration, QC, PT, complaint and test data), training (internal and external), auditing (internal and external), third party assessment, annual review, participation in relevant PT studies and other management and technical requirements according to ISO/IEC17025 have also been fully implemented in order to achieve reliable test results, satisfy customer requirements and embrace all elements of the laboratory's operations with potential to impaction results.

Introduction

The Department of Medical Sciences (DMSc), Ministry of Public Health functioning as national reference laboratories performing analyses and research study on health products, biological products, narcotics and conducting study to resolve problem in medical sciences and public health. For the role of national reference laboratories, especially in chemical testing of health products for confirmation and post-marketing surveillance, the laboratories should provide credible and reliable test results. The quality assurance (Qs) program is therefore need to be implemented according to the ISO/IEC 17025 and the relevant standards e.g. WHO Guideline for National Laboratories : 2005.

The DMSc quality assurance scheme in chemical testing has been established and the first chemical test was accredited for ISO/IEC Guide 25 by the National Association of Testing Authorities (NATA), Australia in 1995. Implementation of ISO/IEC 17025 covers all laboratories within the DMSc. Chemical tests within the DMSc have been extended for ISO/IEC 17025 accreditation and thousands of tests have been accredited since then. Laboratories seek for accreditation from both national and international bodies e.g. NATA such as the Division of Cosmetics and Hazardous Substances which there analysis of hazardous substances products for public health use and cosmetic products have been accredited for about 80 tests covering all techniques available in the laboratories.

Other than ISO/IEC 17025 standard, WHO Guidelines for National Laboratories : 2005 (WHO/CDS/WHOPES/GCDPP/2005.15), which the requirements are similar to the ISO/IEC 17025, has also been implemented in the hazardous substances testing laboratory. Implementing and maintaining a good quality management system is the responsibilities of everyone in the DMSc. It is therefore important to promote the concept and practice of quality control to staff at all levels in order to achieve the consistency reliable test results.

Objective

Implementation and accreditation of laboratories in the DMSc according to ISO/IEC 17025

The essential elements of analytical quality assurance

QA scheme implemented in the DMSc consists of the following

Elements	Implementation
1. Management structure and responsibility	Department level : • Quality Assurance Director (QAD) • Quality Assurance Committee (QAC) • Sub-committee/committees (method validation and measurement uncertainty, equipment calibration) Division/Bureau/Institute/Regional center level : • Quality Control Coordinator (QCC) • Technical Working Group (TWG) • Management Administration working group • QA working group
2. Documentation	Department level : • Quality Assurance Management Manual (QAMM) • Quality Policy Statement • Scientific Requirement Name and Code (SENAC) • Scientific Requirement Maintenance and Calibration (SEMAC) • Guidelines (Single Laboratory Method Validation of Chemical Methods, Estimation of Measurement Uncertainty of Chemical Analysis, Statistical Method for Chemical Analysis and Proficiency Testing Division/Bureau/Institute/Regional center level : • Quality Control Manual (QCM) Type of DMSc's QA document 1) Standard Operation Procedure (SOP) 2) Work Instruction (WI) 3) Worksheet (WS) 4) Form (F)
3. Records	validation data, calibration data, test data, QC, PT, complaints
4. Training	internal and external
5. Auditing	internal and external annually
6. 3rd Party assessment	Undertaken at regular intervals e.g. NATA for ISO/IEC 17025 accreditation
7. Annual review	Management review and review of QA document
8. Assuring the quality of results • QA and QC	Use of second standard, QC sample
9. Participation in PT schemes	Participated in relevant PT studies at least 7 schemes/year
10. Customer/laboratory relationship	Annual seminar with the customers

Other management and technical requirements according to ISO/IEC 17025 are also followed.

Conclusion

Quality management system is a tool for controlling, measuring quality and managing risk. A well integrated QA program will satisfy customer requirements and embrace all elements of the laboratories operation with potential to impact on results. Quality control, conducted at a level commensurate with the purpose and complexity of the test lists performed, is an essential feature of QA. Participation in relevant PT studies is one of the lot ways for a laboratory to monitor the effectiveness of QA and evaluate its performance compared test specifications and other laboratories.