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Approach to Quality System in Research and Development

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Abstract There is growing interest in developing a general strategy and quality standards for possible accreditation or certification of R&D laboratories. This article discusses the scope and limitations of Quality Systems in R&D activities. The extension of QA to R&D centres in general requires emphasis on project management and scientific competence in addition to quality management and technical competence.

Key words Quality · QA · R&D · Research

Introduction

In the wake of growing interest in globalisation of industrial activities and market economy, as well as deep concern for risk and safety factors, the importance of Quality Assurance (QA) Systems to improve the quality of laboratory services has long been recognised and implemented in three major fields: (1) testing the conformity of products and services, (2) calibration of equipment, (3) safety testing of chemicals required by regulatory authorities. Two important factors have contributed to the evolution of accreditation and certification systems: (1) progress in standardisation procedures, and (2) the global approach of the European Community [1] to create harmonised procedures.

There is increasing interest among the accreditation and certification bodies as well as the scientific community in the development of a general strategy to apply a Quality System in research and development (R&D) activities in laboratories. The prospect of introducing a Quality Assurance System in research centres has raised deep concern and scepticism among certain groups (particularly academic research centres). It is argued that the rigidity of a formal QA system and an excessively normative approach are a serious setback to scientific progress, discouraging creativity in research and increasing bureaucracy. Nevertheless, QA in industrial R&D is generally integrated as part of the production cycle of a product to meet the challenge of a dynamic and competitive market economy.

This article presents an overview of the existing quality standards in the perspective of R&D in general, analyses the scope and limitations of a QA system for R&D laboratories, and finally puts forth some proposals.

The role of standards in Quality Assurance Systems

A Quality Assurance System implies a planned management and an organisational structure in compliance with standards. The QA standards specify criteria for quality management and technical competence.

Quality Management System

A Quality Management (QM) System means the general organisation of a laboratory in terms of quality requi-

rements to assure proper management and organisation.

Technical Competence

Technical Competence (TC) means the competence of a laboratory to carry out technical procedures in compliance with specific requirements relative to the test methods, test parameters, validation of methods, equipment maintenance and calibration, qualification and training of personnel, environment and safety-related factors.

Existing standards for accreditation and certification

Accreditation and certification of a laboratory or organisation are based on one of the following international guidelines and quality standards or their national equivalents: EN 45001 [2], ISO 9001 [3], GLP [4].

Quality standards

The European standard EN 4500 [2] is based on ISO/IEC Guide 25 [5]. It specifies criteria for the evaluation of testing and calibration laboratories for accreditation (technical competence and general quality management system). Certification based on ISO 9001 [3] standard relates primarily to the quality management system for facilities involved in the design, development and production of a product and to providing services. The principles of Good Laboratory Practice (GLP) [4] place emphasis on the organisational structure and conditions under which laboratory studies are planned, performed, recorded, monitored and reported in safety testing of chemical substances, as required by regulatory authorities.

The principal objectives of these standards are (1) to ensure the quality and integrity of data and the quality of products and services, and (2) to establish mutual confidence among all parties concerned. The quality of results refers to reliability, credibility, accuracy and precision of values obtained within the performance limits, whereas the quality of a product or service implies conformity to specifications, taking into account the design, production, environmental protection and safety issues.

Comparison of standards in the light of R&D

Both EN 45001 [2] and GLP [4] emphasize a link between the QM system of an organisation and the production of reliable data. The EN 45001 standard emphasizes the exactitude of measurements and the validation of methods. The requirements of ISO 9001 [3] and GLP principles [4] in the field of technical competence are limited in comparison with EN 45001 [2].

There is a convergence of many issues related to general requirements specified in these standards [2–4]. The common features termed "Essential Quality Tools" are indicated below:

- Structured organisation.
- Controlled documentation for all procedures and activities.
- Use of adequate facilities, resources and environmental conditions.
- Quality assessment of equipment to assure their proper functioning at the time of actual measurements.
- Qualifications of staff in terms of adequate education, training, and motivation at all levels.
- Assignment of responsibilities.

However, som details vary, including the terminology employed.

Revision of existing standards

Work is in progress [6] to revise the EN 45001 [2] standard for accreditation in response to evolving needs and demands from all parties concerned (clients, laboratories, regulatory authorities, accreditation bodies, industry, etc.). The main features concerning the revision are (1) more direct harmonization of ISO 9000 series, ISO/IEC Guides, and EN 45001 to assure greater confidence in the quality system and (2) extension of the scope of accreditation to include non-standard laboratory activities.

Research and Development (R&D)

The commonly accepted practice in R&D involves investigative methodology (experimentation), searching for new ways to achieve functions, innovation, and incentive for creativity and continuous evolution as distinct from repeated performance of routine tests and measurements using standard methods.

Generally, research activities follow two orientations:

Basic research (theoretical or experimental) represents original investigations and experimentation with the main objective of acquiring fundamental knowledge and understanding, without prior consideration for any specific application.

Applied research involves original investigations or improvement of existing information in the interest of practical or industrial applications. In general, addition-

al criteria for quality management assume an important role in this case. A sharp boundary cannot be drawn between basic and applied research.

Development in general comprises testing the feasibility of a project, building a prototype, verification of known facts, validation and standardisation of sequential steps in a procedure, and optimisation of conditions. Two pathways are possible for development processes: (1) development of procedures, products and concepts that are a direct result of basic and applied research, and (2) development (supported by basic and applied research) of new products, methods, or improvement upon the existing ones in response to demands arising from "extrinsic" factors such as the market economy, health risks, environmental hazards and other scientific needs.

Quality System in Research and Development

R&D activities and testing/calibration services

The complexity of introducing a quality system in R&D is apparent from the interactive nature of R&D activities illustrated in Fig. 1. On the other hand, the successive steps followed in testing/calibration services using standard procedures are shown in Fig 2. In R&D, the final results do not necessarily represent the end point (see Fig. 2); the review programe may re-initiate the complete cycle of processes as shown in Fig. 1.

The achievements of any R&D project essentially depend on (see Fig. 1) (1) Scientific Competence (SC) (i.e., scientific knowledge and intellectual eminence) to develop fundamental concepts, elaborate experimental design and planning, interpret and evaluate the results, and (2) Technical competence (TC) to achieve validated, reliable and feasible results conforming to requirements set in the project. An important contribution of a QM system for R&D laboratories is to assure the TC necessary to accomplish the objectives of the project. Finally, an efficient project management (PM) programme (including review and evaluation programmes) is important to coordinate all scientific and technical activities within a flexible structural organisation.

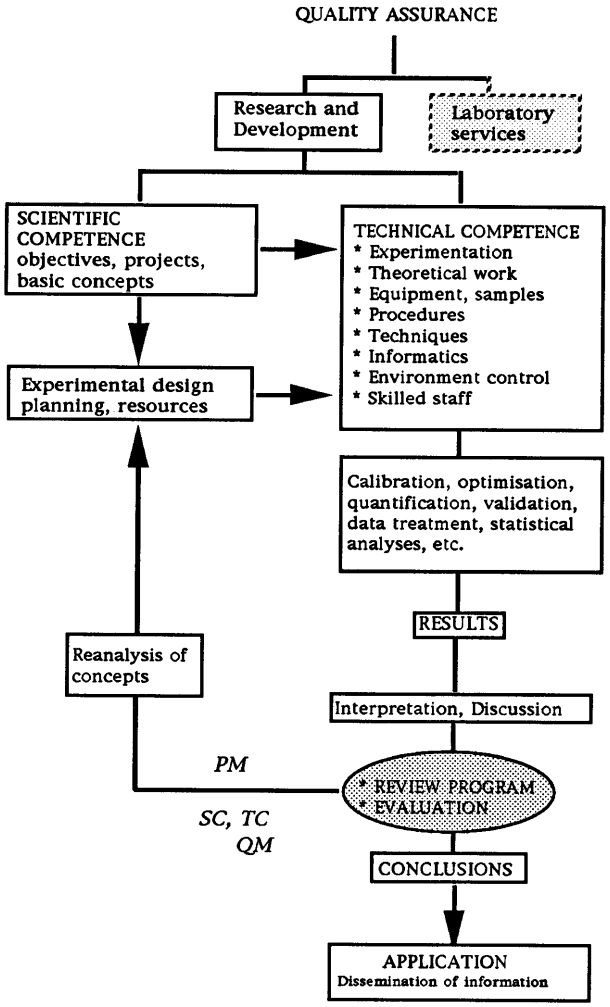

Fig. 1 General scheme for Quality Assurance in R&D laboratories

Quality in research

In general, the following criteria are important for quality in R&D activities:

- Originality, sound fundamental concepts, and rigour in experimental design, planning and performance,
- A combination of scientific knowledge, intellectual competence and technical skills.
- Adequate and reliable technology and methodology employed under appropriately controlled environmental conditions.
- Intrinsic quality of raw data and scientific value of results obtained.
- Full knowledge of uncertainty and validity limits of final results, and validation of new methods.
- Dedicated spirit of innovation, creativity and initiative.
- A well-constructed and well-documented project.
- Complete mastery over related scientific principles, technical operations, and problem-solving strategies.
- Potential for application of results in different domains.
- Scientific prestige and the dissemination of scientific and technical knowledge by way of publications, patents, etc.

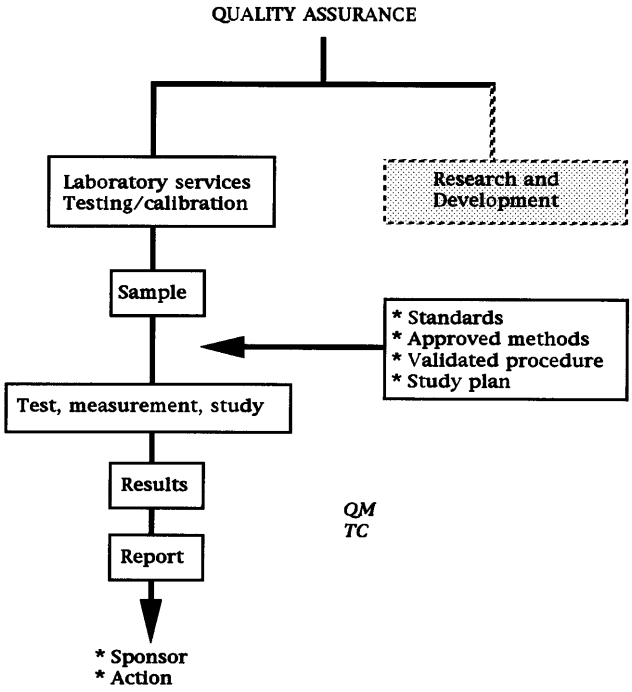

Fig. 2 General scheme for quality assurance in laboratory services (testing/calibration/measurements)

Several documents have presented guidelines for QA in R&D [7–10]. When R&D is integrated into the production cycle of a product, the control of quality is essentially based [11] on ISO 9000 standards.

Limitations and problems of QA in R&D

The major limitations to the implementation of a standard QA system in R&D laboratories arise from two sources: the inherent nature of R&D activities and the rigid requirements of existing standards.

Limitations due to the nature of R&D activities

1. A research project generally involves a vast scope for exploration, including a multitude of unknown facts and variable parameters. This necessitates the use of various methods, multiple techniques and different scientific disciplines.
2. As a result, there are requirements for a flexible approach and the continuous adaptation of scientific and technical procedures during the evolution of a project.
3. The different phases of ongoing R&D activities and participating groups are interactive (see Fig. 1).
4. The possibility of two different pathways for development processes, as illustrated in Section "Research and Development (R+D)", implies a different approach for a suitable quality system in each case.

Limitationn due to the requirements of existing standards

1. The existing standards and guidelines [2–5] include a rigid organisational structure, require step-by-step application of pre-defined procedures and an approved study plan based on GLP, and lack the flexibility needed for technical operations.
2. The accreditation system for testing/calibration laboratories covers specific activities, e.g., specified tests and use of pre-defined methods,
3. EN 45001 [2] and ISO 9001 [3] standards include limited reference to scientific competence and expert judgement that are essential for critical evaluation and interpretation of results in R&D.

Advantages of QA in R&D

The implementation of a quality system in R&D laboratories, in general, provides multiple advantages. These are enumerated below:

1. A formal QA system in R&D promotes mutual confidence among all parties concerned such as the scientists and specialists, the sponsors, and other decision-making authorities that are necessarily not specialists in the field. This is particularly important in the context of globalisation of R&D activities, current trends in economic culture, and competitiveness.
2. It assists in developing an organisational structure in order to
   - clearly define the objectives, working plan and resources,
   - ensure evolution of R&D projects according to set objectives, planning, time schedule (committment score),
   - develop efficient problem-solving strategies in the course of evolution of the project,
   - lower the risks of doubtful results,
   - save time and reduce overall cost of the project.
3. The implementation of a QM System in R&D laboratories ensures comparable and optimum quality standards in all interdependent phases of a research project and in the various facilities involved. This becomes a crucial issue when individual R&D projects constitute an integral part of a concerted research programme that are to meet specific requirements and targets. Furthermore, a QA system in R&D can also facilitate the transfer of knowledge.

4. Communication established between different parties via a network of harmonised QA system allows smooth functioning of multi-centre and/or multi-disciplinary research programmes (national or international).
5. A formal QA system applied in R&D laboratories can avoid multiple evaluation exercises by various organisations that employ different evaluation criteria. This is particularly advantageous for centres relying on contract-based research.

Proposals and discussion

The preceding discussion raises three major issues concerning the application of a quality system in R&D.

Recognition scheme

Two systems may be used to approve the quality system applied in research laboratories:
– "Formal recognition" of a laboratory in terms of accreditation or certification based on third party evaluation. Accreditation refers to the formal recognition of technical competence of a laboratory within a defined scope, including its QM system. Certification of a laboratory or an organisation mainly concerns its quality system.
– "Acceptance" of the quality system by way of a self-declared statement of compliance to basic requirements set in general guidelines or harmonised standards, such as the DOE standard [8].

In the case of accreditation of R&D facilities, the significance of accreditation needs to be clarified and considered in a wider perspective than for laboratory services (specific tests, measurements or studies [2, 4]). A particularly important point is the validation of a new approach to problems, and demonstration of the reliability of results.

The implementation of a quality system in R&D centres may be either optional or mandatory, depending on the nature of the projects:
– Optional implementation of a QA system is via accreditation and certification or "Acceptance" of a quality system by a statement of compliance to harmonised standards. This approach can be used in cases such as R&D related to industrial sectors or pre-normative research for developing standards. The research may be financed by external sources and performed as contract-based and/or customized research projects (e.g., national or international funding to research centres, industrial funding to university laboratories, etc.).
– Mandatory accreditation may be necessary for laboratories carrying out applied research and development in specific fields (e.g. health and safety aspects or the development of methods for regulatory testing).

Scope for QA in R&D

Quality Assurance in R&D combining QM, PM, SC and TC requires flexibility within a framework of structural organisation. Flexibility implies the ability to alter and adapt the research plans and procedures on the basis of scientific and technical knowledge acquired. The assessment of TC for R&D needs to place great emphasis on complete mastery to ensure correct application of the methodology and technology under optimum conditions rather than strict conformity to standard procedures. The scientific judgement of a project, research planning, choice of methods and techniques, needs to be entrusted to the competence of a scientific "review committee" of specialists. A QA programme may eventually complement peer reviewed scientific publications.

Field of application for accreditation

An important feature of accreditation of R&D laboratories is the identification of the extent to which the R&D activities are covered by a QA System. Three major levels are possible, depending on the size and activities of the centre:
– General accreditation of a laboratory for R&D activities involving many related research areas with a common objective. These may involve several multidisciplinary and multi-technique projects.
– Accreditation of a laboratory for a unique and well-defined project, using single or multiple techniques and methods.
– Accreditation of a laboratory concerning the application of a highly specialised method or technology for a variety of research problems in a single centre or multiple centres.

Conclusions

Many controversial issues surround the application of a formal QA system to R&D laboratories because of basic differences between research activities and laboratory services (see Figs. 1 and 2). An efficient PM is a key factor for extending a quality system to R&D laboratories. The need for formal recognition of the quality system of R&D laboratories will essentially depend on the objectives of the project, the eventual application fields, and the mode of finance (e.g., contract-based and customized R&D supported by grants).

No single existing standard is satisfactory with respect to its integrity for QA in R&D activities. A hierarchical structure of quality documents for R&D, based on existing guidelines and standards [2–5] is required. This should comprise (1) generic standards with minimum requirements covering, in general, project Management (PM) quality management (QM) and technical competence (TC), and (2) harmonized sectorial standards providing complementary recommendations for requirements relevant to specific sectors of R&D.

Basic research requires an independent and flexible approach to investigate problems because of the large number of unknown factors and undefined parameters. On the other hand, applied research and development processes are generally based on a background of available knowledge that may not be exact or sufficient at the outset, but lay the ground for subsequent development of specific applications. Therefore, harmonised standards can be more readily formulated for applied research and development than for basic research projects. For independent basic research performed by self-supporting resources, intuitively applied quality criteria constitute an integral part of the research.

Increasing numbers of R&D projects in research centres (including universities) are required to be carried out in the interest of a third party providing financial support (fully or partly, e.g., contract-based and customised R&D). Therefore, the recognition of an acceptable general quality system applied in R&D centres eventually becomes an important issue in spite of many constraints.

The extension of a QA System to centres involved in R&D activities involves additional concepts related to project management (PM), comprising quality management (QM) and technical competence (TC) to efficiently exploit scientific competence (SC) (see Fig. 1 and the Section "R&D activities and testing/calibration services" above). The real challenge for implementing a QA system in R&D concerns the development of standards specifying quality requirements (general and sectorial) that allow flexibility and originality indispensable for R&D and the identification of the domains where QA can contribute positively.

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