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GENERAL PAPER

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Quality assurance in analytical laboratories engaged in research and development activities

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Abstract Research and development activities are carried out by various types of laboratories that are not the typical testing and calibration laboratories for which the ISO/IEC 17025 is the quality assurance implementation reference. In this paper, such laboratories engaged in R&D activities are classified and different approaches they can adopt with a view to implementing a quality system that are suited to their characteristics and the type of work they conduct are proposed. These approaches take account of existing standards for the certification/accreditation of laboratories and of guides on quality assurance for non-routine analytical laboratories.

Keywords Quality assurance · R&D laboratories

Introduction

Analytical chemistry is known to encompass two complementary facets (namely basic and applied activities, which are conducted in R&D and routine analyses). This is acknowledged in many definitions of analytical chemistry including that from the former Working Party of FECS ("Analytical Chemistry develops and applies" [1]) and others such as the following: "Analytical Chemistry develops, optimises and applies" [2]. This last definition additionally states that solving analytical problems is a substantial part of this scientific discipline. Based on their basic and applied nature, analytical sciences should adopt an integral approach to quality assurance.

Measurement standards and intangible written standards constitute the conventional generic references for analytical chemistry. However, they do not suffice to characterize it in an integral manner. Thus, the client's information needs are frequently missed as a reference [3]. These are the three essential references to be used with a view to achieving analytical quality, which in fact consists of two major elements, namely: metrological quality, which is related to both measurement standards and written standards; and practical quality, which is related to written standards and the client's information needs. A well-designed, wise combination of both elements leads to integral analytical quality in the context of the analytical problem [4].

There are many definitions for research, development and innovation involving regularly sequential activities that differ mainly in extent of application; however, there is some overlap between them. Predictability increases from basic research to fundamental research to innovation. In the analytical context, for example, basic research is mandatory with a view to developing, characterising and validating new biochemical sensors. The development stage involves setting up a prototype based on the particular development. The last stage is the production of a portable analyser for marketing.

Analytical R&D&I involves two complementary facets, namely: basic research focussing on the development of analytical tools and methods or improving existing ones; and applied research focussing on solving analytical problems derived from the client's chemical and biochemical information needs. Very often, applied research involves some basic research.

This paper provides a description of the different types of analytical laboratories in relation to quality assurance systems and discusses the compatibility between analytical R&D laboratories and quality assurance prin-

ciples and practices. It also deals with the systematic implementation of quality systems in the most relevant analytical laboratories engaged in R&D activities, such as those working in an industrial field, those exclusively devoted to R&D work and those performing other activities in addition to R&D.

Types of analytical laboratories

First of all, a classification of analytical laboratories based on their principal activity is necessary in order to facilitate the adoption of an appropriate analytical quality system (see Fig. 1).

Few calibration laboratories are concerned with chemical measurements despite their relevance to some technical requirements included in ISO/IEC 17025:1999. Reference laboratories or laboratories of excellence established by authorities (e.g. the EU Commission) are usually responsible for managing a network dealing with a specific topic of impact (e.g. veterinary residues). Routine laboratories analyse a wide variety of samples in order to determine an also wide variety of measurands daily. They can be independent laboratories or parts of a parent organisation. Many universities have teaching laboratories devoted to analytical sciences.

In public and private enterprises engaged in research and development activities, analytical laboratories are set to provide support for such activities. On the other hand, some R&D analytical laboratories are almost exclusively concerned with the basic and applied advancement of analytical sciences.

Often, laboratories are assigned with a dual or triple purpose (i.e. two or three major activities, such as routine analyses and research work). This situation is inadequately covered in the literature on analytical quality.

Accreditation based on ISO/IEC 17025:1999 standards can be applied to both calibration, reference and routine laboratories. Problems arise from the difficulty of establishing quality systems in analytical laboratories engaged in R&D, which is the subject matter of this paper.

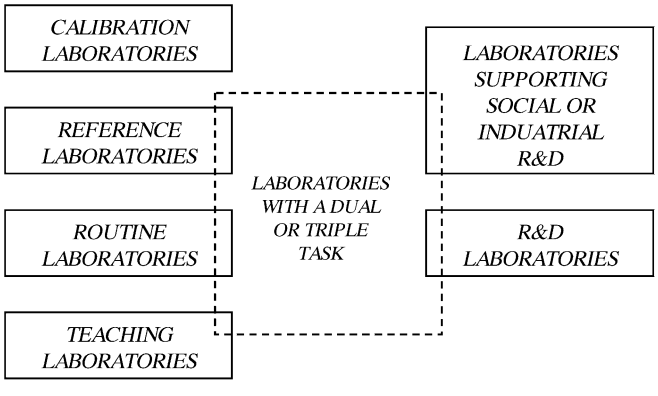

Fig. 1 Types of analytical laboratories in relation to goals and tasks

Compatibility between analytical R&D and quality assurance principles

The positive and negative aspects of both quality assurance systems (plan-do-check-act) and R&D activities (discover-investigate-use-improve-adapt-innovate) are contradictory (there is little consistency between them) [5].

Quality assurance systems are predictable and controllable; they have both a fitness for purpose and an error-prevention orientation. However, flexibility, creativity and inventiveness are minimal and errors potentially leading to subsequent major advances in R&D are not exploited.

Research and development activities feature flexibility, inventiveness and creativity; also, they capitalise on errors and unexpected results. In relation to quality systems, these activities are unpredictable and uncontrollable, and rely heavily on unregulated, unexpected facts.

A body of well-known errors connected with the R&D QA binomial should be avoided, the most relevant of which are direct extrapolation of well-established quality systems from routine to R&D activities, straight application of inflexible quality standards, minimising the freedom for creative R&D activities and unwarranted departure from essential quality assurance principles and practices.

The most important objective in this context is the careful adaptation of quality assurance principles and practices in such a way that they are made compatible with the general and specific characteristics of R&D. According to Krapp [5], effectively combining quality systems and analytical R&D activities endows them with flexibility, consistency and transparency, and facilitates their monitoring and assessment.

Analytical laboratories supporting external R&D

The principal duty of analytical laboratories engaged in social or industrial R&D is to solve analytical problems [4] arising from the need to obtain (bio)chemical information in support of R&D. Analytical R&D work teams in public and private organisations should be aware that just applying existing analytical tools and methods is a wrong approach, i.e. using analytical chemistry as a service performing routine analysis makes no sense in this context. Analytical chemists should constitute an integral part of the R&D system; in addition to performing routine analyses and having the specific skills required in some analytical fields (e.g. chromatography, MS, atomic spectrometric techniques), they should posses a high lev-

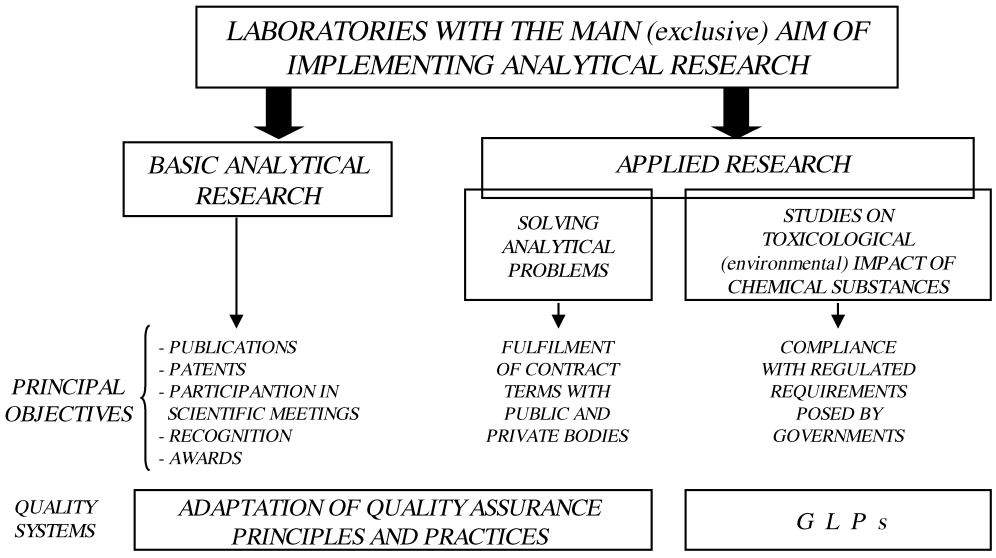

Fig. 2 Principal activities, goals and quality systems of analytical R&D laboratories

el of analytical knowledge, multi-analytical skills, problem-solving capabilities and a sound knowledge of related chemical, technological and business concepts. In many cases, analytical tasks should involve the development of new tools, methods and measurement standards. Only in this way can analytical chemistry actively and efficiently participate in contribute to social and industrial R&D.

In a recent paper, Kleijn states that analytical laboratories engaged in external R&D activities should rest on three essential pillars (namely scientific quality, business dedication and logistical quality) [6]. In order to ensure log-term stability Kleijn suggests that the organisation of R&D analytical laboratories should rely on prioritisation of the pillars, flexibility being one essential feature of the scheme. R&D laboratories have rarely been hierarchically structured and their serving scientists constitute an amorphous team of experts rather than an orderly army of analysts.

Analytical R&D laboratories

The principal difference between laboratories essentially concerned with the direct implementation of R&D as related to analytical sciences and those supporting external R&D activities, lies in their targets. As can be seen in Fig. 2, laboratories can conduct two general types of analytical R&D activities, namely (a) those exclusively devoted to basic analytical research and (b) those involved in applied research, which in turn can be undertaken for different purposes, namely: (b.1) to solve analytical problems (e.g. in the environmental, food, nutritional, clinical areas), and (b.2) to investigate the toxicological (environmental) impact of chemical substances within the framework of GLPs.

The principal goals of these three types of activities, shown in Fig. 2, are obviously different. Thus, the main outputs of basic research are publications, patents, participation in scientific meetings, recognition, awards, etc. In applied analytical research, the main goal is fulfilment of the contract terms with the client and compliance with regulated requirements impose by governments in the two variants shown in Fig. 2. The corresponding quality systems for the two variants are also obviously different (see Fig. 2). In the first two cases, adaptation of conventional quality assurance principles and practices is necessary. In the third, adopting principles and practices of good laboratory practices (GLPs) is mandatory.

Written standards for routine analytical laboratories are based on ISO/IEC 17025:1999 [7], which involves management and technical requirements within the framework of the now obsolete ISO 9000:1994 group of standards. The EURACHEM-CITAC Guide on Quality Assurance for R&D and Non-routine Laboratories [8] establishes a nested structure of activities based on organisational, technical quality and analytical task elements that have a correspondence with the written standards for routine analytical laboratories. However, it should be noted that the situation is only transient as ISO/IEC 17025:1999 is not consistent with the new ISO 9000:2000 group of standards and nor is the EURACHEM-CITAC guide [8] (which is closer to the former ISO 25:1989 and EN 45001).

One must combine two different approaches in order to accomplish the systematic adaptation of management and technical requirements to the specific characteristics of each analytical R&D laboratory or group of them, namely (a) a mixed, flexible framework based on ISO 9001:2000, ISO 9004:2000 and ISO/IEC 17025:1999 and (b) the philosophy and specific technical aspects of the EURACHEM-CITAC guide. In this way, quality sys-

tems can be gradually implemented in analytical R&D laboratories by prioritising management and technical requirements, and introducing a differential compliance level for each requirement.

Assessment is a substantial activity in quality assurance systems. Analytical R&D laboratories in particular can be assessed in many ways. Thus, the human factor can be assessed internally or externally. Internal assessment can rely on the existence of a quality unit and/or the conduct of internal audits similar to those established in ISO/IEC 17025:1999. External assessment, which is well planned in the EURACHEM-CITAC guide, can be done in various ways including peer review, benchmarking and, in special cases, external audits against internal and external written standards. Assessment can also be suited to the particular target, i.e. the object under evaluation, which can be (a) the implemented quality systems based on compliance with formal or informal (internal) standards, (b) the R&D results (i.e. the quality of publications, patents, fulfilment of project requirements and research contracts, among others) and (c) both items.

Analytical laboratories with a dual or triple duty

Analytical research laboratories are often involved in other activities such as routine analyses and/or teaching. In this situation, making such duties compatible introduces an additional difficulty in implementing a quality system. There is a need to approach this usual situation. One should take into account that a laboratory quality system must combine different aims, targets, written standards, implementation procedures, and internal and external assessment systems; the success of such a combination is no doubt uncertain. One of the possible solutions to this problem involves structuring the laboratory in different activity areas. There are three different choices for this purpose. One involves the establishment of isolated activity areas, which entails the application of independent quality systems. This approach is inflexible, expensive and artificial. Alternatively, one can use the same facilities for all laboratory activities; designing and using a single quality system in this situation is unrealistic as it is usually very difficult to make two different activities compatible under the same quality umbrella. The third choice can be called the "tree area approach" and is based on the establishment of a common area for coordinating both management of technical activities in relation to the two main duties of the laboratory. This is the most efficient choice as it ensures acceptable internal compatibility and flexibility, and it can provide mutual benefits.

An university analytical laboratory can be used as a typical example of laboratories with a threefold goal, namely (a) teaching, (b) basic and applied research and (c) conducting routine analyses under contracts with their social and industrial environment. The quality system to be used in each activity differs. A "light" quality system can be used by teaching laboratories for a dual purpose, namely to improve efficiency and to introduce students into analytical quality. However, a self-contained quality system should be applied to all R&D activities. Thus, a quality system based on the ISO/IEC 17025:1999 standard, which can lead to accreditation, should be applied to service activities of the laboratory. With appropriate organisation and management, these three types of quality system can provide mutual benefits.

Concluding remarks

There is a pressing need for analytical laboratories involved in R&D activities to implement gradually quality systems with a view to improving performance. The first step in the process could involve clarifying written quality standards (ISO 9000:2000, ISO/IEC 17025:1999, EURACHEM-CITAC guide) in order to develop a general framework for developing various practical guides. In a second step, quality assurance approaches could be adapted to the different types of analytical laboratories. Then comparability between R&D activities and quality assurance principles and practices could be systematically examined. The fourth, final step, could be a systematic dissemination campaign focussing on the advantages of conducting analytical research activities under the umbrella of quality.

References

1. Kellner R, Mermet JM, Otto M, Widmer HM (eds) (1998) Analytical chemistry: preface. Wiley-VCH, Weinheim
2. Valcárcel M (1997) Trends Anal Chem 16:124–131
3. Valcárcel M, Ríos A (1999) Anal Chim Acta 400:425–432
4. Valcárcel M, Ríos A (1997) Trends Anal Chem 16:385–393
5. Krapp M (2001) Fresenius J Anal Chem 371:704–713
6. De Kleijn JP (2001) Trends Anal Chem 20:49–52
7. ISO/IEC 17025 (1999) General requirements for the competence of testing and calibration laboratories. ISO, Geneva, Switzerland
8. EURACHEM-CITAC (1998) Guide on quality assurance for research and development in non-routine analysis. LGC, Teddington, UK