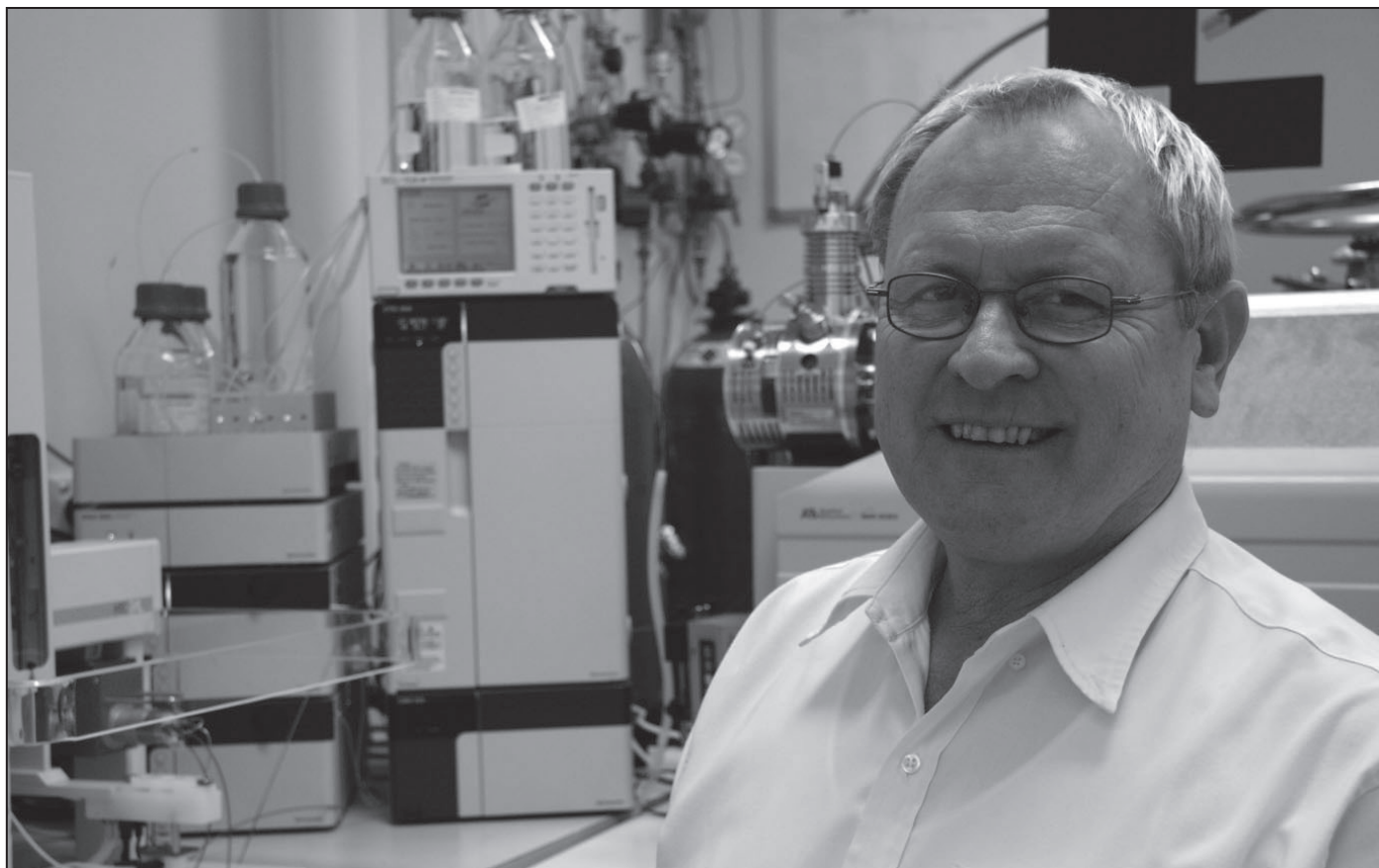


# Australia leads the way in research and development accreditation

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**T**etraQ-ADME provides preclinical research and testing services to pharmaceutical companies in the areas of drug absorption, distribution, metabolism and elimination and has recently become the first organisation to achieve NATA accreditation for research and development (R&D). TetraQ-ADME (then called the Centre for Studies in Drug Disposition, of The University of Queensland) initially volunteered to pilot an assessment of R&D by NATA, which eventually developed into the accreditation program, which has recently been launched (see also page 20 in this issue of NATA News). The Centre had previous experience with application of the OECD Principles of Good Laboratory Practice in the medical testing program [the accreditation, held since 1997, moved when the relevant

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activities were moved to the privatised facility, Q-Pharm Pty Limited, in 2002]. TetraQ-ADME was attracted to a system that could reliably recognise our application of “good research practices”, since systems developed for accredited activities had also been applied to research.

## **The need for R&D Accreditation**

Australian academics have been encouraged by recent Federal policies to conduct commercial research and development. Clients and users of R&D have various expectations of R&D quality but there is currently no commonly agreed standard, although particular standards are applied by regulatory authorities in certain areas such as the testing of pharmaceutical drug candidates. However, accreditation of research and development appears problematic to most researchers. While its potentially detrimental effects on creativity are voiced by opponents, accreditation is increasingly attractive to companies that seek to outsource R&D work.

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The accreditation process began when NATA convened a meeting in September, 2002 to assess perceived R&D accreditation needs. Private sector participants came from a variety of industries such as pharmaceutical and geotechnical, and represented the views of parties who were both producers and users of R&D. Researchers experienced difficulty determining an appropriate standard to apply, while R&D customers experienced difficulties regarding assurance of data, especially in organisations where personnel, and organisational structures, often changed or where clear requirements for retention of documents and data did not exist.

### **The Nature of the NATA R&D Assessment**

A variety of guidelines and standards (such as *The OECD Principles of Good Laboratory Practice*, research guidelines produced by various universities and the Australian Vice-Chancellors Committee and ISO 9001:2000) might be applicable to R&D accreditation. The Australian Standard AS ISO/IEC 17025: 1999 (*General Requirements for the Competence of Testing and Calibration Laboratories*, Standards Australia International) was chosen as the prime reference, to be interpreted for research using EURACHEM/CITAC Guide CG2 (1998, *Quality Assurance for Research and Development and Non-Routine Analysis*). A major factor in the decision was the familiarity of all parties with ISO/IEC 17025.

An on-site visit was conducted similar to most NATA assessments for ISO/IEC 17025 compliance, beginning with document review and followed with assessment by a team comprising NATA staff and relevant technical assessors. The unfamiliar ground was application of the standard to non-routine research activities. The long held pharmaceutical testing mantra of "if it wasn't written down then it wasn't done" proved its worth—assessment of R&D was satisfactory for activities, and decisions, that were recorded as thoroughly as the industry would expect. Technical assessors were able to recognise the value of documents and records mandated by regulators and used wherever possible

to avoid unnecessary replication of work. For example, a project plan should not be (re)designed if an animal ethics project (mandatory for such work) or a legal contract schedule can be used (or adjusted to suit).

*“R&D accreditation is powerful evidence of commitment to quality.”*

### **Lessons and Implications from the NATA Assessment**

When the idea of R&D accreditation was discussed in 2002 we were doubtful that a standard as particular as ISO/IEC 17025 could be applied to R&D activities. The success of the assessment was attributed in part to the knowledge and understanding of the assessors. Key to this was the judgement at assessment of documentation and records as satisfying requirements. The value, and cost, of technical assessors is critical to an assessment of R&D if an assessment of competence is to remain connected with good practices.

Organisations can now demonstrate that their work is conducted to a recognised standard with R&D Accreditation. Clients of R&D can be assured by accreditation that minimum requirements have been satisfied. Furthermore, accreditation is powerful evidence of commitment to quality. Some clients have shown considerable interest in R&D accreditation. The purpose of accreditation should be clearly understood and client awareness, and agreement, is essential for the return on investment to be favourable.

In general terms, accreditation is a demonstration that:

- the facility is managed to ensure good research practices and protect the interests of clients and other stakeholders,
- the facility and the client agree the nature and milestones of the R&D to be undertaken,
- the R&D is conducted by staff competent to do so,

- processes, equipment and instrumentation are validated and records exist to support the validity of R&D output,
- reports reflect the R&D aims, the experimentation and the data,
- reports supplied to the client are supported by archived documentation and records that are satisfactory for their intended purpose.

### **Considering R&D Accreditation?**

These additional considerations are provided for facilities considering R&D accreditation:

- Understand clearly the return on investment that accreditation provides.
- Design the quality system carefully for effectiveness and efficiency. Where possible it is better to have one document for multiple audiences than multiple documents or records; this is especially important when considering the growth of compliance issues.

### **The Future of R&D Accreditation**

This accreditation program is timely given the increasing amount of R&D that is outsourced. In large (often global) organisations, this R&D is sometimes supervised by managers who are not able to assess the specialist techniques concerned. R&D accreditation assists these managers in the diligent supervision of such work.

Issues that may need careful handling, by facilities and NATA, include:

- Access to technical assessors for specialist techniques.
- The cost (and value) of technical assessment of a large range of R&D activities.

Whatever the challenges of R&D accreditation, the key to success will be providing a satisfactory return on investment for participating facilities and their clients. ♦

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