



# **LIFE SCIENCES QUALITY MANAGERS FORUM**

## **Research and Development Accreditation**

**25 June 2014**

## Presentation Overview:

- Overview
- Seven Principles of the Program
- Accreditation criteria
- Scopes of Accreditation

# Overarching Principles

**Principle 1: Staff**

**Principle 2: Accommodation and Environment**

**Principle 3: Processes and Methods**

**Principle 4: Equipment**

**Principle 5: Records**

**Principle 6: Outcomes**

**Principle 7: Management System**



# Accreditation Criteria

- Adoption of a standard such as ISO/IEC 17025 - General requirements for the competence of testing and calibration laboratories, to demonstrate compliance to the seven overarching principles
- CITAC guide CG2 Quality Assurance for Research and Development and Non-Routine Analysis
- Research and Development Accreditation Application Document
- Relevant Application Documents for specific discipline

# ISO/IEC17025 in an R&D Context

## Section 4

**4.1 Organisation**

**4.4 Review of requests, tenders and contracts**

**4.9 Control of nonconforming testing and/or calibration work**

**4.13 Control of records**

# ISO/IEC17025 in an R&D Context

## Section 5

**5.2 Personnel**

**5.4 Test and calibration methods and method validation**

**5.4.5 Validation of methods**

**5.4.6 Estimation of uncertainty of measurement**

**5.5 Equipment**

**5.9 Assuring the quality of test and calibration results**

- Internal measures
- External measures

**5.10 Reporting the results**

# R&D Scope of Accreditation

- Flexible and descriptive
- Sets the boundaries of the research
- Initially drafted by the facility
- Confirmed and refined at assessment

# Coverage of R& D Program

- Pharmaceutical sector;
- Wine industry;
- Genome research;
- Environmental research;
- Clinical trials and clinical research;
- Forensic research;
- Biotechnology sector;
- Veterinary research;
- Agricultural research;
- Medical research and
- Biobanks



# Examples of Scopes

**ACCREDITATION NO: 14376**

**Department of Defence, Chemical Agents Analysis Facility**

**ACCREDITATION NO: 18858**

**Collaborative Crystallisation centre (C3)  
CSIRO Materials Science and Engineering**

**ACCREDITATION NO: 18884**

**Australian Museum – Australian Centre for Wildlife Genomics**

**ACCREDITATION NO: 19049**

**Biota Pharmaceuticals**

**ACCREDITATION NO: 15153**

**CIPDD/TetraQ**

# R&D Program Accreditation

## TECHNICAL ASSESSORS

- Selected in consultation with facility
- From aligned field

## AAC

- No specific AAC
- Support is provided closely aligned AAC.

## Contacts & References

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**THANK YOU!**

