

Animal testing replacement for vaccines A One Health View: Global outlook and future strategy

Building competence in new testing strategies in National Control Laboratories



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Responsibility

- The quality, safety and efficacy of a vaccine is the responsibility of the manufacturer.
- The regulatory authority of the country is responsible for establishing procedures to ensure that this responsibility is met.
- The same requirements of regulatory oversight should apply to the production of vaccines, whether they are intended for domestic use or for export.



Responsibility

Laboratories are essential to ensure that NRAs are able to assess the quality of medical products. The reliability of the tests performed and the credibility of their results, depends on the quality of the work performed by the laboratories.

► Building competence in new testing strategies within National Control Labs (NCLs) requires a multifaceted approach focused on personnel, infrastructure, and quality management - which a manufacturer should contribute to.



Building Competence

1. Personnel Training and Development:

- **Targeted Training Programs:** Assist in developing and implementing training programs specifically designed for new testing strategies
- **Competency Assessments:** Shall help in establishing robust competency assessment frameworks to verify that personnel can reliably perform new tests and interpret results.



- **Continuing Education:** To foster a culture of continuous learning by providing access to scientific literature, conferences, and participation in relevant professional networks.
- **Mentorship and Knowledge Transfer:** Assist in Implementing mentorship programs where Subject Matter Experts (SMEs) guide and train colleagues in new techniques.

Building Competence

2. Infrastructure and Equipment:

- **Investment in Technology:** Assist in acquiring and maintaining necessary equipment and instrumentation required for new testing strategies, ensuring proper calibration and maintenance.
- **Method Validation:** Help in validating new test methods to ensure their accuracy, precision, and reliability before routine implementation.
- **Reagents and Chemicals:** Ensure in making adequate stocks available.
- **Reference Materials and Standards:** Ensure access to appropriate reference materials and standards for quality control and method validation.
- **Implementation of 3Rs:** Transfer *in vitro* analytical methods for implementation so as to replace tests involving animals.



Building Competence

3. Quality Management System (QMS):

Accreditation: Help and support in assessment by an independent body and getting accreditation to internationally recognized body (usually ISO 17025)

- **Integration into QMS:** Integrate new testing strategies seamlessly into the existing Quality Management System
- **Proficiency Testing:** Evaluation of a participating laboratory performance against pre-established criteria by means of multiple interlaboratory comparisons.
- **Inter-Laboratory comparison:** Evaluation of measurements or tests on the same or similar items by two or more laboratories
- **Internal Audits and Reviews:** Conduct regular internal audits and management reviews
- **Risk Management:** Implement risk management strategies to identify and mitigate potential risks associated with the adoption of new testing strategies.



Building Competence

- **4. Collaboration and Information Sharing:**
- **National and International Collaboration:** Engage in collaborations with other NCLs e.g. WHO NCL's Network, research institutions, and international organizations to share knowledge, best practices, and resources related to new testing strategies.



- **Networking:** Encourage staff to participate in professional networks and scientific communities focused on relevant testing areas.



THANK YOU!



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