

How to build NCL competences?

A case study from the Belgian national control lab
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How to build competences?



Aspects to be taken into account:



- Buy and qualify key equipment
- Train lab personal
- Source reference and reagents
- Ensure reagents supply sustainability
- Validate method according to regulatory requirements (GMP, ISO 17025)

How to build competences?



2 approaches:

Strategy	Equipment	Training	Reference and reagents	Validation
Internal development	According to your needs	Equipment supplier In-house expertise	Commercial and/or Ph.Eur. Or WHO	Full validation ICH Q2(R2)
Method implementation from manufacturer	Same equipment	On-site SOP manufacturer	Critical references & reagents from manufacturer	Method verification Results comparison

Benefits and risks



2 approaches:

Strategy	Benefits	Risks
In-house development	<ul style="list-style-type: none">• Full independency• Equipment fitted to your needs• Knowledge• Different angle• Publication	<ul style="list-style-type: none">• Longer approach• Reagents supply & bridging• Selection of reference• In house Specifications setting• OOS Handling
Method implementation from manufacturer	<ul style="list-style-type: none">• More efficient timewise• Benefit from manufacturer expertise during development• Results comparison• Reagents Bridging• Defined specifications• OOS handling	<ul style="list-style-type: none">• Dependency on reagents and reference material• Error Transfer• Reliance on manufacturer SOP, reagent & reference stability studies, shelf-life extension,...• Good communication and transparency needed

Other approaches?



Third approach: mix of 2 approaches

- Optimize method according to your constraints in the lab, to your knowledge & expertise
- Harmonize method to be able to analyze different products with the same method
- Share workload with other Labs
- Need to go back to official method (registered) in case of OOS (2 methods in place)
- Ask help from peers !

The Road Ahead



- **NCLs must evolve to remain relevant and ensure public trust in vaccine quality when moving from in vivo to in vitro testing**
- **Collaboration, innovation, and harmonization will be key to a worldwide successful transition to non animal testing!**





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Back-up slides- example: Serology

Reagents for the development of an internal serology potency assay for D&T on mice:

- Coating:

Tetanus Toxoid for use in Flocculation Test (3rd International Standard) 16/302

Diphtheria Toxoid for use in Flocculation Test (3rd International Standard) 13/212

- Detection: anti-mouse coupled to peroxidase commercial kit
- Standard ELISA, BRP aP de l'EDQM (BORDETELLA PERTUSSIS MOUSE ANTISERUM BRP2) generated with a vaccine DTaP -Ab presents for D & T (Arbitrary titer 100EU/ml)
- Internal control : Pool sera in house
- Reference Vaccines EDQM (BRP3 pour tetanos et BRP4 pour diphteria) used for the challenge assay

Back-up slides- Serology

Hurdles:

- No international ELISA standard for Diphtheria and Tetanus serology in mice
- Demonstrating equivalence between challenge assay and Serology assay results
- Need to calculate and apply corrective factor for diphtheria
- Calculation of in-house specification (NCL: mice – manufacturer:Guinea-pigs)
- Development of single dose assay: calculation of specification on small data set to allow rapid implementation to reduce number of mice used (reassessment of specification on larger data set when sufficient data has been acquired)