Health for Animals
global animal health association

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Clostridium tetani ELISA – applicability in veterinary industries

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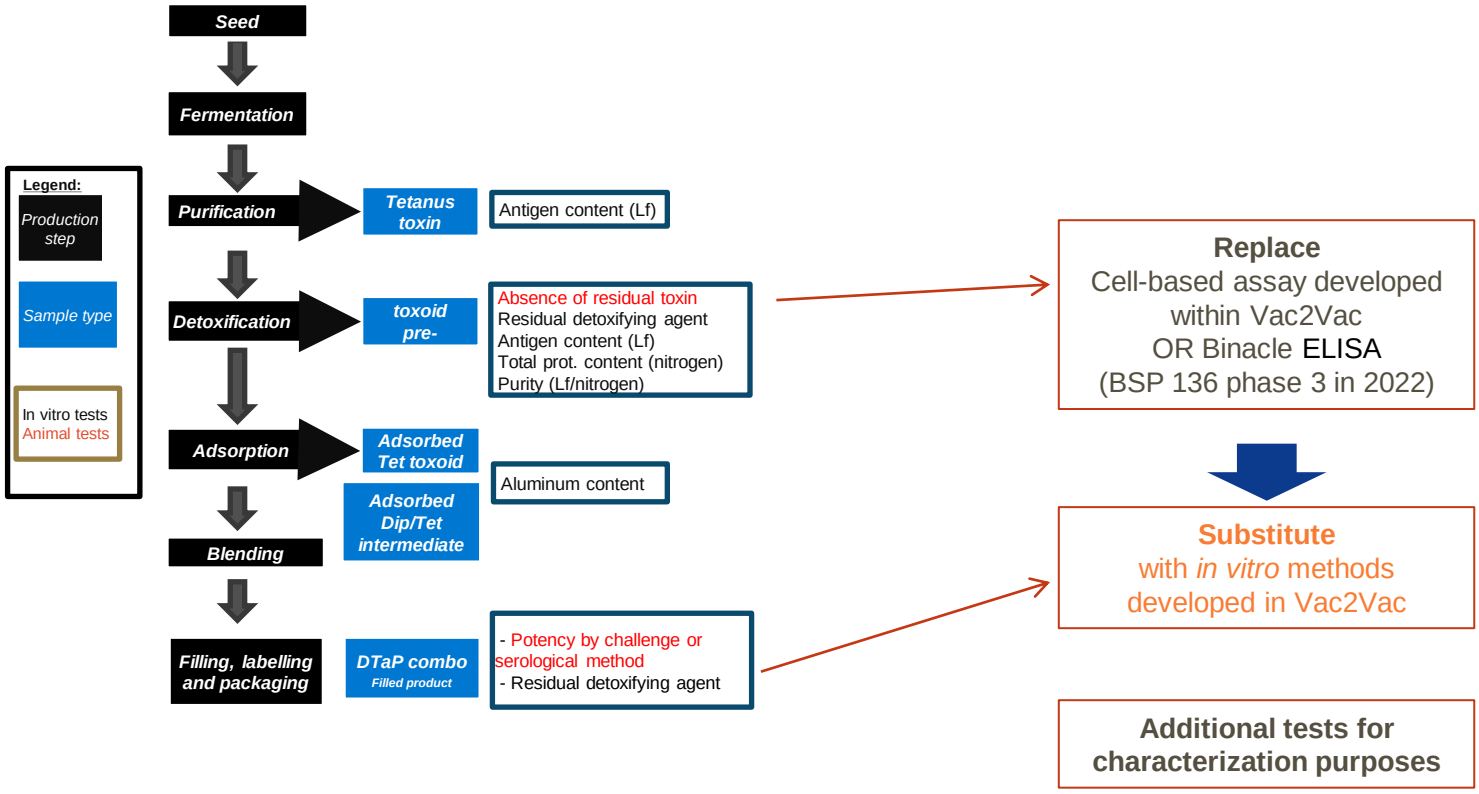
Vac2Vac

Example – Current Tetanus Control strategy as per Ph. Eur.



(*) not done in routine)

Critical Points for ELISA applicability in Veterinary Industries

1. Applicability in Quality Control (GMP) environment

- Analytical Target Profile/Quality Attribute
- Applicability : Matrix effect, Equipment, Software,…
- Controls/Reference-Standard in place, stability indicator
- Feasibility/Qualification prior Validation according to VICH guidelines
- Specifications
- Transferability and Robust method for long term use in Quality Control labs

Previous studies run during Vac2Vac project have promising results

Critical Points for ELISA applicability in Veterinary Industries

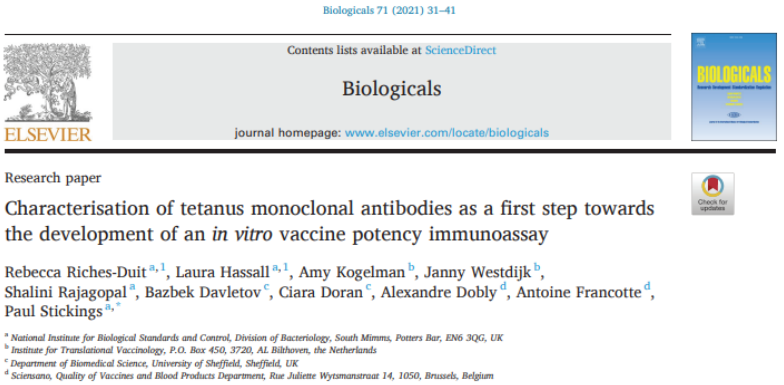
2. Quality of reagents (e.g. antibodies)

- Characterization of Reagents (e.g. antibodies)

✓ Affinity study e.g. Biosensor
✓ Neutralisation study
✓ Epitope study e.g. Epitope Competition study

- Testing of Reagents (e.g. antibodies)

✓ SDS-PAGE/SE-HPLC
✓ Dilution/dose response curve
✓ Stability after reconstitution



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Research paper

Characterisation of tetanus monoclonal antibodies as a first step towards the development of an *in vitro* vaccine potency immunoassay

Rebecca Riches-Duit [a,1], Laura Hassall [a,1], Amy Kogelman [b], Janny Westdijk [b], Shalini Rajagopal [a], Bazbek Davletov [c], Ciara Doran [c], Alexandre Dobly [d], Antoine Francotte [d], Paul Stickings [a,*]

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3. Sustainability of reagents (e.g. antibodies)

- Long term supply (!commercial reagents)
- Production consistency
- Minimization of batch-to-batch variability

Hybridomas-central distribution of purified antibodies

Next steps for substitution

1. Analytical target profile/quality attribute

- Assessed during development within Vac2vac
- Can substitute *in vivo* potency assay as quantitative and specific test targeting relevant immunological epitope and stability indicator

Previous studies done during Vac2Vac project have promising results based on

- Multiple products tested
- Altered products tested

2. Applicability

- Equipment/software (different requirements depending on countries); controls for validity of the test; standard/reference for the product; To optimize analytical test with each new matrix and check if presence of interferences by testing different formulations; Might need different antigen extraction process (depending on each product tested)

3. Feasibility/Qualification prior going to validation

Next steps for substitution

4. Validation according to VICH guidelines

VICH Topic GL2 (validation-methodology)

- *Specificity*
- *Linearity*
- *Range*
- *Accuracy*
- *Precision (repeatability, intermediate precision, reproducibility)*
- *LOD/LOQ*
- *Robustness*

Previous studies done during Vac2Vac project have promising results based on

- multiple products tested to date
- good specificity, linearity, accuracy, precision observed

5. Specifications

Next steps for substitution

6. Transferability in GMP environment

- For release and stability testing
- Routine use
- Multiple operators
- Multiple products
- During decades

Previous studies done during Vac2Vac have promising results based on Involvement of multiple labs at different locations

Conclusions

Veterinary industries are working towards company specific ELISA approach to substitute current *in vivo C. tetani* potency test