Modern science for better quality control of medicinal products

“Towards global harmonization of 3Rs in biologicals” – Workshop Feedback

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Case Study 4

• Swine Erysipelas vaccine; in vitro ELISA assay to replace in vivo immunization challenge test

• Moderator: David John (IFAH-Europe)
• Presenter: Pieter-Jan Serryn (Huvepharma)
Case study 4 - outcomes

- Both regulators and industry willing to accept good *in-vitro* methods.
- Discussions wider than just the erysipelas vaccine
- No barrier in the European Pharmacopeia for erysipelas.
- Major hurdle is the validation of the test for individual products
- New products are not a big issue
- Existing products are
Case study 4 - outcomes

Any investment in an old product must be justified.
Industry needs some certainty.
Regulators need assurance.
Can industry work with the regulators at the start of a collaborative study to improve the design to minimise the work at the individual company stage?
Case study 4 - outcomes

Industry to examine the possibility of collaborative work and early regulator involvement

To be answered:
Is there enough interest in the erysipelas vaccine?
If not is there a better candidate?
Consider ongoing work at JEG3Rs and EDQM.