bio outsource
cGMP compliant biotesting

Vaccine in USA
Draft Guidance for Industry

Characterisation of MVSS/MCB

Master Cell Bank

- Morphology – light microscopic observations
- Identity – DNA Fingerprinting
- Sterility (21 CFR 610.12)
- Mycoplasma test
- *in vivo* – Adult and Suckling mice, Guinea Pigs, Rabbits, eggs
- Transmission Electron Microscopy
- Bovine viruses following methods outlined by 9CFR 113.53 and 113.47
- Porcine viruses following methods outlined by 9CFR 113.53 and 113.47
- tests for specific agents using antibody production tests
- tests for specific agents using PCR tests
- RT Assay
- Mycobacterium
- Infectivity tests for Retroviruses
- *In vitro* tests for viruses using Monkey Kidney, Human diploid and cultures of the sames species and tissue type as the production cells

Working Cell Bank

- Morphology – light microscope observations
- Identity – DNA Fingerprinting
- Sterility (1% of cell bank)
- Mycoplasma test

End of production bank

- Morphology – light microscopic observations
- Identity – DNA Fingerprinting
- Sterility (21 CFR 610.12)
- Mycoplasma test
- *in vivo* – Adult and Suckling mice, Guinea Pigs, Rabbits, eggs
- Transmission Electron Microscopy
- Bovine viruses following methods outlined by 9CFR 113.53 and 113.47
- Porcine viruses following methods outlined by 9CFR 113.53 and 113.47
- tests for specific agents using antibody production tests
- tests for specific agents using PCR tests
- RT Assay
- Mycobacterium
- Infectivity tests for Retroviruses
- *In vitro* tests for viruses using Monkey Kidney, Human diploid and cultures of the sames species and tissue type as the production cells

MVSS Testing

- Identity using appropriate methods
- Sterility (21 CFR 610.12)
- Mycoplasma test
- Infectious titre
- tests in adult and suckling mice, embryonated chickens eggs and Guinea Pigs
- *in vitro*/haemagglutinating virus test using Simian and Human cells
- RT assay
- Bovine viruses following methods outlined by 9CFR 113.53 and 113.47
- Porcine viruses following methods outlined by 9CFR 113.53 and 113.47
- Mycobacterium

Production Control Cell Testing

- Observation/Morphology
- *in vitro* adventitious virus test
- *in vivo* adventitious virus test
- Haemadsorbtion
- Mycoplasma/Spiroplasma
- Sterility
- Species specific viruses
- Mycobacteria
- RT Assay
- Bovine viruses following methods outlined by 9CFR 113.53 and 113.47
- Porcine viruses following methods outlined by 9CFR 113.53 and 113.47

Characterisation of Virus Bulk Harvests

- Sterility
- Mycoplasma/ Spiroplasma
- Mycobacterium
- Appearance
- Identity
- Potency/Infectious titre
- RT Assay
- 14 Day *in vitro* – MRC-5, Vero and cells of same species and tissue type as the production cells
- *in vivo* assay in adult and suckling mice and embryonated chickens eggs
- Bovine viruses following methods outlined by 9CFR 113.53 and 113.47
- Porcine viruses following methods outlined by 9CFR 113.53 and 113.47

Final Product Testing

- Sterility
- Mycoplasma/Spiroplasma
- General Safety
- Identity
- Appearance
- Residual Host Cell Protein
- Residual Host cell DNA
- Potency
- Osmolality
- Residual Serum, antibiotics etc.
- pH
- Bacterial endotoxins

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