**CMO – GMP Manufacturer Outline Requirement**

APHA require a Contract Manufacturing Organisation (CMO) that is certified to EU Good Manufacturing Practice (GMP) standards to manufacture an expressed protein that will be used as an in vivo skin test to differentiate infected from Vaccinated animals (DIVA)  in a food producing animal.  The APHA is working towards holding a Marketing Authorisation (MA) for the in vivo skin test as an Immunological Veterinary Medicinal Product (IVMP).

The DIVA in vivo skin test is to be used to differential Bacillus Calmette–Guérin (BCG) vaccinated cattle form unvaccinated cattle and will provide an additional control option for the UK governments to consider as part of their bovine tuberculosis (bTB) control strategies in the future    An MA application for a BCGCattle vaccine is also under development.

The contract will require the CMO to work with the current manufacturer, who produces small scale batches of the protein for research purposes, to transfer the technology to an appropriate industrial scale of GMP manufacture ensuring quality consistent with the development batches.  The CMO would be required to perform all steps of manufacture from seed material to filling the final product and conducting the necessary QC controls;

APHA will require the CMO to produce three batches of the product for demonstration of consistency and with the intention, depending on timing, to use a GMP batch during the conduct of GCP veterinary field trials in the UK planned for 2021.

Subject to satisfactory performance of the DIVA test in field trials, the successful CMO will be required to provide the Part 2 Quality section of an MA dossier to support an MA application for the in vivo DIVA test to the UK Competent Authority. It is intended that the CMO will be contracted to supply the DIVA product commercially to APHA once the UK MAs for the BCGCattle vaccine and DIVA test are granted.