

# AUSTRALIAN PORK LIMITED

Out of Session Call for Tender 2019/20

Research, Development & Extension (RD&E)

**August 2019**



**To access and identify a streamlined approach for autogenous vaccine approval to assist with a faster approval process by the APVMA.**

## **Background**

Improved livestock industry access to autogenous vaccines is seen as critical to reduce a reliance on antimicrobials in controlling significant bacterial diseases. Despite recent advances there are opportunities for new vaccines as well as increasing the efficacy of current ones together with new delivery mechanisms. Autogenous vaccines are widely used in the USA pig industry and have played an important role in trialling timely immunological approaches in managing animal health.

While autogenous vaccines are widely sought by the industry, currently processing times for applications through the APVMA for autogenous vaccine permits could undermine the agency of any innovative and responsive use of these vaccines. It places a costly administrative burden and commercial uncertainty on manufacturers seeking new permits and to a lesser extent, but still significant extent, permit renewals.

Access to safe and effective agricultural and veterinary (agvet) chemicals is important to Australian agricultural and livestock industries, the community and the environment. Agvet chemicals sold in Australia must be authorised by the Australian Pesticides and Veterinary Medicines Authority (APVMA), via registration or permit.

The APVMA must also approve the specific uses of every product, based on its assessment of information contained in a comprehensive data package provided by applicants.

## **Project requirements**

The project is seeking an experienced consultant with a track record in the Australian veterinary chemical registration process to work with the national autogenous vaccine manufacturers to develop an application to the APVMA for novel killed autogenous bacterial vaccinations. The ultimate aim is streamlining application submission and processing.

This application will aim to develop standardised documentation addressing all the key questions APVMA are required to address in assessing permit applications, clearly stating where the steps/procedures/reagents meet existing APVMA standards so that the regulatory authority can streamline assessment.

The consultancy will develop a small number of form applications for killed bacterial vaccines (following advice from manufacturers) based on key criteria, for example gram negative and gram positive bacteria, or based on media types; or for aerobes and anaerobes. The documents need to provide the assurance allowing APVMA to give prior approval of applications using these forms, such that new permit applications complying with the form applications can receive rapid/automatic permits. Ideally permits would be available to manufacturers supplying advice of the intention to prepare a vaccination for a named bacteria, farmer and prescribing veterinarian. Annual reporting and APVMA laboratory auditing would provide the assurance needed to prove the integrity of the process.

We envisage that the consultant will liaise with the following companies to ensure that the draft documentation can, as much as possible, reflect the range of steps/procedures/reagents they are likely to use in upcoming proposed vaccine production.

- Treidlia Biovet Pty Ltd – Dr Mark White 02 9674 2488 [mark@treidlia.com.au](mailto:mark@treidlia.com.au)
- ACE Laboratory Services – Dr Aileen van der Feen  
[aileen.vanderfeen@acelabservices.com.au](mailto:aileen.vanderfeen@acelabservices.com.au) 03 544 9665
- Pig Services Centre Bendigo, DEJTR – Dr Youssef Abs el Osta [Youssef.abel-osta@ecodev.vic.gov.au](mailto:Youssef.abel-osta@ecodev.vic.gov.au) 03 5430 4595
- APIAM – Dr Chris Richards [chris@apiam.com.au](mailto:chris@apiam.com.au) 0429 843 184

## Project deliverables

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## Timeline

Date	Activity
23 August 2019	Application open
6 September 2019	Application close
30 September 2019	Review applications
30 October 2019	Expected execution of contract/issue of Provider Agreement
31 January 2020	Expected project completion date

## Submissions

How to make a submission

Register or log in via PigConnect - <https://pigconnect.australianpork.com.au/>

- Submit and manage Project Applications
- View and manage your in-progress Projects
- Review Project Applications referred to you

## Submissions close 5pm Friday 6 September 2019

## Contact

If you are interested in submitting an application, please contact

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Manager Production Stewardship

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