Australian Government
Australian Pesticides and Veterinary Medicines Authority

Manufacturers' Licensing Scheme

APVMA-Authorised GMP Auditors

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APVMA-AUTHORISED GMP AUDITORS – EXPERIENCE AND QUALIFICATION PROFILE

Experience	K Alchian	A Dowling	W Free	P Marshall	T Rowland	L White	S Williams
Manufacturing Experience							
Immunobiologicals	✓		✓	✓	✓	✓	✓
Sterile	✓	✓	✓	✓	✓	✓	✓
Non-sterile	✓	✓	✓	✓	✓	✓	✓
Ectoparasiticides	✓	✓	✓	✓	✓		
Premix/Supplements	✓	✓	✓	✓	✓		
Laboratory	✓	✓	✓	✓	✓	✓	✓
Practical experience (see legend below)	a,b,c,d,e,f	a,b,c,e,f	a,c,d,e,f	a,b,c,d,e,f	a,b,c,d,f	a,b,c,d,e,f	a,b,c,d,f
Quality Experience							
TGA compliance	✓	✓	✓	✓	✓	✓	✓
NATA compliance				✓			
FDA compliance	✓	✓		✓	✓	✓	✓
EU / PIC/s compliance			✓	✓	✓	✓	✓
NZMAF (ACVM)				✓			
ISO compliance		✓	✓	✓	✓	✓	✓
Educational qualifications							
Microbiology	✓	✓	✓			✓	
Chemistry		✓		✓	✓		
Pharmacy							
Biochemistry	✓	✓	✓	✓	✓		✓
Audits							
Available to conduct **interstate** audits in Australia	✓	✓	✓	✓	✓	✓	✓
Available to conduct **overseas** audits	✓	✓	✓	✓	✓	✓	✓

Practical experience legend:

(a) short run, multifaceted operations, (b) long run dedicated equipment, (c) small company experience, (d) large company experience, (e) veterinary manufacturing experience, and (f) veterinary manufacturing experience as a consultant.

Khristapour (Kris) ALCHIAN

Kris holds a Bachelor of Science degree with Majors in microbiology and biochemistry, as well as the equivalent of a Diploma in Mechanical Engineering, from the California State Polytechnic University.

Kris has over 30 years' experience in managing food and veterinary pharmaceutical companies. During this period he has designed and developed a number of manufacturing plants including the recent protein fractionation and purification plant.

Specific experience and areas of expertise include:

- molecular biology and genetic engineering
- design and development of food and pharmaceutical manufacturing plants
- auditing veterinary pharmaceutical manufacturing
- auditing various manufacturing production and processing systems which will require different materials and line separation
- designing Master Document, Quality assurance and Quality control systems.

Alastair DOWLING AAIMS

Alastair Dowling is a medical scientist with more than 30 years of diverse experience in the pharmaceutical, veterinary chemical and medical device manufacturing industries.

Following work in laboratories in the public and private sectors, he established a consultancy specializing in environmental microbiology and then co-founded a pharmaceutical manufacturing company producing a range of sterile and non-sterile products.

This resulted in hands-on knowledge of manufacturing procedures together with the corresponding establishment, application and surveillance of Quality Systems to local and international standards as well as validation of GMP procedures.

He is experienced in the auditing of manufacturer and supplier Quality Systems, both locally and overseas, to Australian, EU & US standards, including GMP, ISO 9001, ISO 13485 and MDD 92/43/EEC (CE Mark).

Wendy FREE B.Sc M.Tech Mngt MASM FAOQ

Wendy holds tertiary qualifications in science (B.Sc Biochemistry/Biotechnology/Life Sciences) and Technology Management (M.Tech Mngt). She has more than 25 years' experience in the medicines manufacturing industry with the last ten as an independent consultant. She has extensive hands-on documentation, training, implementation, utilisation and auditing experience in PIC/s and APVMA GMP (including liquid dose forms and industrial microbiology), with additional expertise in a number of allied areas including ISO 13485, ISO 22716, as well as troubleshooting, scale up and safety and regulatory aspects of product development.

Wendy currently holds executive roles in a number of biotechnology businesses including OzStar Therapeutics (Glyconmedics USA) and Bioactive Solutions and is affiliated with several Queensland universities, a community reviewer for the Cochrane Collection, a Business Mentor and Expert Network Member for Accelerating Commercialisation, Community Panellist for QCAT, a Voluntary Park Ranger for Logan City Council and an active member of Australian Society for Microbiologists (Cosmetic and Pharmaceutical Special Interest Group), and maintains membership of RACI, Australian Organisation for Quality and Association of Therapeutic Goods Consultants.

Philip Andrew MARSHALL BSc(Hons) PhD FRACI CChem MAICD

Philip is a Fellow and chartered chemist with over 35 years commercial experience having held senior executive positions within multi-national companies in the areas of drug discovery and development, manufacturing, quality assurance, compliance, international scientific & regulatory affairs, IP and product commercialisation. He has extensive and hands-on experience in the development and manufacture of all therapeutic sterile and non-sterile dosage forms, (including vaccines), liquids, solids and complimentary medicines.

Specialities and interests include:

- GMP, GLP audits
- technical advice on pharmaceutics, product development, process analyses and manufacturing issues
- product development concept to commercialisation, including scale-up and validation, risk mangement and in patents.

Philip is also a member of several professional organisations including a Fellow of the RACI, Association of Therapeutic Goods Consultants and the Australian Institute of Company Directors.

Tony ROWLAND B.Sc.

Tony has over 40 years senior management experience within the pharmaceutical and medical devices industry in training, manufacturing, R & D, engineering and packaging. He has extensive experience in factory management and the preparation of facilities and personnel for regulatory inspections. Tony conducts regular audits to GMP and ISO 9000 standards on behalf of a wide range of clients.

Louise WHITE B.App.Sc., Grad. Dip. Qual.Man., CPIM.

Industry Experience: 13 years' experience in a sterile vaccine manufacturing company, CSL and 15 years within SeerPharma responsible for GMP consulting and training. While in industry, Louise held roles in Virology R&D, Bacterial Vaccines Production, Quality Control and Production Planning. She has experience in tissue culture (viral vaccines), fermentation (bacterial vaccines), and Quality Control.

As a partner in SeerPharma, Louise has worked with biopharmaceutical organisations to design and implement Quality Management Systems to both FDA and European cGMP standards. She has also worked on many major validation projects for both sterile and non-sterile multinational companies to international GMP standards.

Louise has been formally trained in auditing and has been conducting APVMA licensing audits since the program commenced.

Steve WILLIAMS B.Sc., MQSA, Grad. Dip. Quality Mgt

Steve has been involved in management of pharmaceutical manufacturing and quality assurance for over 40 years in both international and domestic pharmaceutical companies as a Senior Quality Assurance and Manufacturing Manager. He currently manages SWA Biopharma, an independent QA compliance consultancy and has formal qualifications in Quality Management and Biochemistry.

Steve has practical experience in the manufacture and quality control of multiple dose forms from sterile, biologicals and non-steriles. He regularly conducts GMP and Compliance audits to APVMA, TGA/PICs and ISO 9000 standards on behalf of a wide range of clients. He has particular strengths in risk management, quality assurance, validation, training and sterile manufacture. He regularly conducts GMP audits and training internationally, particularly in Asia.

THERAPEUTIC GOODS ADMINISTRATION (TGA)

PLEASE NOTE: *TGA no longer conducts GMP audits of veterinary manufacturers who are not also licensed by the TGA, except where such audits are necessary under the Mutual Recognition Agreement (MRA) on conformity assessment between Australia and the European Community (EC).*

For further information on these audits, please contact the APVMA on (02) 6210 4899 or mls@apvma.gov.au or refer to the heading 'Discretion to accept reports from recognised regulators' on webpage https://apvma.gov.au/node/1074 and heading 'Exporting to Europe under the MRA' on webpage https://apvma.gov.au/node/19641.