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	J Montgomery	T Rowland	L Rudd	R Warren	I Wheatley	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,e	a,b,c,d,f	a,b,c,d,f	a,b,c,d,f	a,b,c,d,e,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.**

APVMA-AUTHORISED GMP AUDITORS' PROFILES

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.

APVMA-AUTHORISED GMP AUDITORS' PROFILES

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.

John MONTGOMERY H.N.C

John holds an HNC for Applied Biology Science (Microbiology/Biochemistry). He has over 20 years of experience in manufacturing, analysis and quality including auditing in the veterinary, blood fractionation, food and minerals industries.

John has experience in development / implementation and management of veterinary and laboratory QMS to GMP/GLP requirements and with the application of quality system standards such as ISO9000 and ISO17025 (NATA). John also has experience with AQIS and OGTR compliance.

John is also a qualified external lead auditor (QMS). John has served with a number of multinational animal health companies including Fort Dodge and Intervet/Schering-Plough in various capacities including Quality Manager

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.

Lex RUDD

Lex has tertiary qualifications in science (chemistry) and business administration. He has 46 years of experience in manufacturing, research and quality assurance in the pharmaceutical industry. He has also been involved with the accreditation of pharmaceutical manufacturing facilities by TGA (Aust), FDA (USA), HPB (Canada) and the MHRA (UK). Lex has specialist knowledge of sterile products manufacture, but has no experience in vaccine manufacture.

Before becoming a consultant, Lex held positions within industry such as research chemist, QC chemist, QA Manager (13 years at David Bull / Fauldings), general manager and technical director. In 1989, he began consulting, trading as Pharmscience. In the last 27 years Pharmscience has provided products and services to some 200 companies in Australia and Asia. As a consultant Lex has provided assistance to companies manufacturing all therapeutic dose forms and medical devices. Lex is a member of the Parenteral Drug Association.

APVMA-AUTHORISED GMP AUDITORS' PROFILES

Rob WARREN

Rob Warren holds a chemistry diploma from UTS and is a Fellow of the Royal Australian Chemical Institute.

His 40+ year career has encompassed many aspects of the pharmaceutical industry including quality assurance, research and development, natural plant derived drug research, technical management and regulatory affairs.

Rob has served with a number of multinational pharmaceutical companies including Roche, SmithKline Beecham and Wellcome. He has also served as Chief Chemist to Blackmore's manufacturer, Tabco Pty Ltd.

Subsequently Rob became a Pharmaceutical Adviser in the NSW Health Department where he specialised in GMP auditing and licensing of pharmaceutical companies to both Australian and international standards. He was authorised as a GMP Auditor by the TGA when the Commonwealth Therapeutic Goods Act 1989 was ratified, and later set up Eden Consulting (a private consulting group engaged in regulatory affairs and GMP) helping new veterinary companies to establish, operate and attain government licences to manufacture therapeutic goods.

Ian S. WHEATLEY **M.Sc, FQSA, MRACI**

Industry Experience: 15 years research with CSIRO Division of Animal Production; over 30 years in the veterinary and human pharmaceutical industries (Manufacturing/QA/QC/IT/Product/Development/ Regulatory) covering all APVMA categories (1 to 6) of veterinary manufacture; 24 years consulting in animal health and pharmaceutical industries. Positions held have been Technical Director with the Upjohn Company and Operations Director of Schering-Plough Animal Health.

A close involvement with Industry Associations such as Animal Health Alliance, APMA, and PMAA, has been maintained over the years. Past member of the NSW Poisons Advisory Committee for >22 years. Assisted in the writing of the codes of GMP for both the human and veterinary industries. Previously represented industry on the APVMA Manufacturers' Licensing Scheme Industry Liaison Committee, now representing the auditors on the committee.

Consulting Experience: 24 years consulting to the Veterinary Chemical Industry, experienced in GMP, GMP auditing, GMP training and a NATA Assessor in the areas of chemistry, pharmaceutical and biological testing for 30 years as well as having wide experience in the Pharmaceutical Industry. Good practical experience in GMP.

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.

APVMA-AUTHORISED GMP AUDITORS' PROFILES

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 900 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 refer to http://www.apvma.gov.au/consultation/international.php