Australian Government

Australian Pesticides and Veterinary Medicines Authority

APVMA–authorised GMP auditors

Manufacturing Licensing Scheme

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Table 1: APVMA–authorised GMP auditors

Name	Address	Phone number	Fax number	Mobile number	Email
Kris Alchian	PO Box 28 Forestville NSW 2087	(02) 9452 1551		0418 692 543	kris@alchianconsulting.com.au
Ladule Donato	PO Box A184 Arncliffe NSW 2205	0469 789 519		0469 789 519	jladule@hotmail.com
Stephen Firmer	Asia Pacific Consultants Pty Ltd PO Box 116 Lane Cove NSW 1595	(02) 9420 4951		0452 211 766	firmers@a-p-c.com.au
Hilary Fong	PO Box 571 Beecroft NSW 2119	(02) 9872 6056		0416 239 868	hilary.fong@gmail.com
Wendy Free	Quality Matters Safety Matters Pty Ltd PO Box 7028 Loganholme QLD 4129	(07) 3806 1297	(07) 3806 1297	0439 782 869	talktous@qualitymatterssafetymatters.com.au
Michael Lee	101 Kenthurst Road Kenthurst NSW 2156	0407 161 704		0407 161 704	gmp101@bigpond.com
Justine Mann	J. Mann Consulting Pty Ltd PO Box 2553 Rowville VIC 3178	0423 781 732		0423 781 732	justine@jmannconsulting.com.au
Bronwyn von Hellens	56 Cooper Crescent Rochedale QLD 4123	0414 843 559		0414 843 559	b.vonhellens@gmail.com

Name	Address	Phone number	Fax number	Mobile number	Email
Louise White	SeerPharma Pty Ltd Level 1, 38–40 Prospect Street Box Hill VIC 3128	(03) 9897 1990	(03) 9897 1984	0438 125 801	louise.white@seerpharma.com.au
Steve Williams	SWA Biopharm P/L Level 11 655 Elizabeth Street Melbourne Vic 3000	0417 116 476		0417 116 476	steve@swabiopharm.net.au

Experience and qualification profile

Table 2: APVMA–authorised GMP auditors – experience and qualification profile

Experience	K Alchian	L Donato	S Firmer	H Fong	W Free	M Lee	J Mann	B von Hellens	L White	S Williams
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,b,c,d ,e,f	a,b,c,d ,f	a,c,d,e ,f	a,b,c,d,f	a,b,c,d,e	a,b,c,d,e	a,b,c,d,e ,f	a,b,c,d ,f
TGA compliance	✓	✓	✓	✓	✓	✓	✓		✓	✓
NATA compliance		✓					✓			
FDA compliance	✓	✓	✓			✓	✓		✓	✓
EU/PIC/s compliance		✓	✓	✓	✓	✓	✓	✓	✓	✓
NZMAF (ACVM)										
ISO compliance			✓	✓	✓	✓	✓	✓	✓	✓
Microbiology	✓	✓		✓	✓		✓		✓	
Chemistry				✓		✓				
Pharmacy			✓							
Biochemistry	✓	✓		✓	✓	✓	✓	✓ (Biology)		✓
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 auditor declared profiles

Khristapour (Kris) Alchian B.Sc, Dip.Eng(Mech)

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 several 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.

Ladule Donato B.Med.Sci. AIMS.

Ladule is a medical scientist specialised in medical microbiology and biochemistry with over 15 years' experience in pathology, R&D, quality, manufacturing and technical management.

Following his works in laboratories in Australia and abroad, Ladule has worked for several pharmaceutical companies accredited by the TGA, FDA and APVMA, manufacturing, biologicals, chemicals and radiopharmaceuticals for humans and veterinary uses. He was also instrumental in establishing 2 sterile manufacturing facilities, where he was particularly instrumental in writing, reviewing and executing URS, IQ/OQ/PQ for Autoclaves, WFI, HPW, HVAC, filling lines, fermenters and aseptic validations, developing QMS documentation, GMP training and GMP audits readiness of the facilities, through to licensing.

Stephen Firmer B.Pharm (Hons), PhD

Stephen has over 25 years of experience in the pharmaceutical, veterinary and medical device industries including senior roles managing manufacturing, quality, logistics and informatics systems as well as time as a TGA lead inspector. He has extensive experience in the Asia Pacific and South Asia Region. Stephen conducts regular audits to PIC/s GMP and ISO standards on behalf of a wide range of clients. Stephen is also a member of several professional organisations including ARCS, Association of Therapeutic Goods Consultants and ISPE.

Hilary Fong B.Sc., M.Sc, MRACI, MASM

Hilary holds Bachelor of Science majoring in Biochemistry and Microbiology and Master of Science in Biochemistry from the University of New South Wales. After graduation, Hilary started his professional career in research and development in Biotechnology and QC in beverage manufacturing before stepping into the cosmetic and pharmaceutical (solid and liquid dosage form) industries, in many disciplines including radiopharmaceuticals, medical device, sterile manufacturing, medical affairs and veterinary vaccine production.

Over the past 35 years, Hilary has worked in QC/QA, and from quality management systems to manufacturing, technical support and as medical science liaison in parenteral nutrition.

Hilary is trained as an assessor in ISO9000 series under Standards Australia and in Auditing Sterile Manufacturing of Medical Device under the TGA.

Most recently, Hilary works as a freelance QMS consultant in Complementary and Veterinary Medicines; as well as a trainer in Certificate III and IV in Pharmaceutical Operations, having been qualified with Certificate IV in Training and Assessment (TAE 40116).

Hilary is a chartered member of Royal Australian Chemical Institute (CChem MRACI) and member of the Australian Society for Microbiology (MASM). He has been on the Committee of the CAPSIG NSW since 1992 and is also a lay member of the UNSW Gene Technology Research Committee.

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.

Michael Lee B.Sc. (Hons), MSc, MRACI, MASM

Michael holds a B.Sc. (Hons) degree in Biochemistry and a master's degree in Analytical Chemistry from the University of New South Wales. Michael has also completed a 6-month course on HACCP based Food Safety, with the University of Newcastle. Michael has a more than 40 years' work experience, including pharmaceutical industry (19 years), food industry (10 years) and veterinary medicine industry (7 years) and GMP/QA/HACCP system consultancy (2 years). Additionally, Michael is fluent in Cantonese, Mandarin and English. Michael has held the following roles:

Pharmaceutical industry

- QC Chemist
- QA/QC Manager
- Technical Service Manager
- Asia Pacific Quality System Manager (Japan)
- Asia Pacific GMP/Quality Systems/Auditor Training Manager (Japan)

Product categories – prescription drugs, OTC, beauty care, health care, cosmetic, laundry and food supplements.

Food industry

- Technical and Quality Systems Manager

Product categories – breakfast cereals, soybean beverages, vegetarian foods and peanut butter.

Veterinary medicine industry

- Global Compliance (GMP/Quality System) Auditor – Asia Pacific and Europe

Audit categories – API supplier, contract manufacturers, logistic service provider and analytical laboratory.

Justine Mann (B.App.Sc, MBA)

Justine has over 20 years' experience in the pharmaceutical industry as a Senior Quality Operations Director and Technical Operations Manager with both international and domestic responsibilities.

Justine has had responsibility for providing technical, operational and strategic leadership to ensure compliance in accordance with US FDA, EU-TGA-PIC/s regulations and local and international standards.

Justine is currently Director of J. Mann Consulting Pty Ltd. and a Partner of Centre for Biopharmaceutical Excellence (CBE) Pty Ltd. consulting firms.

Justine specialises in developing strategic quality plans and risk management plans, focusing on remediation strategies, auditing, quality enhancements and process improvements for operational efficiency. Combining a microbiology background with an MBA specialising in business management and leadership, Justine's interests focus on developing strategic and compliant solutions.

Bronwyn von Hellens B.Hlth., MBA

Bronwyn has over 10 years' experience in the animal feed industry. Prior to this, she worked in the healthcare, blood supply and pharmaceutical industries for over 10 years. Instrumental in building manufacturing capabilities to meet APVMA GMP/GLP and FAMI-QS regulation requirements, she has successfully navigated the changing international feed/food regulatory systems over the last 8 years to ensure products continue to meet stringent quality and feed safety requirements both for sale in Australia and for export. This includes laboratories for quality control and research. She was the first person to implement the European FAMI-QS system in an Australian based company. Bronwyn is a qualified auditor and currently holds an executive role in Feed Ingredients and Additives Association of Australia.

Areas of interest:

- Feed safety (including feed fraud and defence) risk management
- Simplifying quality assurance systems to meet GMP, GLP and food safety
- Designing one quality system to meet multiple regulation bodies
- Mentoring and training
- Gap analysis to international regulation requirements
- Exporting

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

Please note: The Therapeutic Goods Administration (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 +61 2 6770 2301 or mls@apvma.gov.au or refer to Discretion to accept reports from recognised regulators and Exporting to Europe under the MRA on the APVMA website.