A190507 *David Richard Buckley* NZCS, BSc, MASM, FQSA	David Buckley & Associates Pty Ltd ABN 69103221 129 7 Catani Place, Monash, ACT 2904, www.navigategmp.com E-mail: david.buckley@navigategmp.com AUSTRALIA, Phone/fax + 61 2 6291 4626		**Rev.:** **Nov 2009**

Curriculum Vitae: David Richard BUCKLEY

1. Experience Summary

- More than 40 years in Pharmaceutical and Biological Quality Systems.
- 20 years multinational industry experience – Wyeth, Welcome, ICI
- 17 years senior GMP auditor with the Australian Therapeutic Goods Administration (TGA)
- 9 years GMP consultant GMP
- experience in pharmaceutical, vaccine biological, and medical device manufacturing and regulation
- Audited or conducted GMP training in 31 countries
- Biologicals auditing and manufacturing experience includes:
    - Blood and blood
    - Vaccines
    - Biologicals - Insulin and MCAb

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2. Major clients

- PT Bio Farma, Bandung, Indonesia, UNICEF Copenhagen (prequalification of Essential Drugs)
- Indonesian Badan POM
- Thai FDA, Thai Red Cross, Queen Sirikit Memorial Institute
- Bionet Asia (Vaccines)
- WHO(Vaccines Prequalification), Medicenes Sans Frontiers (MSF-Paris) (prequalification of Essential Drugs), UNICEF (prequalification of UN essential drugs and medicines)
- Australian Atomic Energy Scientific Organisation (ANSTO)
- Alkem Laboratories Ltd, Mumbai India, Indchemie (Daman), Medreich (Bangalore)
- Gutis Farmaceuticos, Costa Rica

3. Highlights

Missions for United nations agencies, including WHO, UNIDO and UNICEF

- Vietnam – vaccines projects
- Nigeria – yellow fever vaccine workshop
- Cuba, USA, Belgium – vaccines prequalification
- China, Bangladesh, Indonesia, Egypt, Bosnia, Nepal, Thailand (some in combination with PATH), Myanmar, Iran, Cyprus, North Korea, Oman, North Korea (DPRK)
- Vietnam – vaccines GMP and capacity building, working with CENCOBI
- India – many projects including vaccines GMP and capacity building, vaccines prequalification
- Pandemic Influenza preparedness projects
- Cyprus – GMP Training on behalf of Quintessence for the Cypriot industry and Cypriot Ministry of Health
- Egypt – Vacsera – vaccines manufactruing

World Bank

- Indonesia 2 month project working with the Indonesian Badan POM (National Agency for Drug and Food Control) project to develop the documented quality system for GMP inspection and certification to PIC/S and WHO standards

4. Qualifications and registrations

- Pharmaceutical Chemistry NZCS (Chemistry), Auckland New Zealand)
- BSc (Microbiology) (Otago, New Zealand)
- MASM (Professional Member of the Australian Society for Microbiology)
- FQSA Fellow of the Quality Society of Australasia (FQSA)
- Quality Management System Lead Auditor: International Register of Certificated

5. Experience with regulatory agencies

1984 – 1988 **4 years with NSW Dept Of Health, GMP auditor**

In February 1984 I joined the NSW Department of Health Pharmaceutical Services Section, when my supervisors were Barry Mewes, the NSW Chief Pharmacist, and Mr John Lumby, the NSW Deputy Chief Pharmacist. I worked at the level of Pharmacist 2 in the GMP inspection unit which regulated the NSW Cosmetic and Pharmaceutical Acts and regulations, and main duties were the inspection of premises licensed for manufacture of pharmaceuticals.

I worked with other GMP auditors such as Bruce Graham, Barry Mewes, and John Martin. My namesake Dr David Buckley took my position when I left in 1988 to join the National Biological Standards Laboratory (NBSL, which became the TGA) of the Commonwealth Department of Health.

During the period in service with NSW DoH I inspected approximately 100 companies ranging from 2-3 employees to multinationals such as Telectronics, Kolmar, Domedica, Cochlear, Reckitt and Colemans, Johnson and Johnsons, Sandoz, Pfizer, Parke Davis/Warner Lambert with greater than 100 and up to 700 employees.

1988 - 2000 **12 years with NBSL/Therapeutic Goods Administration of Australia - Senior GMP Auditor. Editor of Codes of GMP**

In August 1988 I joined the NBSL section concerned with GMP inspections and GMP standards settings as a Senior GMP Auditor

A major NBSL function in the period 1988 to 1990 was the revision of the Code of GMP.

I served on the Code of GMP review committee (headed by Bruce Graham) which met regularly. I was the Code of GMP sub-editor and did all the desk top publishing that resulted in the final 1990 Code of GMP. During this period the revised Therapeutic Goods Act was developed which resulted in a uniform federal licensing system for all therapeutic goods manufacturing in Australia for corporations.

In 1990 I carried out the development in collaboration with the Blood Banking industry and was Editor and Principal Author of the Code of GMP for Blood and Blood Products and introduced a system of Australia-wide licensing for human blood collection for production of plasma for further processing y CSL.

In 1993 after Bruce Graham retired I took over as Editor of the Codes of GMP, and Secretary of the GMP subcommittee of the Therapeutic Goods Committee.

During the time 93-98 I was author of the various Manufacturing Principals which instrument gave effect to the Minister's requirements for GMP to be followed, and Editor and Principal Author of the Code of GMP for Sunscreens, Compressed Medical Gases, Good Distribution Practices, and Editor of the Code of GMP for Human tissues.

A requirement of the Minster and the Therapeutic Goods Committee was that any proposed Code of GMP, or change in the Act or regulations be given as wide a consultation as possible before the change was agreed and implemented. A consensus view was to be obtained and a regulatory impact assessment made.

6. 2000 – 2009 Consultancies and retainers

David Buckley and Associates Pty Ltd now has signed a new retainer agreement with one major client PT Bio Farma (Indonesia) to provide 30 days training and GMP consulting on seasonal influenza and EPI vaccines in period 7-12/2007. The Associates who will conduct the work will be David Buckley FQSA (15 days GMP training only), and Dr Gordon Firth, BVSc, MSc (15 days veterinary services for SPF chickens, small and large animals, vaccine risk analysis and management, validation protocol development, QC laboratory proficiency verification).

Major clients that provide more than 75% of current work

- UNICEF Copenhagen (prequalification of Essential Drugs)
- Medicenes Sans Frontiers (MSF-Paris) (prequalification of Essential Drugs)
- Micronutrient Initiative of India
- Other UN agencies (Eg UNIDO, UNFPA) and World Bank projects

Projects in the last 6 years included

- Bangladesh, India and China - 7 missions for UNICEF - assignment for qualification of pharmaceutical manufacturers and GMP training.
- World Bank - Indonesia 2 month project working with the Indonesian Badan POM (National Agency for Drug and Food Control) project to develop the documented quality system for GMP inspection and certification to PIC/S and WHO standards.
- WHO assignments in Belgium, Bosnia, China, Cuba, Cyprus, DPRK, Egypt, India, Indonesia, Iran, Japan, Nepal, Myanmar, Nigeria, Sultanate of Oman, Switzerland, Thailand, United States of America, Vietnam (various projects including sterile and non-sterile pharmaceuticals, and vaccines manufacture and supply)
- WHO committee member for revision of Codes of GMP relating to biologicals and vaccines.