


A190507 <i>David Richard Buckley</i> 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.: Jan 2008
Curriculum Vitae: David Richard BUCKLEY			

1. Experience Summary

40+ years Quality Systems and GMP experience in pharmaceutical, vaccine biological, and medical device manufacturing and regulation, comprising - 20 years industry experience, 17 years senior GMP auditor, and 7 years GMP consultant.

Biologicals auditing and manufacturing experience includes:

- Blood and blood products eg Hyperimmune plasma (antisera antitoxin separation and purification), FFP, antihemophilia agents, platelets separation, etc;
- Vaccines (bacterial – D, T, P, Hib; viral – rabies, polio, MMR, Yellow fever; and recombinant – HepB),
- Biologicals - Insulin and MCAb.



2. Highlights previous 5 years

Missions for WHO in

- 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
 - GMP, training and capacity building
 - Workshops on GMP for NRA GMP auditors
 - Various projects including sterile and non-sterile pharmaceuticals, and vaccines manufacture and supply
- Vietnam – vaccines GMP and capacity building, working with CENCOBI
- India – many projects including vaccines GMP and capacity building, vaccines prequalification
- Pandemic Influenza preparedness projects

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.

Projects, Missions for UNICEF and MSF included

- Bangladesh, India and China
 - 7 missions for UNICEF - assignment for qualification of pharmaceutical manufacturers and GMP training.
 - prequalification GMP assessments for essential drugs and medicines
- China, North Korea, Bangladesh, India – prequalification for supply to UN agencies (antibiotics, anti-TB, anti-malarials, essential drugs and medicines)

3. 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)
- Medicines Sans Frontiers (MSF-Paris) (prequalification of Essential Drugs)
- Micronutrient Initiative of India
- Other UN agencies (Eg UNIDO, UNFPA) and World Bank projects

Current retainers:

- Alkem Laboratories Ltd, Mumbai India
- Subcontractor for Rockwell Automation in respect of GMP training and validation on computers used in manufacturing pharmaceuticals.
- PT Bio Farma (vaccines) Indonesia - GMP training and consulting
- Medreich PLC (UK) to provide GMP training for six Medreich Ltd pharmaceutical manufacturing sites in India
- Indchemie Pte Ltd (Mumbai India) to provide GMP training and advice to three sites in India

Retainers held but now expired more than 24 months

- Biological Evans (Vaccines) Hyderabad, India. GMP training and consultancy
- Haupt (Wolfrathausen) Germany – sterile and non-sterile pharmaceuticals GMP consultancy and GMP training
- Gutis Pharmacos - Costa Rica – – sterile and non-sterile pharmaceuticals
- Sigma Pharmaceuticals – sterile and non-sterile pharmaceuticals
- Cypriot Ministry of Health – Capacity building and GMP training

4. Employment

1964	Wyeth Pharmaceuticals (American Home Products NZ) (QC laboratory)
1969	Burroughs Welcome (Roseberry, NSW Australia) (QA/QC)
1976	ICI Pharmaceuticals (Villawood, NSW, Australia) (QA/QC)
1984	4 years with NSW Dept Of Health, GMP auditor
1988	12 years with Therapeutic Goods Administration of Australia - Senior GMP Auditor. Editor of Codes of GMP
2000	Consultant on quality systems in general and Good Manufacturing Practice, Good Laboratory Practice, Good Distribution Practices for pharmaceutical products, biological products (including blood collection and processing, and vaccines), quality systems for medical devices, active pharmaceutical ingredients and quality control laboratories with Pharma Systems International.

2001 David Buckley & Associates Pty Ltd conducting GMP consulting for pharmaceuticals, vaccines, biologicals, medical gases, blood and blood products and medical devices. (Currently CEO)

5. Qualifications and registrations

- NZCS (New Zealand Certificate of Science (Chemistry) Auckland Technical Institute, New Zealand)
- BSc (Bachelor of Science (Microbiology) Otago)
- 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 Auditors, IRCA A002974