David Richard Buckley

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Title:

Curriculum Vitae: David Richard BUCKLEY

1. Experience Summary

40+ years pharmaceutical and medical device GMP experience comprising - 20 years industry experience, 17 years GMP auditor, and 3 years GMP consultant.

2. Consultancies during last 3 years

- India and Indonesia – May - June 2005 – vaccines GMP project work, and GMP inspections on behalf of UNICEF
- Indonesia, Cyprus and Cuba April 2005 for consultation work and as invited speaker for Proceasep 2005 in Cuba (cleaning validation workshop and a paper on formal investigation techniques)
- Indonesia February and March 2005 major vaccines project in India with 4 experts 9including veterinary, viral vaccine, and bacterial vaccines experts) and consultation for viral, bacterial and recombinant vaccines project
- India – Jan 05 vaccines manufacturing consultation for DPT, combination and viral vacciens
- Bangladesh Dec 2004 – 4 week UNICEF assignment for qualification of pharmaceutical manufacturers.
- Indonesia – Oct/Nov 2004 - 8 week project working with the Indonesian Badan POM (National Agency for Drug and Food Control), Jl. Percetakan Negara No.23 - Jakarta 10560, Indonesia, on a World Bank-funded project to develop the documented quality system for GMP inspection and certification to PIC/S and WHO standards.
- Australia – July/September 2004 subcontractor for Rockwell Automation in respect of GMP aspects of computers used in manufacturing pharmaceuticals.
- Australia July/August/September 2004 – 6 week project as expert witness on GMP
- Costa Rica – June 04 Gutis Pharmaceuticals
- Australia – May – June 2004 - consultancy for Sigma Pharmaceuticals Limited.
- Germany –April 2004 GMP consultation for Haupt Pharmaceuticals, Wolfrathausen, Germany.
- India, March 2004 due diligence inspections on behalf Micronutrient Initiative (Canada) in India
- Australia Sep, Nov and Dec 2003, Jan Feb 2004 – major pharmaceutical manufacturer – independent product review in partnership with TGA.
- India Nov 2003 inspections for UNICEF in India
- Germany, Nov 2003 – major German generics manufacturer,
- Belgium Sep 2003, major multinational vaccine manufacturer assessing GMP standards gap analysis and risk assessment on behalf of World Health Organisation, V&B ATT.
- Costa Rica – Sep 2003, design phase of new USD30m multipurpose factory to meet US FDA standards
- Australia - August 2003 – consultancy and retainer work for largest Australian-owned manufacturer.
- Iran, Indonesia, India – July and August 2003 – assignments for WHO and UNICEF, investigation of vaccines manufacturing conditions, and GMP training of GMP inspectors. Setting up MSc curriculum in GMP for Iranian MoH at 3 Iranian Universities.
- India – June – prequalification GMP inspection of Vaccine manufacturer for WHO, medicines manufacture for UNICEF (4 week assignment)
- Cyprus – May – June 2003, solid dose manufacturing plant qualification trials and GMP training in preparation for German regulatory audit .
- Germany – May 2003, 3 weeks for a large contract generics manufacturer, internal auditor training, gap analysis and risk assessment for FDA project.
- Costa Rica – April and February 2003 – consultancy on construction of large, multipurpose pharmaceutical factory for manufacture of sterile and non-sterile, in association with French and German GMP consultants.
- India - March and April 2003 – World Health Organisation (WHO) project on assessment and GMP audit of Oral Polio Vaccine manufacturers in India with assessment of National Control Laboratory at Kasauli.
- Indonesia February 2003 – WHO GMP audit of vaccine manufacturer, oral polio, tetanus, measles, diphtheria, and pertussis vaccine. Lead by Dr Nora Dellepiane (WHO), with Dr Morag Ferguson (NIBSC, UK),
- Cyprus January 2003 – consultancy on construction and qualification of solid dosage forms pharmaceutical factory.
- India - Nov 2002 - Kasauli and Pune Vaccine inspection in Pune India for WHO Vaccines and Biologicals ATT unit, and inspection of Indian Government laboratory and vaccine facility at Kasauli, India.
- Cuba - Oct 2002 Vaccine inspection for WHO V&B ATT, assessment of National Control Laboratory and National Regulatory Agency.
- Australia October 2002 GMP Workshop Sydney, (CHC) - Sole facilitator and trainer at a 2 day GMP seminar conducted for the Complementary Health Care Council for its member industry on the PIC/S Guidelines on GMP
- Cyprus - September 2002 -A 4 week mission for the Cypriot Ministry of Health conducting GMP training
- Vietnam - August 2002 - A 3 week GMP training mission for WHO (WPRO) for CENCOBI, the Vietnamese human vaccine regulator. Solo trainer

- India - July-August 2002 (SEARO) - A three week mission for WHO with a 2 week GMP training workshop
- Nigeria July 2002 (WHO V&B ATT) A one week GMP training workshop for the Nigerian GMP inspectors and the Yellow Fever Vaccine production facility. Solo GMP trainer but with support from Ms Emma Uramis (WHO GTN co-ordinator, Vaccines and Biologicals, and Mr Lahouari Belgarbi, WHO V&B ATT)
- Iran/Egypt - June 2002 - 4 week GMP training for the Iranian Ministry of health and Education, together with formal classroom lectures, in Tehran and Isfahen. One week follow up in Cairo at WHO EMRO, with Mr Peter Graaff, Regional Advisor WHO EMRO, Nasr City.
- Switzerland April 2002, Working in Geneva with WHO EDM team, to finalise the 9 GMP training modules that I prepared in Dec 2001.
- China - (April 2002 Souzhou) and Taiwan (May 2002 Hsinchu) - 2 x 2 week consultancy for Wyeth Pharmaceuticals including GMP audit
- India - April, 2002)One week in Hyderabad for Recombinant Hepatitis BsAg vaccine inspection with Dr Nora Dellepiane (WHO V&B ATT) leader, Dr Jaspal Sohkey (WHO SEARO) and Dr Morag Ferguson (NIBSC, UK)
- Bangladesh - Feb 2002 - A 5 week mission consisting of GMP inspections for UNICEF prequalification and a GMP training workshop for industry and Bangladeshi GMP inspectors.
- Switzerland - Dec 2001 - Project for WHO, Geneva to write GMP training modules, 3 for Water for Pharmaceutical Use, 4 on Validation, one each QC Validation, and Inspection of QC laboratory
- Egypt - November 2001 - A one-week GMP training workshop sponsored by WHO for GMP inspectors from eg, Egypt, Syria, Lebanon, Libya, Yemen, Jordan, Pakistan, UAE, Oman.
- India - 3 weeks October 2001 - Hyderabad to check recombinant Hepatitis B sAg vaccine manufacturers, Uttar Prudesh to check Oral Polio Vaccine manufacturer and advise Government of India GMP inspectors.
- Australia Oct 2001 - Medical device (high risk) for TUV Product Services (California) for CE marking in Sydney,
- Bosnia-Herzegovina - Oct 2001 - A one week GMP training workshop for WHO for GMP inspectors from Central Europe
- Japan - September 2001 – 3 week mission for WHO to prequalify vaccine manufacturers for supply to UN agencies (measles vaccine at Biken and BCG vaccine at BCG Tokyo), together with assessment of the MoHWL
- Cyprus - July 2000, 4 week GMP training for The Republic of Cyprus MoH GMP Inspectors
- Sultanate of Oman – GMP training on behalf of WHO for the Omani Ministry of Health.
- Nepal, Myanmar, and India 2000 – Training of GMP Inspectors on behalf of WHO

3. 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.
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	3 years: with: David Buckley & Associates Pty Ltd conducting GMP consulting for pharmaceuticals, vaccines, biologicals, medical gases, blood and blood products and medical devices.

4. Qualifications and registrations

NZCS New Zealand Certificate of Science (Chemistry) Auckland Technical Institute, New Zealand

BSc Bachelor of Science (Microbiology) Otago

Fellow of the Quality Society of Australasia (FQSA)

Professional Bodies Professional Member of the Australian Society for Microbiology (MASM)

Previously held Quality Management System Lead Auditor: International Register of Certificated Auditors, IRCA A002974