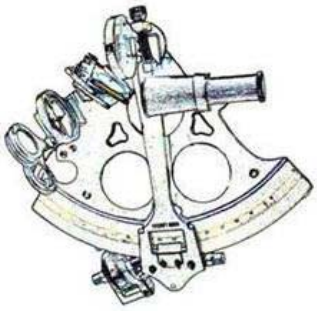
Navigate GMP with DBA™
Capability statement



Name of organisation

David Buckley & Associates Pty Ltd
ABN 69103221129
7 Catani Place, Monash, ACT 2904, AUSTRALIA Phone/fax + 61 2 6291 4626
Directors: David and Gillian Buckley

CONSULTANCY SERVICES:

Consultancy services to the pharmaceutical products and cosmetic manufacturers that include:

Scientific and Regulatory Affairs

- QA, QC and GMP for TGA, EMEA, APVMA, and FDA
- QA audits on GMP, G(QC)LP, GXP
- Compliance audits against world best practices in pharmaceutical GMP and QA
- Technology transfer
- Due diligence – contract manufacture and product acquisition
- Expert reports on GMP
- Expert Witness on GMP in litigation
- Materia medica
- Nursing practices

Associates

We have associates signed up who specialise in microbiology, regulatory affairs, pharmaceutics, pharmaceutical factory architecture, design and building, project management and patent matters:

Our associates can undertake a wide range of additional activities including:

- Manufacturing troubleshooting
- Regulatory affairs
- Adverse drug reaction and investigation
- Due diligence audits and product acquisitions
- Regulatory submissions: pharmaceutical, OTC, complementary medicines and veterinary products
- Audits for compliance with global best practices in pharmaceutical GMP and QA
- Critical appraisal of registration data to WHO, UNICEF, EMEA, TGA, FDA and APVMA
- requirements
- APVMA authorised GMP Auditor
- Product and Intellectual Property evaluation
- Expert reports on pharmaceutical compound, process and composition patents
- Expert Witness in international patent litigation cases
- Medical device registration
- Medical Device registration and medical device design dossiers