Links

Regulators

- TGA www.tga.gov.au
- FDA www.fda.gov
- FSANZ
 <u>www.foodstandards.gov.au</u>
- NICNAS
 <u>www.nicnas.gov.au</u>
- APVMA
 <u>www.apvma.gov.au</u>
- AQIS
 <u>www.aqis.gov.au</u>

Industry Associations

- ASMI
 <u>www.asmi.com.au</u>
- QNIA
 <u>www.qnia.com.au</u>
- CHC
 <u>www.chc.org.au</u>
- PDA
 <u>www.pda.org</u>
- ASCC
 <u>www.ascc.com.au</u>



CN Quality Consulting

TGA License Release for Supply

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CN Quality Consulting

Assisting Industry Achieve their Goals

Consultants for the Pharmaceutical, Complementary, Veterinary, Agricultural, Industrial, Cosmetic and Food Industries

Tel: 0410 065 125

Our Services

We provide an encompassing service that enables our clients to source reliable support from one supplier. We provide a wealth of experience and expertise in Research, Technical, Regulatory and manufacturing environments in the following industries:

- Pharmaceutical and complementary medicines
- Veterinary and agricultural products and systems
- Cosmetics
- Industrial Chemistry
- Foods

Research

- New product development,
- Support for redevelopment of existing products,
- Trouble shooting for manufacturing scale up,
- Evaluation of new starting materials and equivalency documentation for raw material substitution.

Technical

- Quality systems design, implementation, management, advice and support.
- cGMP training and implementation
- Review and design of product dossiers, specifications, Technical / GMP agreements and Validation Master Plans
- Provide release for Supply services by a qualified person.

Regulatory

- Advise on registrations and listings
- Support in Post-market surveillance audits from claims substantiation
- Dossier preparation and submission of dietary supplements and medicines for Europe
- Development of Starting materials and Finished product specifications,
- Stability study design and facilitation

- Preparation of Consumer Medicine Information leaflets, Label compliance, MSDSs and claims advice
- Analytical method development and validation support
- Design and facilitation of Process validation documentation and testing.

Manufacturing

- Advice to Manufacturers on manufacturing processes and procedures according to Australian and international codes of GMP, ISO and HACCP.
- Provide pre-audit of Manufacturing facilities in preparation fro regulatory audits (eg. TGA, FDA, ISO) and support response process to regulators post audit.
- Design and preparation of Quality documentation
- Implementation of Training of Quality Systems in manufacturing plants.
- Design and preparation of manufacturing and packaging documentation.

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