

## Available Quality Consulting Services

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The Blood Service - TS Quality provides a service which helps to develop and maintain a quality system. This is achieved through various stages during the consultation process.

### **Stage 1 - Conducting and reporting on gap analysis of manufacturing processes**

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- On site inspection;
- Analysis of protocols and practices;
- Written report on the audit or gap analysis investigation, and;
- Presentation of the report which will include the observed status, the identified gaps and if requested, the recommended actions required to achieve conformity with cGMP and increase the likelihood of complying with Therapeutic Goods Administration regulations;
- Review and report on corrective action plan response to gap analysis.

### **Stage 2 - Training of staff in Quality Systems and cGMP**

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- Training:
  - Develop an appropriate induction training program for all staff in cGMP;
  - Develop, document, implement the system of training which includes identifying training needs and developing an appropriate training program for all staff;
  - Provision of training and to act as an information resource to staff on quality, cGMP and use of problem solving tool
  - Promote and facilitate cGMP, continuous improvement and organisational learning.
- Assist in the facilitation of strategies to encourage staff involvement in process innovation, redesign, improvement to enhance organisational efficiency and effectiveness.

### Stage 3 - Quality Systems Consulting Support

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- Work with customer (manufacturer) to set up cGMP compliant Quality Systems planning, development, implementation, management, review and improvement of Quality Systems.
- Assist in the development of Quality Systems in accordance with applicable policies, procedures and standards which can include:
  - Quality policy
  - Develop, document, implement (and maintain if required) the Quality System and quality policy
  - Auditing
  - Change Control
  - Continuous Improvement
  - Facility Management
  - Document & Records Management
  - Equipment Management
  - Management Review
  - Materiel Management
  - Product Recall
  - Process Development
  - Process Control

### Stage 4 - Licence Application

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- Assist customer to apply for a TGA Licence (and/or accreditation) where applicable.
- Assist with responding and closing out TGA (and/or accreditation) audits in order to successfully achieve licensing (or accreditation) as required.

**Maria Maroulis**  
Quality Manager  
National Transplantation Services  
Australian Red Cross Blood Service

P: 03 9863 1676 | F: 03 9863 1670 | M: 0409 805 200

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