

ISO 13485 Consultancy Approach

Stage 1- Gap Analysis

- ✓ Review current manufacturing processes with HOD.
- ✓ To enable Consultant to understand the work culture and Client's processes with ISO 13485 Requirements.



Stage 2- Design and Development

- ✓ Provide ISO 13485 Understanding training.
- ✓ To plan and development the ISO 13485 documents that fully comply with ISO 13485 requirements



Stage 3- Implementation

- ✓ Provide Implementation planning
- ✓ Providing the Implementation support on the ISO 13485 documents
- ✓ To perform internal ISO 13485 audit training and support of internal audit



Stage 4- Management Review Support

- ✓ To perform Management review in compliance with ISO 13485 requirements



Stage 5- External Audit Support / Close out advice

- ✓ To assure the Client obtain the ISO 13485 certificate and reply to Certification Body audit report