

D-722-4-2 SUPPLIER EVALUATION_V1

Supplier Evaluation Audits is a tool that allows companies to measure the ability of suppliers /OEMs to manufacture products as required. Audits performed by Vee Care are executed by full-time IRCA certified ISO 13485 lead auditors.

The audit is based on ISO 13485:2016 and cover all aspects of the standards. Specific country guidance may be included per customer request e.g., FDA MDSAP/QRS.

- Quality Manual and Objective
- Medical Device File
- Document and Record Control
- Management Review
- Personnel Training
- Equipment and Facilities Maintenance
- Work Environment Control
- Batch Record
- Risk Management
- Design Control/ Design Transfer
- Purchasing Control
- Production Control
- Process Control -Validation
- Inspection, Measuring and Test Equipment
- Software Validation
- Product Traceability and Identification
- Product Preservation
- Non-Conforming Product Control
- Data Analysis
- CAPA