

Turn-key projects: Scope of services

Stage	Activities
1	Project management
1.1	Assignment of Project Manager
1.2	Project communications
2	Project initiation
2.1	Contract review
2.2	Contract amendment and signature
2.3	Manufacturing resources planning (MRP)
2.4	Project management in ERP system
3	Manufacturing readiness / engineering services
3.1	Design of jigs and fixtures
3.2	Product tree definition
3.3	Process flow definition
3.4	Preparation of standard operating procedures (SOP)
3.5	Training of technicians / inspectors
3.6	Equipment maintenance
3.7	Product configuration control
4	Manufacturing services
4.1	Laser cutting
4.2	Laser welding
4.3	Heat treatments
4.4	Surface treatments
4.5	Clean room assembly from components to sterilized products
5	Purchasing materials and services
5.1	Supplier: raw materials, off-the-shelf products
5.2	Sub-contractors
5.3	Sterilization
5.4	Inventory management
6	Quality Assurance (based on ISO 13485)
6.1	Verification of purchased products
6.2	Equipment validations
6.3	Process validations
6.4	Suppliers and sub-contractors qualification
6.5	In-process control
6.6	Preparation of SOPs for Product final inspection
6.7	Final product inspection
6.8	Control of non-conforming products
6.9	Management of Customer's complaints
7	Logistical Support
7.1	Final packaging, labeling and storage of finished Product
7.2	Product distribution to Customer's clients