

ISO 13485:2016 - LIST and DESCRIPTION of
QUALITY MANAGEMENT SYSTEM FLOW CHARTS

ISO 13485:2016 Flow Chart #	Description
Note	The 5 main flow charts (FC-xxx-xxx in bold) provide a summary of the QMS while dealing with the 5 clauses of ISO 13485:2016 and integrating information from the QMS Docs package.
Note	The remaining 18 flow charts expand on the 5 main ones and deal with understanding what can be done to meet the requirements by providing examples of typical activities and processes.
FC-400-001	The flow chart demonstrates the elements of Clause 4 dealing with the quality system, documentation requirements, medical device file, control of documents, control of records, assigns the responsibility for the system and points out the supporting procedure, the forms and flow charts.
FC-420-001	Outlines the documentation requirements, identifies the procedure and the forms used to organize, control and retain the documents and records.
FC-500-001	The flow chart demonstrates the elements of Clause 5 dealing with management responsibility, assigns the responsibility for the process and points out the supporting procedure, the forms and flow charts.
FC-510-001	Provides a typical business process map that shows the core business processes and the management and support processes required for business system management.
FC-512-001	The flow chart shows the management functions and their interactions in the QMS that provide commitment and focus on the customer.
FC-530-001	Provides typical examples for an organization's quality policy, quality objectives, operating principles and direction that demonstrate the commitment of management to the QMS.
FC-540-001	Outlines the planning of quality objectives and with the P-D-C-A approach provides typical examples of objectives at the relevant functions in a company.
FC-550-001	Provides typical SME Organization chart. The chart can be included as attachment A-550-001 in a Quality / Operations Manual.
FC-600-001	The flow chart demonstrates the elements of Clause 6 dealing with the management of resources, assigns the responsibility for the processes and points out the supporting procedures, the forms and flow charts.
FC-610-001	Outlines the 5-M resource contributors to effective realization of the products and points out the relevant QMS activities and procedures.
FC-700-001	The flow chart demonstrates the elements of Clause 7 dealing with product realization, assigns the responsibility for the process and points out the supporting procedures, the forms and flow charts.
FC-710-001	Provides an example of a manufacturing process flow and includes the typical steps from receipt of order to provision of product and service support.
FC-710-002	Shows a product realization service / quality plan with typical activities from customer needs assessment to final release of product and invoice submission.
FC-720-001	Outlines the customer related processes, includes activities from customer inquiry to delivery and points out the supporting procedure and flow charts.

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FC-730-001	Outlines the design and development processes, includes typical activities from design input to customer production order and points out the supporting procedures, forms and flow charts.
FC-730-002	Provides an example of the sequence of product / service development activities for the Stage-Gate processes from idea to launch.
FC-740-001	Outlines the purchasing process for the procurement of products / services from external suppliers, including out-sourced processes required for production orders and points out the supporting procedures and forms.
FC-750-001	Outlines the system control points and the process control activities to show the controlled conditions required to realize process control objectives for products / services and points out the supporting procedures and forms used.
FC-750-002	Provides an example of a process control system that identifies the process steps with control / inspection points and the control / inspection points where data is generated for typical manufacturing processes.
FC-758-001	Outlines the identification and traceability process and points out the activities and supporting procedures required to achieve status, identification and traceability of products.
FC-800-001	The flow chart demonstrates the elements of Clause 8 dealing with monitoring, analysis, and improvement, assigns responsibility for the process and points out the supporting procedures, the forms & flow charts.
FC-850-001	Outlines an example of a planning cycle showing the activities for the continual improvement of the QMS via the analysis of data, and points out the supporting procedures, forms and flow charts required to be successful.
FC-852-001	Provides an example to show the sequence and the typical steps used for an effective corrective action process.