Organization of this manual is the same as the sectional organization of ISO 13485:2003. Close correspondence between the manual and the standard helps to demonstrate compliance of the system and ensures that all clauses and requirements have been addressed systematically.

Note that each section of the manual is an independent document with its own page numbering, approval and release signatures, and revision level.

You have probably noted that some sections have titles that are not exactly the same as in the standard. The changes are intentional, to better describe the content of the section, or to use a more established and traditional terminology.

QUALITY SYSTEM MANUAL

QUALITY SYSTEM OPERATIONAL PROCEDURES

Instructions in 'Procedures' folders explain which procedures are mandatory and which are optional. After you remove a procedure from the system make sure to coordinate pertinant references in the Quality Manual and in other operational procedures.

QOP-85-04 Corrective and Preventive Action

MANUAL RECORDS/FORMS

(these are printable, manual forms)

QF-42-02-1 Device Master Record Index

QF-73-01-1 Design Project Plan and Schedule

QF-73-01-2 Design Review Report

QF-73-02-1 Design Risk Analysis

QF-73-03-3 Engineering Change Notice (ECN)

QF-75-01-1 Production Work Order

QF-75-04-1 Service Report

QF-82-02-1 Internal Audit Checklist

ELECTRONIC ISOXpress RECORDS/FORMS

(these forms are data entry windows in ISOXpress software)

ER-42-01-1 Document Control Record (ISOXpress system)

ER-56-01-1 Management Review Report (ISOXpress system)

ER-56-01-2 Quality Objectives Record (ISOXpress system)

ER-62-01-1 Training Program Record (ISOXpress system)

ER-62-01-2 Personnel Training Record (ISOXpress system)

ER-62-01-3 Competency Certification Program Record (ISOXpress system)

ER-62-01-4 Personnel Competency Certification Record (ISOXpress system)

ER-74-01-1 Approved Supplier List (ISOXpress system)

ER-74-01-2 Supplier Nonconforming Product Records (ISOXpress system)

ER-74-01-3 Supplier Corrective Action Requests (ISOXpress system)

ER-76-01-1 Measuring Device Records (ISOXpress system)

ER-82-02-1 Internal Audit Plan (ISOXpress system)

ER-82-02-2 Internal Audit Report (ISOXpress system)

ER-82-02-3 Internal Audit Finding Report (ISOXpress system)

ER-83-01-1 Product Nonconformity Report (ISOXpress system)

ER-85-02-1 Customer Complaint Reports (ISOXpress system)

ER-85-03-1 Corrective/Preventive Action Records (ISOXpress system)