Organization of this manual is the same as the sectional organization of ISO 13485:2016. 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 MANAGEMENT SYSTEM MANUAL

QMS OPERATIONAL PROCEDURES AND FORMS

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-xx-xx are Quality Operational procedures

QOP-xx-xx-Fx are traditional, manual (MS Word files) forms that you must open in Word or print out to fill them out.

EF-xxx-x are electronic data entry forms in the IMSXpress software. These are the windows with data entry fields (text boxes, drop-downs, date pickers, etc.) that you open when you want to create a new record or open ann existing record.

QOP-41-01 Risk Management
EF-380-1: Risk Project
EF-380-2: Risk Case

QOP-41-02 Risk Reduction Actions and Controls
EF-380-3: Risk Reduction Action

QOP-41-03 Validation of Software
QOP-41-03-F1 Software Validation Plan/Report
QOP-41-03-F2: Software Validation Test Case

QOP-42-01 Control of Documents
EF-120-1: New Document
EF-120-2: Document Revision Record

QOP-42-02 Control of Document Changes
EF-390-1 Change Request

QOP-42-03 Control of Records

QOP-42-04 Device Master Record
QOP-42-04-F1: Device Master Record Index

QOP-56-01 Management Review
EF-150-01: QMS Management Review
EF-150-02: Review Items
EF-150-03: Quality Objective

QOP-62-01 Competence, Awareness and Training
EF-160-1: Document Training Program
EF-160-2: General Training Program
EF-160-3: Job/Position
EF-160-4: Job/Position Certification
EF-160-5: Personnel Record

QOP-62-02 Work Instructions and Training

QOP-63-01 Equipment Maintenance
EF-270-1: Equipment
EF-270-2: Maintenance Program
EF-270-3: Maintenance Work Order
EF-270-4: Maintenance Part

QOP-64-01 Production and Work Environment

QOP-71-01 Design Transfer and Production Planning

QOP-71-02 Process Risk Management
EF-380-1: Risk Project
EF-380-2: Risk Case
EF-380-3: Risk Reduction Action

QOP-72-01 Order Processing and Review