Quality management system (QMS) structure

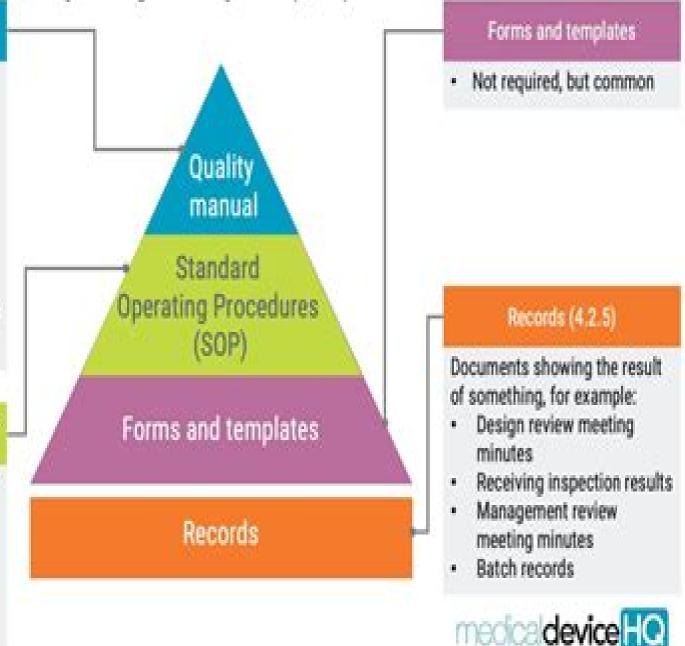
The quality manual (4.2.2)

- The starting point of your QMS (where to start reading)
- The scope of the QMS (exclusions, nonapplicabilities)
- The procedures of your system
- Description of the processes
- · Documentation structure

Standard Operating Procedures (SOP)

Procedures that tell you how to work with, for example:

- Document control
- Design control
- Complaints
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Medical Device Iso Manual

Minjie Lin



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