

 = required DOCUMENTS (25)  
 = required RECORDS (62)

## Setting the Stage



## Plan ➡



## Do ➡



## Check ➡



## Act ➡

## Annex A (informative)

Comparison of content between  
2003 & 2016 editions

## Annex B (informative)

Correspondence between ISO  
13485:2016 & ISO 9001:2015

## Bibliography

Citations [1] – [13]

<https://www.concentricglobal.co/iso13485>

# Iso 13485 Pocket Reference Guide

**RC Schank**



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