response from SDO

PERSPECTIVE FROM ISO/TC 210

Peter Linders, chair
Health software + QM and RM

• Health software = medical device software plus ...
• Health software is not a health product - neither is medical device software
  • HSW can become a product with labeling, UDI, IfU, etc. → SaMD / SaHD
  • HSW integrated in a product is part of that product → SiMD / SiHD
• Validation, clinical evaluation, etc. can only be done at product level
• Quality mgt and risk mgt aim for safe, effective & secure products
  • Regulatory requirements for QM and RM apply at product level, yet can trickle down
  • Regulatory requirements for HSW that is not in a medical device can differ
• Standards for health software must be coherent with standards for QM and RM

QM = quality management; RM = risk management; HSW = health software
SaMD = software as a medical device; SiMD = software in a medical device
SaHD = software as a health device; SiHD = software in a health device