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