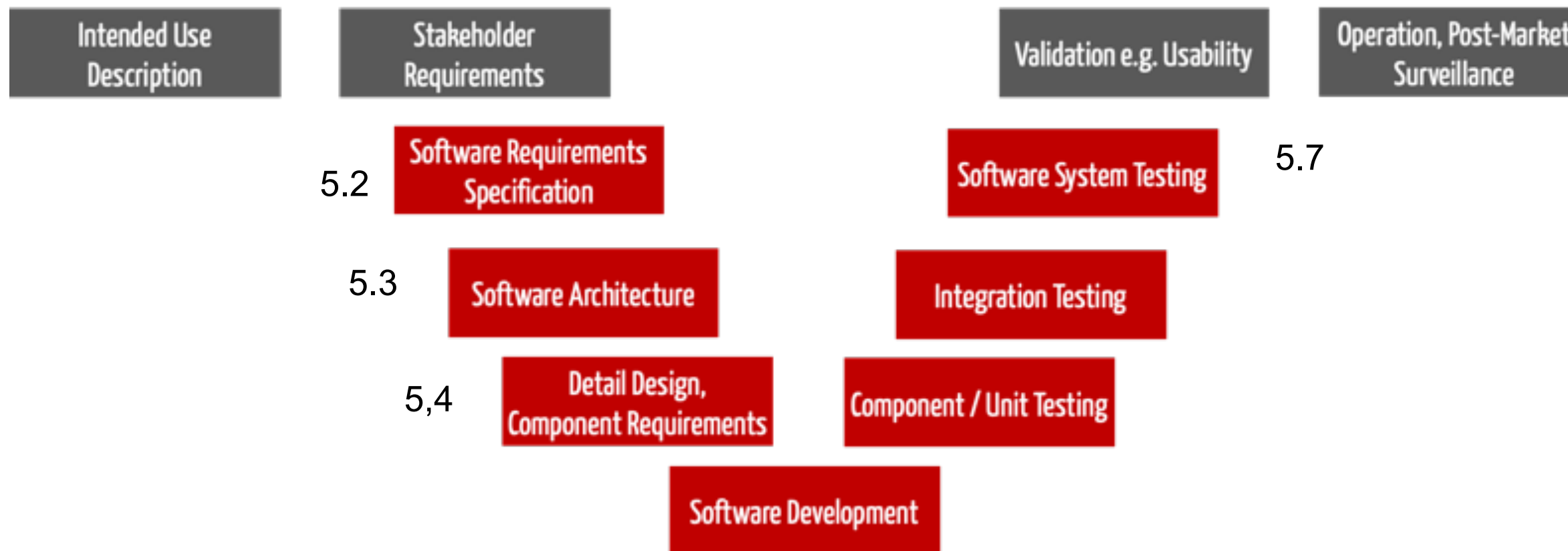


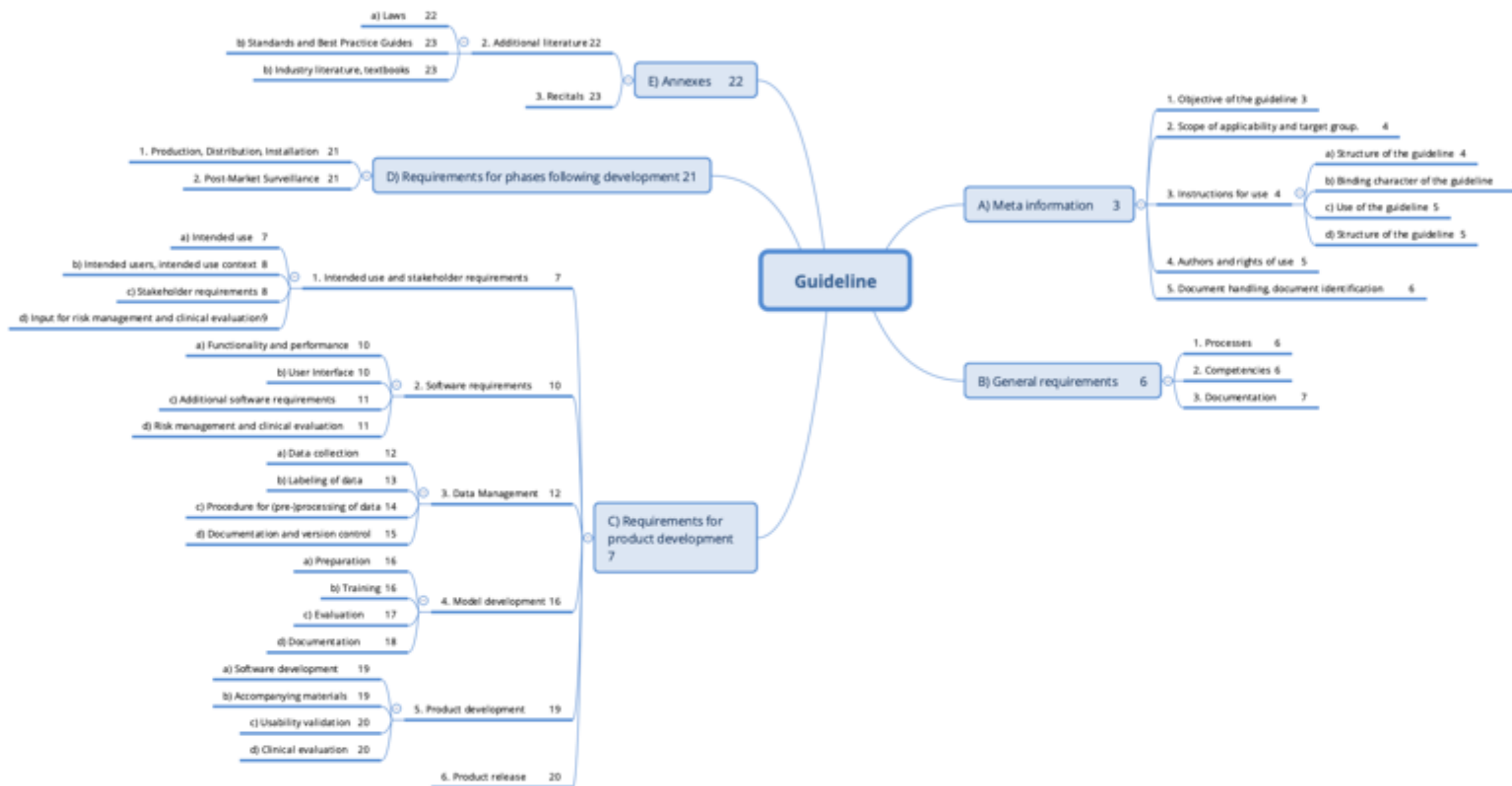
MDR & ISO 13485 (Quality Management Systems)

FGAI4H-H-034-A02
Brasilia, 22-24 January 2020



IEC 62304: Software Life Cycle Processes

Structure of the Guideline



Proposals

- provide sample documentation
- generate sub-document that only contains AI specific checklist item
- consider checklist items to be included in the topic description document
- discuss whether checklist becomes part of AI4H framework
- checklist poses the questions to be answered. Give standardized guidance how to fulfill these checklist items including development of tools to determine compliance

Next steps

- compile high level overview document (5 pages) for IMDRF referencing other documents (best practices, guidelines)
- compile union of different checklists (Pradeep, Christian,)
- map "checklist items" to best practices (specifically to the domains / topic groups)
- validate results with topic group and update framework accordingly
- add priorities for different markets