SCSD Portfolio

Summary

Learning Outcomes (LO)

- These characterize what you will gain by passing the course.
- In SCSD the LOs structure the course and we will spend around two weeks focusing on each of the LOs in turn.
- The grading scheme for the assessed work is also structured by the LOs where the grade for each LO contributes 20-30% of the final grade.
- To pass the course you need to demonstrate you have achieved the LOs. Each LO has some grading criteria associated with it.
- Remember demonstrate a criterion you just need to show an example you do not need to do the full task.

Learning Outcome 1

Describe the structure of typical standards and regulation for a range of domains of application.

1. Range of domains considered
2. Diversity of the chosen domains
3. Clarity of identifying relevant standards
4. Quality of the analysis of standards to identify overlaps and conflicts
5. Quality of the analysis of standards to identify differences and gaps

LO1 – what goes in the portfolio?

- Some discussion of potential domain/application
  - Medical device/blood pressure measurement
  - Automotive/sleeping driver detection
  - Cloud/authorization management
- Some discussion of the requirements e.g. for the blood pressure we might want good performance but also accessibility, usability, sustainability etc.
- Good list of standards and what they do e.g. ISO 13485, 14971 and 62304 together with the areas they cover and how they interact.
- Gaps e.g. for the blood pressure we perhaps don't list accessibility e.g. PD ISO/TR 25555:2024

Learning Outcome 2

Explain and motivate the goals set by regulation and standards and how they influence the requirements for compliant systems.

For a group of related standards:

1. Quality of the analysis of a group of standards for comprehensiveness
2. Quality of the analysis of a group of standards for interdependency
3. Quality of the overview of how do they constrain the systems
4. Quality of the explanation of the motivation for constraints on products
5. Quality of the explanation of the motivation for constraints on process

LO2 – what goes in the portfolio?

- Some mapping of the dependencies between the standards you have chosen e.g. that one standard requires the use of another or references or there is some other interaction.
- Pointing out gaps and the standards that could fill those gaps (mostly driven from the nature of your chosen app).
- Constraints, so for medical devices the class of the device constrains the process and puts requirements on the device.
- Explaining how the use context of the product is likely to require the sorts of constraints on the product (application)
- Usually this will require you to point out how some process constraint helps ensure some property of the system. E.g. usina a constrained programming language eliminates some sources of failure.

Learning Outcome 3

Given an example system and standard or regulation, justify what evidence would be needed to comply with the regulation or standard

For a group of related standards:

1. Quality of the analysis of what needs to be evidenced
2. Quality of the identification of the means of evidencing
3. Quality of the analysis of how much evidence is necessary
4. Quality of the analysis of how evidence can be shared across standards
5. Quality of the analysis of the effort needed to generate appropriate evidence

LO3 – what goes in the portfolio?

- Here you should think about what needs to be documented. Often you can get this from the QMS or the Lifecycle you choose.
- You should provide some account of the sort of information that will be used as evidence (e.g. test results, performance analysis, user trials, …)
- Many standards differentiate requirements on evidence on the basis of context of use. E.g. medical device class helps determine evidence. In IEC 61508 the SIL does this.
- For example, the risk analysis often feeds into the development process standard.
- You should make some attempt to estimate the level of effort (you can do this in a qualitiative way (no effort, little, moderate, high effort) along with a justification.

Learning Outcome 4

Given an example system development process and standard or regulation, evaluate how effective the process can be in generating evidence of compliance to the standard or regulation

- Coverage of key aspects identified in (3)
- Where/How is evidence produced and managed in the process
- Assessment of quality of products
- How well is the process instrumented?
- What is possible in terms of identifying improvement

LO4 – what goes in the portfolio?

- Here you should look at the lifecycle or development process standard and perhaps the QMS and identify where the evidence you need is produced.
- Discuss how the evidence is produced – what techniques, where any by whom.
- Think about how the QMS or other audit/review process helps assure the process and product is adequate
- Identify the sorts of measures in the process that would help you identify if some part of the process is falling below required standards.

Summary

- This is a very brief outline of the contents of the portfolio
- It is also a summary of what you have learned throughout the course.