LO4 Tutorial – week 1

Recall LO4: **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 the LO3 activity.
- 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.

The table below lists some relevant software development standards. Recall you can download personal copies of any of these standards at: https://bsol-bsigroup-com.ezproxy.is.ed.ac.uk/ (you will be required to authenticate to the University to access BSI information).

STANDARD	MEDICAL DEVICE	GENERIC SOFTWARE
LIFECYCLE	IEC 62304	ISO 12207
RISK MANAGEMENT	ISO 14971	ISO 16085[1]
QUALITY MANAGEMENT	ISO 13485	ISO 25002 (also 25010, 25019)

1. From the previous activity you will have identified some key risks associated with your chosen domain and product. You should review these and then continue with this activity. You can work together with a partner and consider one of your product/domain combinations. We will take 10 mins of working in pairs on each of these topics followed by 5 mins of group discussion. We will probably only have time for two topics today but will follow up next week. The idea is to take some of the requirements and risks you have identified and see how they are dealt with in a lifecycle.
2. Choose an appropriate lifecycle this could be one of the ones in the table above or a lifecycle more closely related to your product/domain combination. Probably the most important parts will cover the **technical management process** and the **technical process.** In ISO 12207 these are covered in clauses 6.3 and 6.4 of the standard. In ISO 62304 this is clause 5. Take some time to review these. [10+5 mins]
3. Looking at the requirements and risks for your product/domain combination you have identified in the LO3 activity. Can you identify where and how these requirements and risks would be dealt with in your chosen lifecycle? [10+5 mins]
4. For your given lifecycle and product/domain combination how do you think quality of the product could be measured in the lifecycle. What information would need to be gathered and where would this take place in the lifecycle? [10+5 mins]
5. For your product/domain and lifecycle, can you identify some key areas of the lifecycle where improvement might be necessary and what information you would need to collect to identify when some aspect of the process needs improvement. [10+5 mins]

[1] Many of you may be interested in systems with embedded AI components. The risk management standard for this is ISO 23894:2023.