US perspective: Possible uses of assurance cases for medical devices

3rd European Workshop on Safety of Programmable Electrical Medical Systems:
"Assurance Cases for Medical Devices"
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Newcastle University

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Raising awareness in the US

- February 2008 – FDA workshop on Assurance Cases
- March 2008 – AdvaMed Software conference
- May 2008 – IQPC Software Conference
- July 2008 – University of Minnesota workshop on Assurance Cases
  http://www.umsec.umn.edu/events/Summer-Software-Symposium-2008
- SEI/Carnegie Mellon work on dependability case
  http://www.sei.cmu.edu/pcs/dependable.html
  https://buildsecurityin.us-cert.gov/daisy/bsi/articles/knowledge/assurance/643-BSI.html

Convincing manufacturers of the value

- Assurance cases can be a powerful tool
- Better understanding of device quality*
  - If it is known what is needed for assurance up front, then we will know when we are done
- Know more about quality* during development
  - Early indication of risks

*insert safety, dependability, security, connectivity, compliance, etc.

Prepare the regulators

FDA sees the benefit

- Assurance cases provide a framework for communicating and reviewing “complex” device designs (safety and effectiveness)

However…

Is the regulator ready to receive an assurance case?

We agree it can be valuable, but…

- There is still a lack of understanding, discipline and methods
- Some of the questions
  - From the manufacturer:
    - Who determines what evidence is necessary?
    - How much evidence is enough?
    - Is the assurance case complete?
    - What is the expense of building an assurance case?
    - What about the lawyers?
  - From the regulator
    - What is the criteria for an acceptable assurance case?

Possible next steps

- Manufacturers
  - require suppliers (COTS) to provide assurance cases for their engineering needs
  - use assurance cases internally to provide assurance/confidence to management
  - pilot in a submission by providing an assurance case for a feature or functionality
- Clinicians
  - Use assurance cases for procurement purposes (connectivity, networked instruments)
- Farther down the road
  - E-submission
  - E-review

Questions:

- Where is the US relative to European adoption of assurance cases for medical devices? (both from manufacturer and regulatory point of view)
- What are/were the barriers to adoption?