Barriers to the adoption of systems engineering in the healthcare industries

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Introduction

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  - Thorough grounding in systems engineering.
  - Subject Matter Expert for system reliability in the United Kingdom’s Ministry of Defence (Procurement Executive).
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- 20 years since at Cambridge Consultants.
  - Managing development projects in Drug Delivery, Diagnostic Instruments, and Medical Devices.
I joined Cambridge Consultants in 1996, the year that the EU’s Medical Devices Directive (MDD) and the US’ Quality System Regulation (QSR) started to make an impact on the healthcare industries:

- I attended a course on the QSR in California.
- “Just” high integrity engineering or systems engineering.
  - Many of the standards recommended to meet the new requirements were Mil-Stds.
- 20 years later, I am still surprised by the different view taken by many in the healthcare industries.
For many healthcare companies, compliance appears to be an overwhelming concern

- Companies operate a compliance process rather than a development process.
- Some examples:
  - Rigid approach to compliance
    - Specification structure to facilitate traceability rules, not architecture
  - Avoidance approach to compliance
    - Nearly the whole project is spent in “Concept Generation” with a rush to get documents approved at the end
    - Dual Documentation Systems
      - One for development
      - One for compliance
  - Design Reviews mis-purposed as stage gate reviews
  - Specifications called “Design Inputs”
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FDA’s Waterfall model of design control:

- **User Needs**
- **Design Input**
- **Design Process**
- **Design Output**
- **Medical Device**
- **Validation**
- **Verification**
- **Review**
Is systems engineering compatible with healthcare regulation? Let's have a look at the evidence:

- The MDD ask that medical device development follow a process.
- The FDA’s QSR ask that medical devices also follow a process.
- Both also have specific requirements for activities such as risk management, design reviews, verification, specification and validation.
- Therefore there appears to be no reason why system engineering would not be adopted from a compliance perspective.
The healthcare engineering industries are different from other engineering industries in that in many cases engineering is not the dominant or lead discipline.

- In healthcare developments quite often the lead professionals are not engineers.
  - In drug delivery pharmaceutical chemists tend to be, quite properly, the leading professionals.
  - In the diagnostics industry quite often companies and developments are led by biochemists.
- Systems engineering comes naturally to most engineers, even if they have not been taught it.
  - Once introduced to systems engineering, it appears to be a obvious modus operandi for them.
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Although systems engineering may be a compliant approach to the medical device development regulations, this is not always evident to the regulators themselves.

- Again, this may arise from the fact that many regulators are not engineers and have come from the life sciences.
- Also as the pharmaceutical industries have been longer established than the medical device industries, and certainly longer regulated, then there is a tendency for the regulatory direction to follow that of the pharmaceutical industries rather than that of engineering industries.
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Because of these influences, often the ability of systems engineering to provide a compliant approach to medical device design compliance is overlooked or not understood

- Rigid approach to compliance
  - A company adopts one specific interpretation of a regulation
- The intent of the regulation is not understood
Symptoms of avoidance

In addition to the environmental factors, there are specific issues that repeatedly appear in a Systems Engineering/adverse environment:

- Document centric not data centric
- Reasons behind documentation not understood
  - Specification TBDs
- No configuration management or at best, weak version control
- Confuse approvals with versioning
- Poor document management tools and processes that only recognise documents when (fully) approved
Is the term “Systems Engineering” impenetrable to outsiders?

The definition of Systems Engineering is necessarily holistic, but lacks the element of “so what do we actually do”

- Life cycle management
- Architecting
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How should Systems Engineers react to this situation?

- **Education**
  - Especially the regulators
    - Show how SE meets the intent of the regulations
Qantas grounds A380s after Singapore emergency landing

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**How should Systems Engineers react to this situation?**

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  - Especially the regulators
    - Show how SE meets the intent of the regulations
- **Engage with your Quality and Regulatory teams**
  - Show how in a well-run SE development, evidence of compliance is a natural output of SE activities
  - Read the original regulation
  - Take back control, it’s “just” engineering