Getting Started with Systems Engineering and Requirements Management

Paul Kostek

Systems Engineer

IEEE Senior Member

Bio

- 40 + years in systems engineering
  - Aerospace
  - Medical devices
  - OEMS, suppliers, start-ups & consulting
- IEEE roles
  - Seattle Section Chair 1990
  - IEEE-USA President 1999
  - IEEE Board of Directors 1999
  - President AESS 2000-2001
  - VP Conferences ITSS 2002-2005

When starting/joining a project I always ask 3 questions:

What are we doing?

Why are we doing it?

How do we know when we are done?

These questions help team members to focus not just on their assignment but how it fits into the overall system.

An organizational approach to developing SE processes and standards is essential for implementation of SE. Providing access to training and adopting tools with a clear expectation of results is an essential to project success.

Product definition

    User needs capture

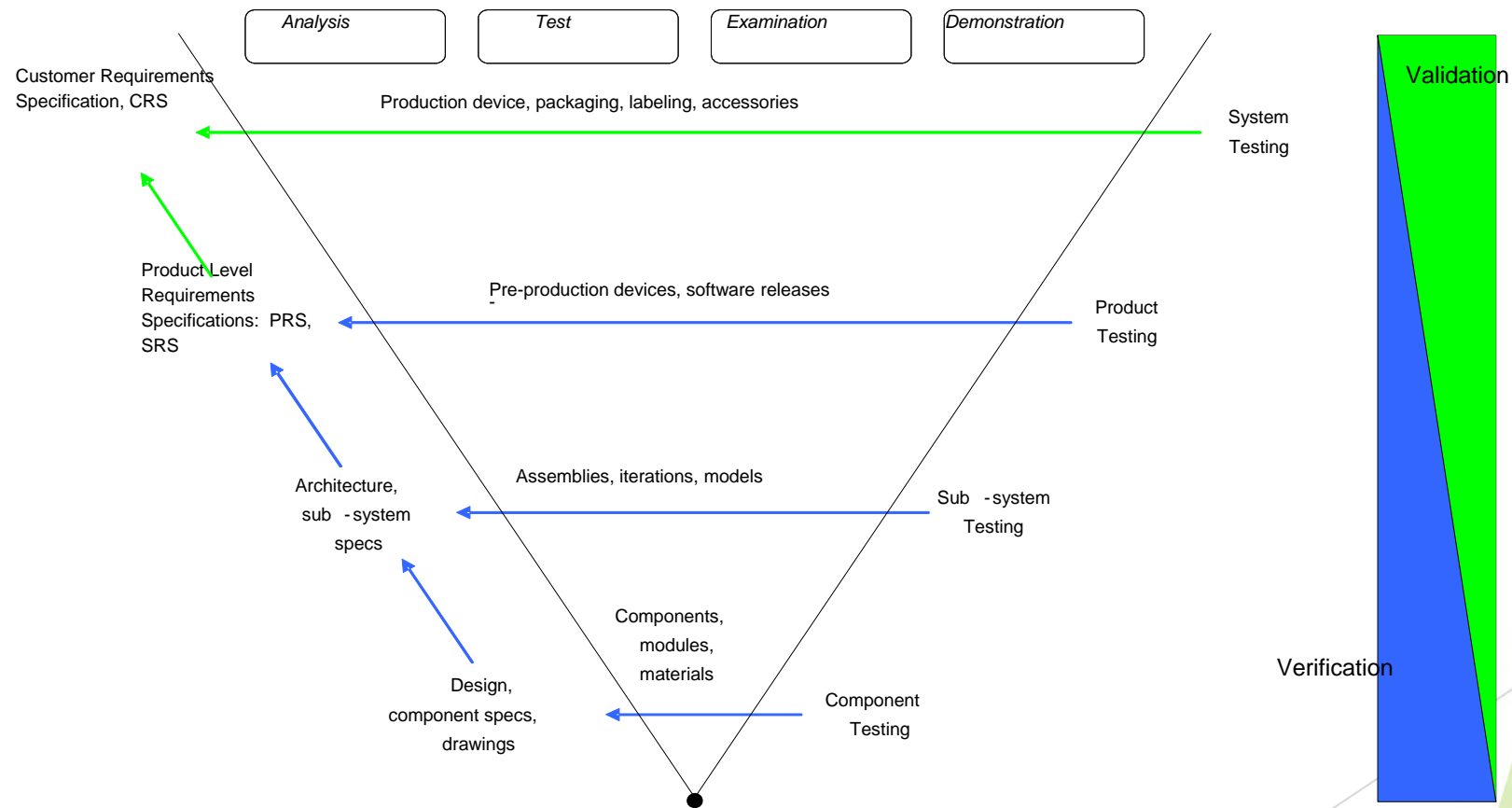   Standards and FDA related documentation

Completeness

Integration

V&V

Product life cycle – Does design support updates?

Audits – Easy to demonstrate coverage and traceability

V - Diagram

▶ Essential systems engineering activities need to be addressed in any organization

Why an SE

- SE brings systems thinking, drives architecture without bias to hardware or software

- Introduce MBSE concepts

- Understanding of how FDA regulations and IEC standards impact system, e.g cyber security and its impact on system design

- Understand the need for tradeoffs to meet current needs

- Implications of technology changes

- Allocation of requirements to subsystems

A Fool with a Tool is still a…

- First question why invest in a tool?
- Setting expectations on what a tool can deliver & how it will impact the users
- Integrating a SE tool into an organization takes time and planning
- Will not solve your problems immediately, will likely slow down development
- Requires training for team members; an admin to maintain and add functions to the tool

Tool Advantage

- Revisions and history

- Allocation of requirements from top level documents

- Incorporation of standards

- Linking and tracing

- V&V planning and storing results and linked to requirements

- Impact of changes can be seen and reviewed

Planning and Implementation

- Planning will require processes being defined for systems engineering and requirements management

- The life cycle of requirements need to be addressed – including initial release, delivery to customers, change management and revisions for technology changes

- Processes need to be rolled out organization wide and adopted by all design teams

- Expect changes to process and schedule impacts as process is implemented

- No waivers should be allowed for projects

Creating a DHF /DMR

- ▶ Using a Tool eases the generation of content for DHF/DMF
- ▶ Proper use ensures latest document versions are available
- ▶ Revision control of content is simplified
- ▶ Able to demonstrate tracing of requirements

Moving Forward

▶ Project success is driven by having requirements that are-
  Clear and verifiable

  Traced to user needs

  Linked to all sub-system requirements

  Changes controlled and managed

▶ Any tool used to collect/manage requirements should be fully supported (administration) and the project team trained on it's use

▶ The SE team also needs to be fully supported with training, well defined SoPs and future opportunities

▶ This all leads to project and company success

Thanks for Attending

▶ Questions?