PROJECT PERFORMANCE INTERNATIONAL

Medical Systems Engineering 5-Day Course

Clarity and Safety in Medical Device Development

Years of Learning in a Single Week

The potential of systems engineering is extraordinary, and creates almost unlimited opportunity for professionals with the practical skills and process understanding needed to *engineer systems and products more effectively*. PPI's approach to sharing SE uses expert presentations, discussions, and team workshop activities. We cover core areas of SE conduct, and explain how each of these elements functions within a development system. You'll discover that SE offers a rich body of sound engineering and management methods that benefit the entire enterprise.

Designed for Busy Professionals Like You

The course is designed with overall development success in mind, and balances theory with a host of practical tools, tips and pitfalls to avoid. Whilst valuable to anyone who holds development responsibility, the primary beneficiaries include:

- Project and program management
- Engineering leadership and all engineers
- Quality, security, specialty engineering areas, system testing, operations, and support.

Earn CE/CPD Credit

PMI Talent Triangle® Suggested PDUs

- 35 Technical Project Mgt
- 2 Leadership
- 3 Strategic & Business Mgt

INCOSE Certified Systems Engineering Professional (CSEP)

- 40 Continuing Education PDUs

Offering a Lifetime of Benefit

Upon course completion, participants will have the ability to create new value in many ways:

- Perform each of the major SE activities, and explain how the SE tasks are integrated into overall project execution.
- Translate fuzzy stakeholder intentions into valid and verifiable requirements, enabling manageable traceability between needs and solutions.
- View all requirements and design as a model, representable in many ways, and recognise when to invest in creation of MBSE and other formal expressions.
- Utilise SE to identify and champion the "voice of everyone" throughout the system life cycle, thereby eliminating entire classes of system risk exposure.
- Effectively apply the logic of SE to fit widely differing needs, ranging from selective use of a few key tools to substantial adoption on major developments.
- If appropriate, unleash your inner entrepreneur and use SE to launch the product of your dreams.

20,000 Professionals Trained Across 43 Countries

Presenters

Mr. Robert Halligan

FIE Aust CPEng IntPE(Aus)
PPI Managing Director, Principal Consultant & Course Presenter

PPI Founder Mr. Robert Halligan is an executive project manager, engineering manager and engineering practitioner, known internationally for his role in the advancement of SE practice. He is an authority on the strengths and weaknesses of a wide range of relevant systems engineering-related standards, and has consulted extensively in the areas of functional analysis, requirements quality and their relationship to project risk.

Mr. John Fitch

ESEP
PPI Principal Consultant & Course Presenter

John Fitch has over four decades of engineering, engineering management, consulting and training experience. John has over 20 years of consulting experience in systems engineering with a focus on decision management, requirements management, risk management, systems design, product/technology road-mapping and innovation. Original work by John on Decision Patterns is ground-breaking.

PPI Training Reviews

*"Even after years, the PPI training course remains **the reference and initial point for further learning**."*

Course participant, Germany

*"Due to the PPI training, I was quickly given the more complex projects in my company because I had the **tools to better manage and execute** these projects."*

Course participant, USA

*"Our SE approach to the entire value chain has been **impacted positively** by a significant number of the team having attended various PPI courses."*

Course participant, South Africa

Trusted Worldwide

We deliver outstanding training and consulting to many hundreds of enterprises, from Fortune100 companies (presently 18% of them) to small start-ups. PPI is a truly international company, with personnel based in eight countries, and clients across six continents benefiting from our work.

Boston Scientific · novo nordisk · Baxter · AstraZeneca · Medtronic · PHILIPS · cambridge consultants · stryker

Medical Systems Engineering 5-Day Course Outline

0. Introduction - Why Systems Engineering?

1. The System Life Cycle and Solution Development

- systems thinking
- defining “the problem”
- the solution domain: key concepts, relationships, information types and work products, Model-Based Systems Engineering (MBSE)
- Concept of Use (CONUSE)/ Concept of Operations (CONOPS)/ Operational Solution Description (OSD)/ Architectural Design Description (ADD) issues
- architectural frameworks
- relationship between problem definition and stakeholder satisfaction
- systems of systems engineering (systems of autonomously managed systems)
- waterfall, incremental, evolutionary and spiral developments
- concepts of agile, lean and concurrent/simultaneous engineering
- Product Line Engineering (PLE)
- digital engineering, digital thread, digital twin
- summary of key concepts

2. Systems Engineering Processes: Principles, Concepts and Elements

- ***workshop - principles of the engineering of systems***
- system concepts
- why MBSE and digital engineering
- SE process elements
- requirements analysis
- development of physical solution description
- development of logical solution description-MBSE: (model-based architecting/design)
- effectiveness evaluation and decision - trade studies
- specification of system elements - specification writing
- system integration
- verification and validation
- engineering management
- ***workshop - matching common activities to the SE process elements***
- work product attributes
  - requirements traceability
  - design traceability
  - test/verification traceability

3. Systems Engineering Standards

- ISO 14971 - Medical Device Risk Management (MDRM)
- ISO/IEC 15288 - Systems Engineering
- standards pitfalls and pointer

4. Requirements Analysis

- what are requirements?
- types of requirements, and how they relate to analysis, specification & design
- requirements quality attributes
- requirements languages other than natural: operational, formal
- requirements analysis (RA) - how to do it. MBSE in the problem domain
- ***workshop - context analysis***
- ***workshop - design requirements analysis (interactive whiteboard exercise)***
- ***workshop - states and modes analysis***
- ***workshop - parsing analysis of example requirements***
- requirements quality metrics
- ***workshop - functional analysis in requirements analysis***
- ERA analysis, rest of scenario analysis, out-of-range analysis, other constraints search, stakeholder value analysis
- the Concept of Use (CONUSE)/Intended Use Description (IUD)
- managing RA
- requirements analysis and management software tools
- common pitfalls in performing RA

5. Development of the System Physical Solution Description - Part 1

- technology and innovation in solution development
- configuration items
- criteria for selecting configuration items

6. Development of the System Logical Solution (MBSE In Design)

- types of logical representation
- functional analysis in design - how to do it
  - functional analysis/architecture process
  - ***workshop - physical and functional design***
- performance threads, SysML, OPM and other systems modelling languages
- state-based modelling
- n-squared charts, behaviour modelling, and other functional notations
- analysis and design software tools
- pitfalls in developing system functional solution

7. Development of the System Physical Solution Description - Part 2

- use of design driver requirements
- the system physical architecture related to the functional architecture
- facilities, procedures and people
- the specification tree
- object-oriented design
- common pitfalls in developing system physical architecture

Medical Systems Engineering 5-Day Course Outline (Continued)

- adding the detail to the design
- DFSS: e.g. Design of Experiment (DOE) and test matrices
- interface engineering
- common interfacing pitfalls

8. Effectiveness Evaluation and Decision-Making

- approach to design optimisation
  - the role of MOEs and goals
  - constructing a system effectiveness model
  - capturing utility functions
  - taking account of risk
  - iterative optimisation of design
- working with budgets, targets and ceilings
- value engineering
- ***workshop - engineering decision-making***
- multiple stakeholders, multiple uses, event-based uncertainty
- handling, in design, conflict of interest between customers and suppliers
- pitfalls in effectiveness evaluation and decision (avoiding the smoke and mirrors)

9. Description of System Elements - Requirements Specification Development

- the eight requirement specification types
- public specification standards
- specification structure principles
- good and poor terminology
- recommended DIDs and templates
- pitfalls in preparing requirements specifications

10. Engineering Specialty Integration (ESI)

- what makes an engineering specialty special?
- common engineering specialties
- a generic approach to ESI
- organisational issues of ESI
- pitfalls, and specialty engineering examples

11. System Integration

- integration planning
- alternative system integration strategies
- integration
- integration testing
- using incremental builds
- configuration audits
- qualification
- pitfalls and pointers in system integration

12. Verification and Validation

- verification and validation terms defined
- lean concepts in V&V
- technical reviews
- test and evaluation
- other verification and validation methods and tools

13. Systems Engineering Management

- Management Principles
- Engineering Planning
- Project Breakdown Structures
- Configuration Management (CM)
- Technical Program Controls
- Risk Management

14. In Closing

- systems engineering summarised
- tailoring to specific activities or projects
- getting the most out of systems engineering methods
- systems engineering capability assessment and improvement

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systems/product engineering training & consulting for project success ...