Medical Device Assurance Cases

28th-29th September 2010
Washington DC

The ASCE Approach

Assurance cases are increasingly required to demonstrate that devices, systems, services or organizations are fit for purpose. This course provides an overview of the Assurance Case approach and a practical introduction to the ASCE system.

Adelard’s ASCE (Assurance and Safety Case Environment) is a powerful, flexible and intuitive system for development and maintenance of assurance cases and delivery of assurance case reports.

ASCE supports

- Development of Claims-Argument-Evidence, and Goal Structuring Notation (GSN) arguments.
- Fine-grained linking of evidence to the argument with hypertext.
- Flexible and sophisticated reporting for efficiently creating deliverable quality custom reports.
- Navigation and validation of complex dependent information (e.g., in hazard logs or fault schedules).

Course tutor

The course will be taught by Dr George Cleland. George is Adelard’s Product Manager for the ASCE system. He has extensive experience in use of ASCE for assurance case construction and has delivered ASCE and Assurance Case training into more than 50 organizations. Each course will have a limited number of delegates to ensure a high tutor/delegate ratio.

Costs

Industry: $1,200
Government/Academic: $1,000

This price includes course notes, lunch and refreshments. Cancellations communicated up to three weeks before the course will be refunded less a 25% administration charge. After this point refunds cannot be made. Substitutions can be made at any time. Adelard reserves the right to change, postpone or cancel any part of its course programme at short notice due to unforeseen circumstances. In the unlikely event of change, postponement or cancellation a full refund will be made of the registration fee. Further liability is disclaimed.

Location

Crowne Plaza Washington DC/Silver Spring, 8777 Georgia Avenue, Silver Spring, MD 20910

To register

Complete the form overleaf supplying credit card details or a company purchase order. Alternatively call Anne Taylor on +44 20 7490 9450 to make telephone payment.

"The course was excellent - can’t wait to start using ASCE!"
Course delegate 2008

"Enjoyable and informative - an incredibly clever and useful tool"
Course delegate 2009
Day 1

- Introduction to structured assurance cases and safety cases and to the Goal Structuring Notation (GSN) and Claims-Argument-Evidence notations.
- Use of ASCE for the creation and maintenance of GSN and Claims-Argument-Evidence cases.
- Management of assurance case content, including use of hyperlinks.
- Analysis techniques, including filtering, validation of case structures, and the use of ASCE’s macro plugin features for safety case analysis.
- Use of ‘user views’ and ‘table views’ for improving management and comprehension of assurance cases.
- Hyperlinking to support effective linking of crucial evidence elements.
- Basic export — to HTML and MS Word

Day 2

- Creating and managing hierarchical and modular assurance cases.
- Use of the ASCE Browser to deliver assurance case reports.
- Advanced reporting — use of export templates and MS Word macros.
- Use of ASCE’s Dynamic Information Mapping capability to import and trace information from other sources (e.g., hazard logs, test reports).
- Use of ASCE’s schema and plugin capability for support for other applications (e.g., fault trees, accident investigation, project management).
- A workshop on Medical Device Assurance Cases: this will use a generic template for an infusion pump based upon FDA guidance.

Learning outcomes

- A good understanding of the concepts of structured assurance cases.
- Competence and confidence in the use of core ASCE features through extensive exercise sessions.
- An awareness of the full capacity of ASCE.
- An understanding of how ASCE can support medical device assurance case requirements.
- Practical ability in use of ASCE’s advanced features (e.g. plugins, custom export).