Model-Based Embedded Software Development

HCES 2003 Kickoff Presentation
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Presentation based on HCES 2002 Focus Group presentation:

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Purpose of This Talk

- Recap last year’s workshop (from the perspective of one of the focus groups).
- Kickoff 2\textsuperscript{nd} day of this year’s workshop:
  - develop roadmap for future HCES research
- Provide FDA (/CDRH/OST) perspective on embedded software development.
Vision for the Future

- Embedded Software Development as a true *engineering* discipline.
- How: Model-based design, analysis, and implementation.
- Formal specification and verification seamlessly integrated into process.
- Model: EDA -- $4bn/yr industry.
Tool Set of the Future

- Requirements
  - Capture and analysis tool
  - Environment (user model etc.)
- Modeling
- Simulation with user interaction, prototyping
- Verification
- Code Generation
- Testing including automatic test generation
- Evolution and Documentation
Tool Set Characteristics

- Traceability
- Formal semantics
- Certifiability (by law or by competition)
- High-confidence accountability
- Usability
- Measurability
Technology Assessment

- Medical device industry process same as fifty years ago.

- Software development technology has kept pace in terms of functionality but not in terms of *ilities*: reliability, security, performance, power, mem. footprint, etc.

- Hardware has separable requirements; EDA an engineering discipline.
Technology Transfer

- Standardization process needed.

- Product Flow:
  - academic (proof of feasibility)
  - open source
  - private sector adds value to productize
Why Fund At All?

- If we don’t fund it, many more people will be injured or die.
- Huge number of embedded applications and huge financial implications.
- Every year, 98% of 5.7bn new processors deployed in embedded applications. Embedded in quality of life.
FDA Interest in HCES

Current devices
- many of today’s devices contain ES
  - cochlear implants, eximer lasers, infusion pumps, etc

Future devices
- biomedical, MEMS, telemedicine, home use
FDA Software Reviews

Present review process
- Quality system process oriented
  - Rely on Regulations
  - Rely on Standards
- Review life cycle artifacts
  - Emphasis on risk mgmt & effectiveness

High Confidence is not an inherent property of this process!!
Future reviews

- Software will be certified by mfr to “some” property(s); e.g. correctness, usage reliability
- Proactive review by FDA before mfr invests in an unapproveable design
Generalized Infusion Pump Project

Research areas:

- Capturing requirements (from diverse domain experts)
- Open system development
- Certifications methods for a regulatory environment

*** Can publish results