Biomedical Device Panel: Model Based Engineering Throughout the Lifecycle…Harvesting the Benefits

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The industry faces many challenges

The medical industry product developers face problems with ……

- Extreme time to market pressures
  - 1st to market usually gains 80% of that market
- Compliance with regulations
  - FDA, IEC, ISO, HIPAA, ICD-10, ACA, etc.
- Defects are VERY costly to handle
  - Want to avoid audit, decrees, warning letters, recalls, etc...
- Most products are developed in a geographically distributed way
  - Need to communicate and define tasks
- Technology is impacting development and delivery
  - IoT, product variants, Mobile Medical Apps, complex deployment models, cloud

Source: IBM Rational

Goal: Benefits to Industry of MBSE

Improved Systems Thinking

- Use Case/Performance/Interface Analysis critical for a complete design specification.
- Logical model to provide high level of abstraction for ease of understanding, improved reuse or design sharing

Improved Communication

- Visual vs. Textual leads to Clearer, more precise communication & better reviews
- Visual designs & models are easier for global teams (less language barrier)

Improved Quality

- Verify correctness and completeness of requirements/design – robustness / stress testing of design rather than simply reviewing in quality
- Improved design of test cases, derived from weaknesses exposed in the model

Improved Predictability and Efficiency (Time to Market)

- Verify correctness and completeness of requirements/design – robustness / stress testing of design rather than simply reviewing in quality
- Improved leveling of requirements (efficiency in verification and documentation)
- Auto code generation (no translation errors in implementation)