

Software quality by design

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Agenda

- What is “Quality by Design”?
- “Quality by Design” model
- Quality by design in pharmaceutical industry
- Software quality by design
- Lesions learned

What is “Quality by Design”

- Joseph M. Juran, back in 1992
- The Juran Trilogy
 - Quality planning
 - Quality control
 - Quality improvements
- “quality could be planned, and that most quality crises and problems relate to the way in which quality was planned”

Meaning of “Quality”

1. The presence of features that create customer satisfaction;
 2. The reliability of those features
- Removing failures is the purpose of quality improvement,
 - Creating features is the purpose of quality by design

Steps in the “Quality by Design” model

- Establishment of the project design targets and goals.
- Definition of the targeted market and customers.
- Discovery of the market, customers, and societal needs.
- Development of the features of the new design that will meet the needs.
- Development or redevelopment of the processes to produce the features.
- Development of the process controls to be able to transfer the new designs to operations

QoD model in picture



Quality by design in pharmacy

- “quality should be built into a product with an understanding of the product and process by which it is developed and manufactured along with a knowledge of the risks involved in manufacturing the product and how best to mitigate those risks”
- Successor to “Quality by Quality Control”, aka “Quality after design”

Quality by design in pharmacy

- Risk-based pharmaceutical quality assessment system (PQAS) established based on the application of product and process understanding
- Problematic for large scale implementations
- Problems in covering the whole process

Software Quality

- Many different models
- *Definition, Assessment and Prediction* of quality
- Amman & Offutt: Test process maturity
- ...

Definition models

- *Definition* models are used in various phases of a software development process.
 - During requirements engineering, they define quality attributes and requirements for planned software systems and thus constitute a method to agree with the customer what quality means
 - During implementation, quality models serve as basis of modelling and coding standards or guidelines

Assessment models

- *Assessment* models often naturally extend quality definition model usage scenarios to control compliance.
 - During requirement engineering, assessment models can be used to objectively specify and control stated quality requirements
 - During implementation, the quality model is the basis for all quality measurements, i.e. for measuring the product, activities and the environment
 - During quality audits, assessment models serve as a basis of the performed audit procedure

Prediction models

- *Prediction* models are used during project management
 - release planning and in order to provide answers to the classical “when to stop testing” problem

Testing process maturity

- Level 0 : There's no difference between testing and debugging
 - Level 1 : The purpose of testing is to show correctness
 - Level 2 : The purpose of testing is to show that the software doesn't work
 - Level 3 : The purpose of testing is not to prove anything specific, but to reduce the risk of using the software
 - Level 4 : Testing is a mental discipline that helps all IT professionals develop higher quality software

Level 4: mental discipline

- This is the way traditional engineering works
 - You don't test buildings after you build them 😊
- Actually, it also means changing the process.
- And changing the process is the hardest thing to do

What can we as CS learn from QbD

- Are we still in Quality by QC mode?
- Not everything can be tested
 - Issues with testability, controllability and observability
- Integration
 - Avoid “big bang” integration
 - Make a quality integration process
- Integrate quality into the development process

Thank you for your attention

