Verification and validation

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DEFINITIONS

“ Design is the prolonged *checking*, pondering, and compromising on *requirements* which are often quite contradictory until there appears – as the end product of numerous associations of ideas, a network of ideas – the design… ”

Source: Richard Matousek, Engineering Design: a Systematic Approach.

Engineering
- *plan*
- *develop*
- *evaluate*
- *do*

Healthcare
- *plan*
- *do*
- *study*
- *act*

DEFINITIONS

Verification and validation is the process of checking that a product, service, or system *meets specifications* and that it *fulfils its intended purpose*.

DEFINITIONS

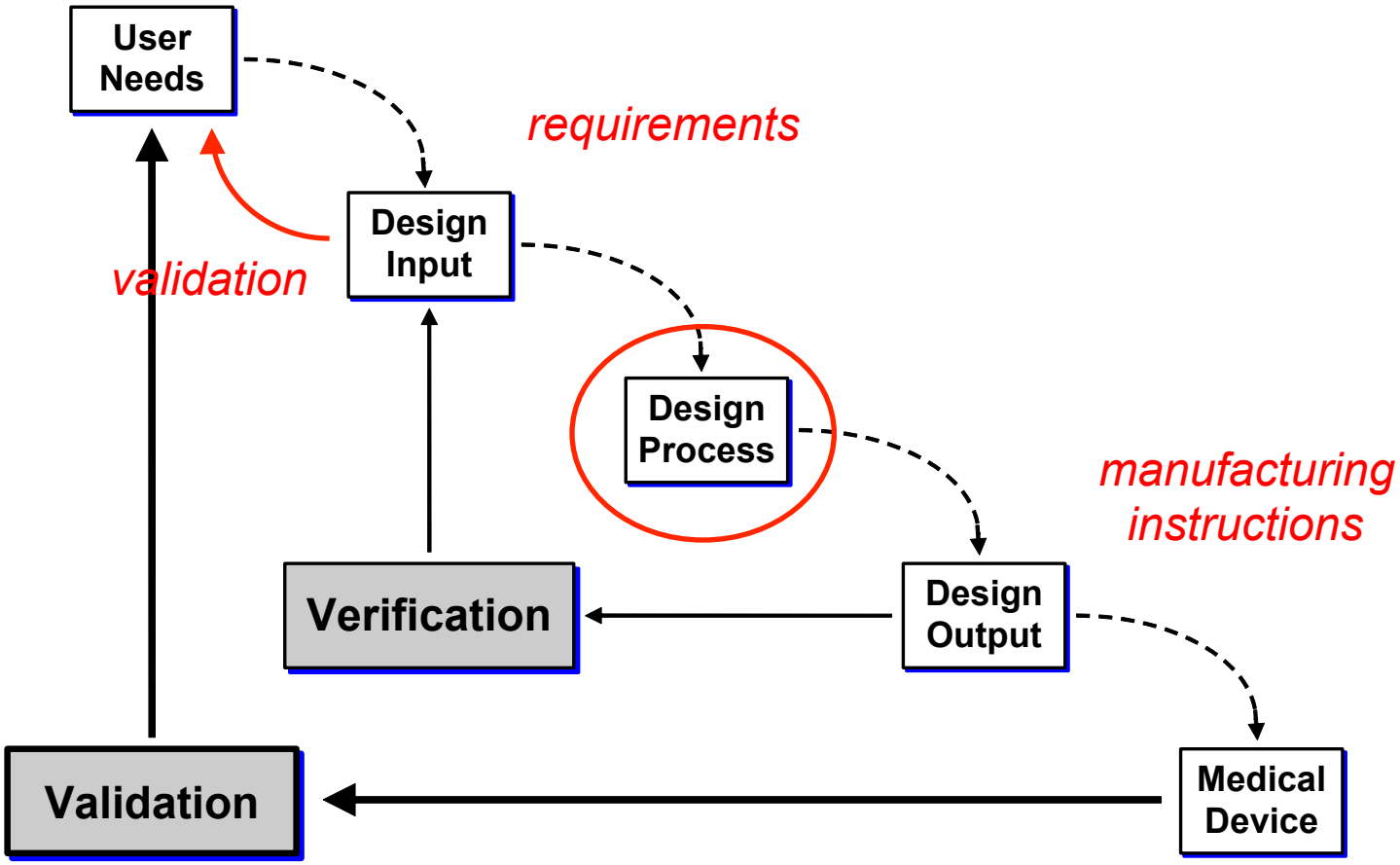
“ Verification is ensuring that outputs for a specific device or activity meet particular input requirements.

“ Validation, a step beyond verification, includes specific intended use and requires that they are consistently fulfilled. ”

Source: ISO 8402:1994 Quality management and quality assurance – vocabulary.

DEFINITIONS

- The Waterfall model of design



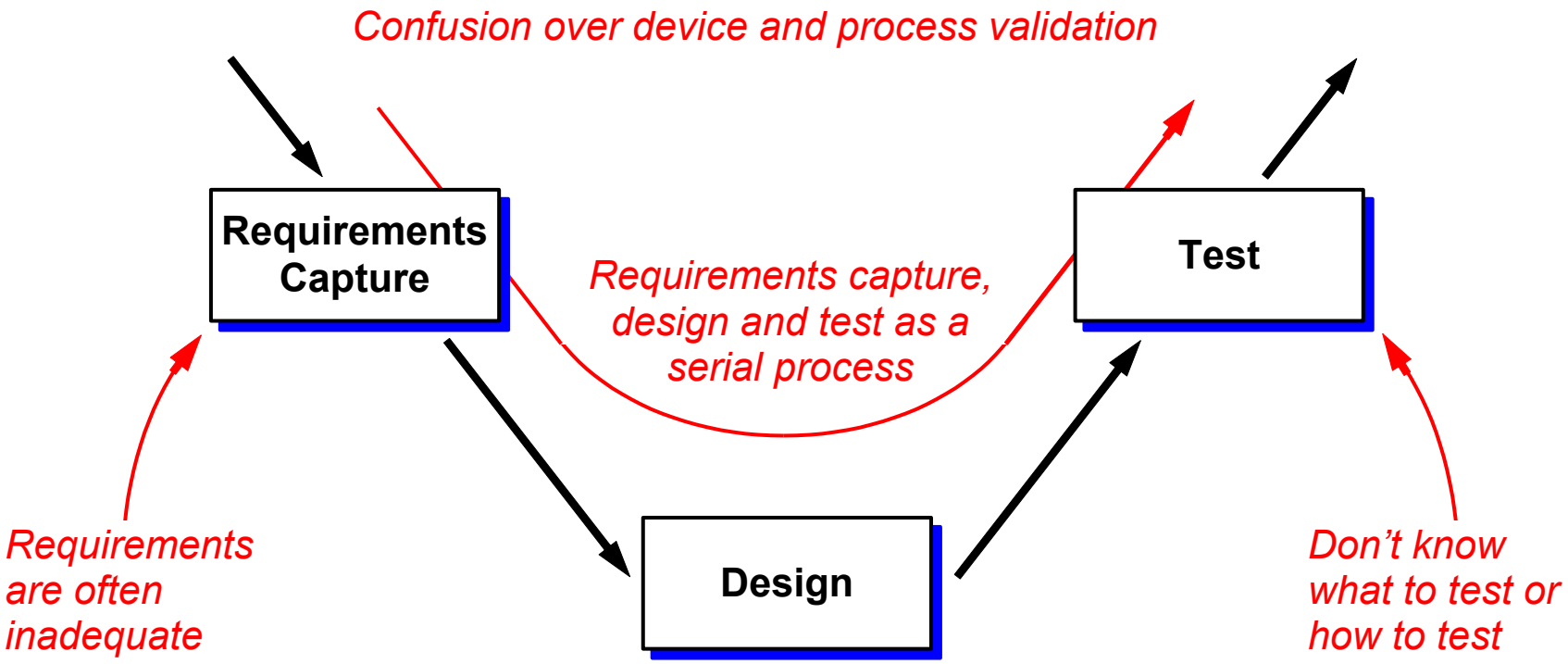
DEFINITIONS

Verification – *“ Are we building the thing right? ”*

Validation – *“ Have we built the right thing? ”*

CURRENT PRACTICE

- A linear view of design and test

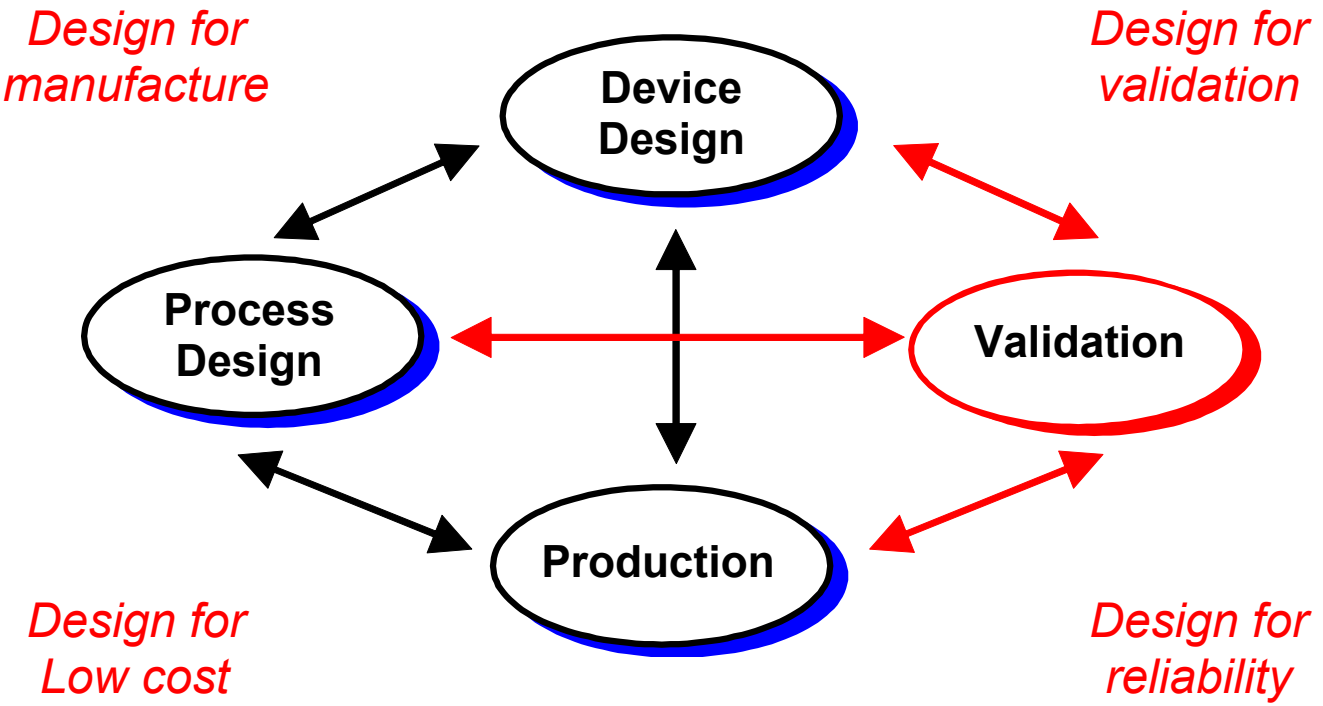


CURRENT PRACTICE

- New device and manufacturing process requirements are often incomplete, incorrect and lack clarity
- Designers often do not know what to test or how to test the emerging product, particularly novel products
- There is considerable confusion relating to the differences and similarities between device and process validation
- Requirements capture, design and test are frequently regarded as a serial process, often with different departments undertaking each activity

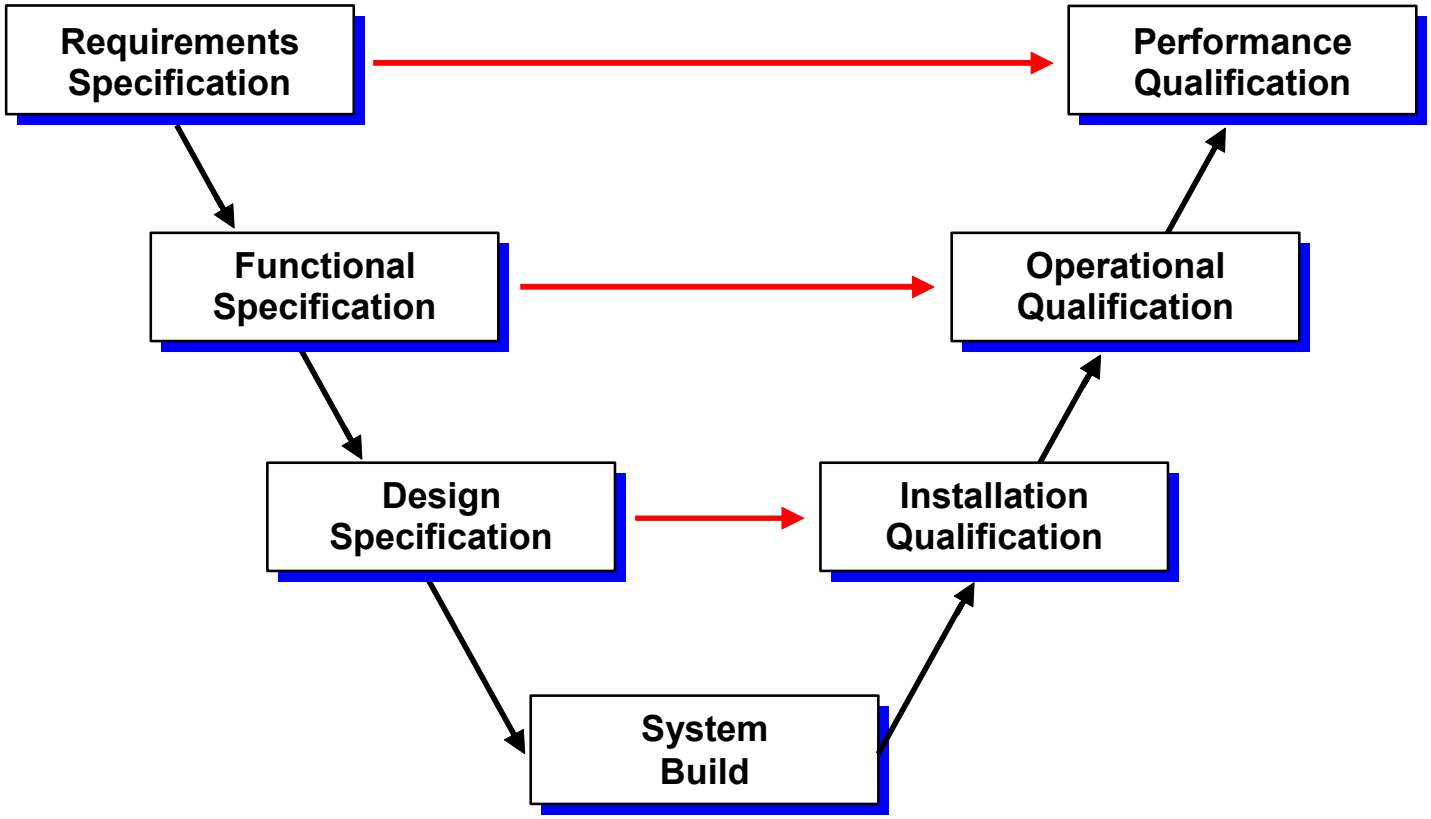
GOOD PRACTICE

- A concurrent approach to product development



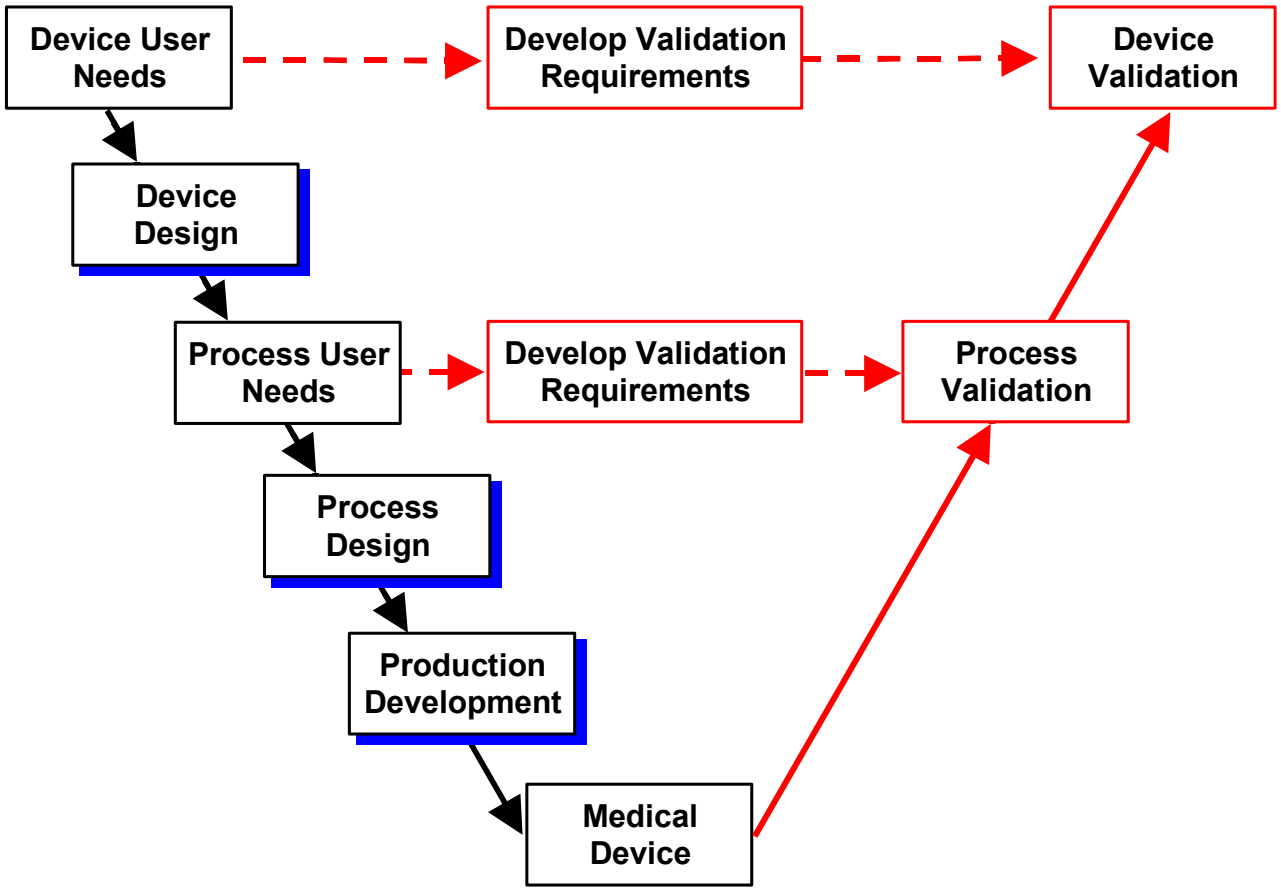
GOOD PRACTICE

- A systematic approach to product development



GOOD PRACTICE

- A systematic approach to product development



DESIGN TACTICS

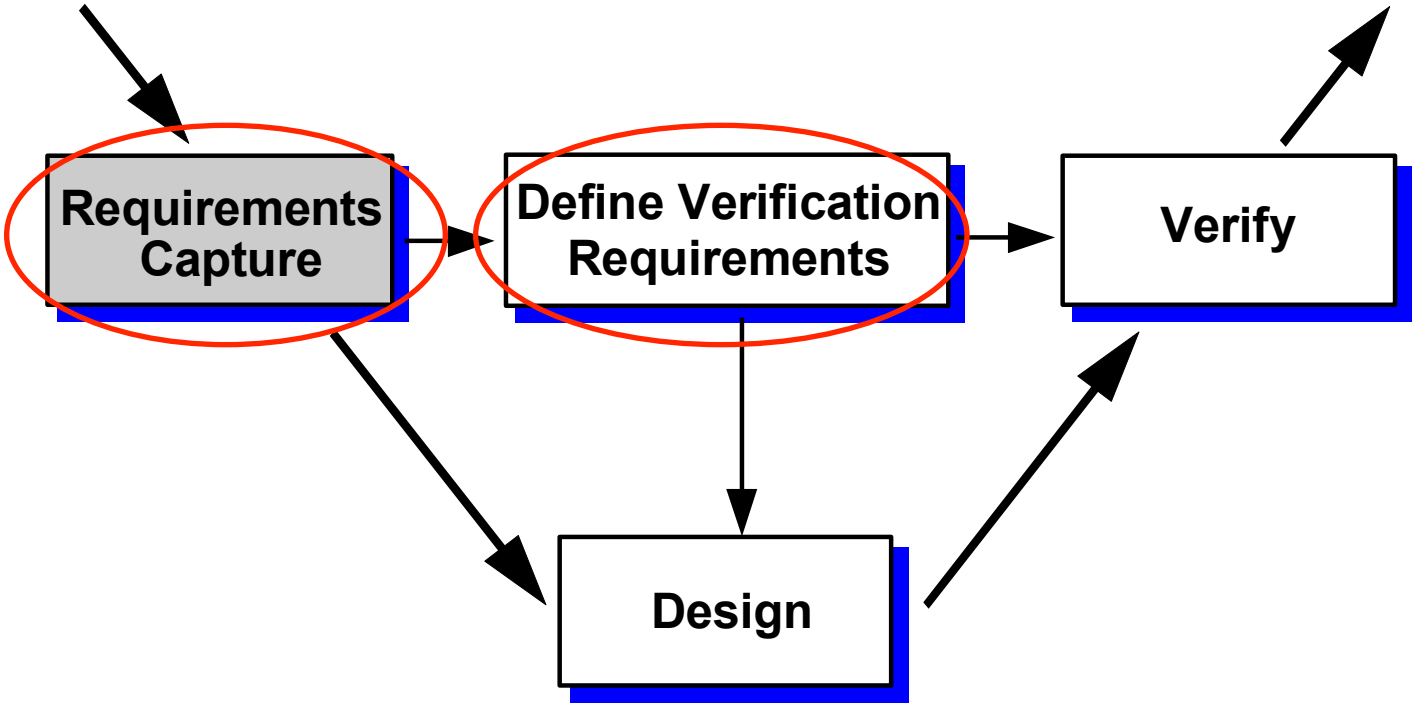
1 Capture implicit and explicit requirements

A systematic approach to requirements capture should be used to ensure the implicit and explicit requirements for the product and process are captured.

DESIGN TACTICS

1 Capture implicit and explicit requirements

implied *observable (obvious)*



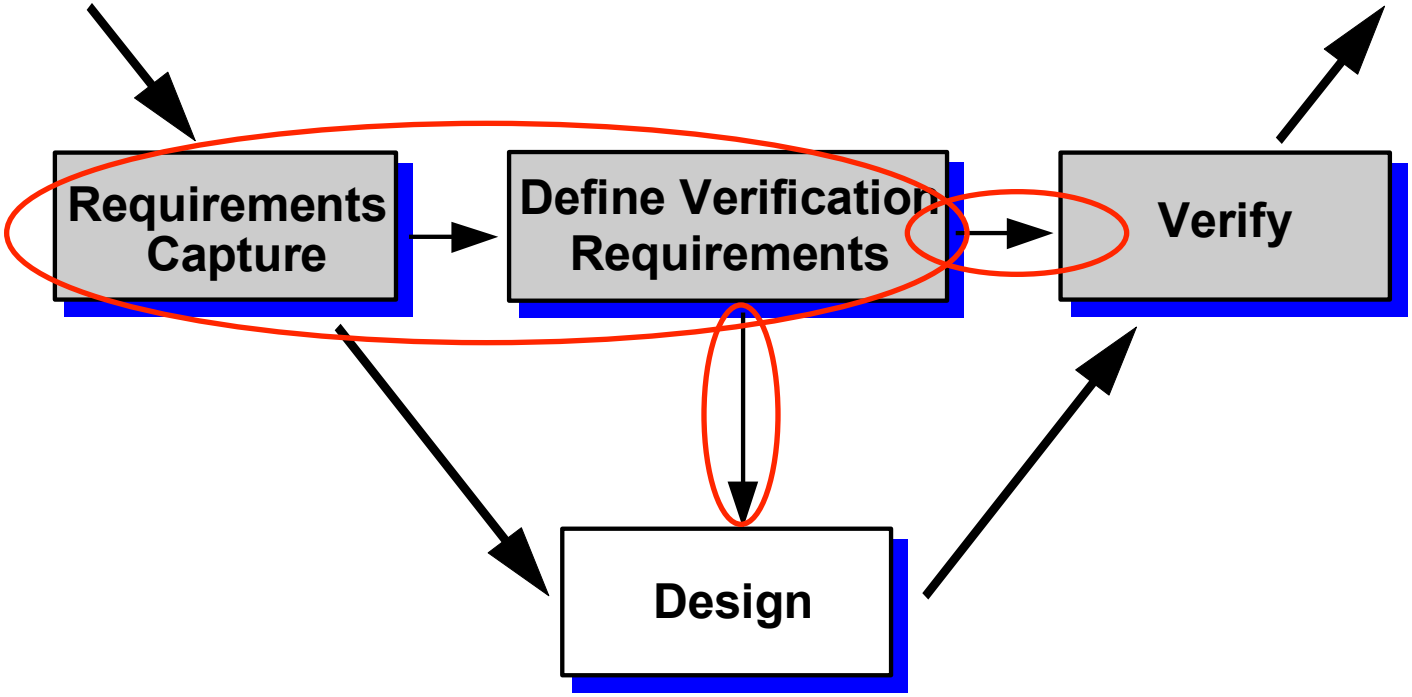
DESIGN TACTICS

2 Requirements should be testable

All requirements should have an intended value that can be measured in order to determine that the requirement is met. Qualitative (numerical) limits, tolerances, and ranges should be specified. Where requirements cannot be qualitatively measured the designer should be able to use professional judgement to verify the design.

DESIGN TACTICS

2 Requirements should be testable



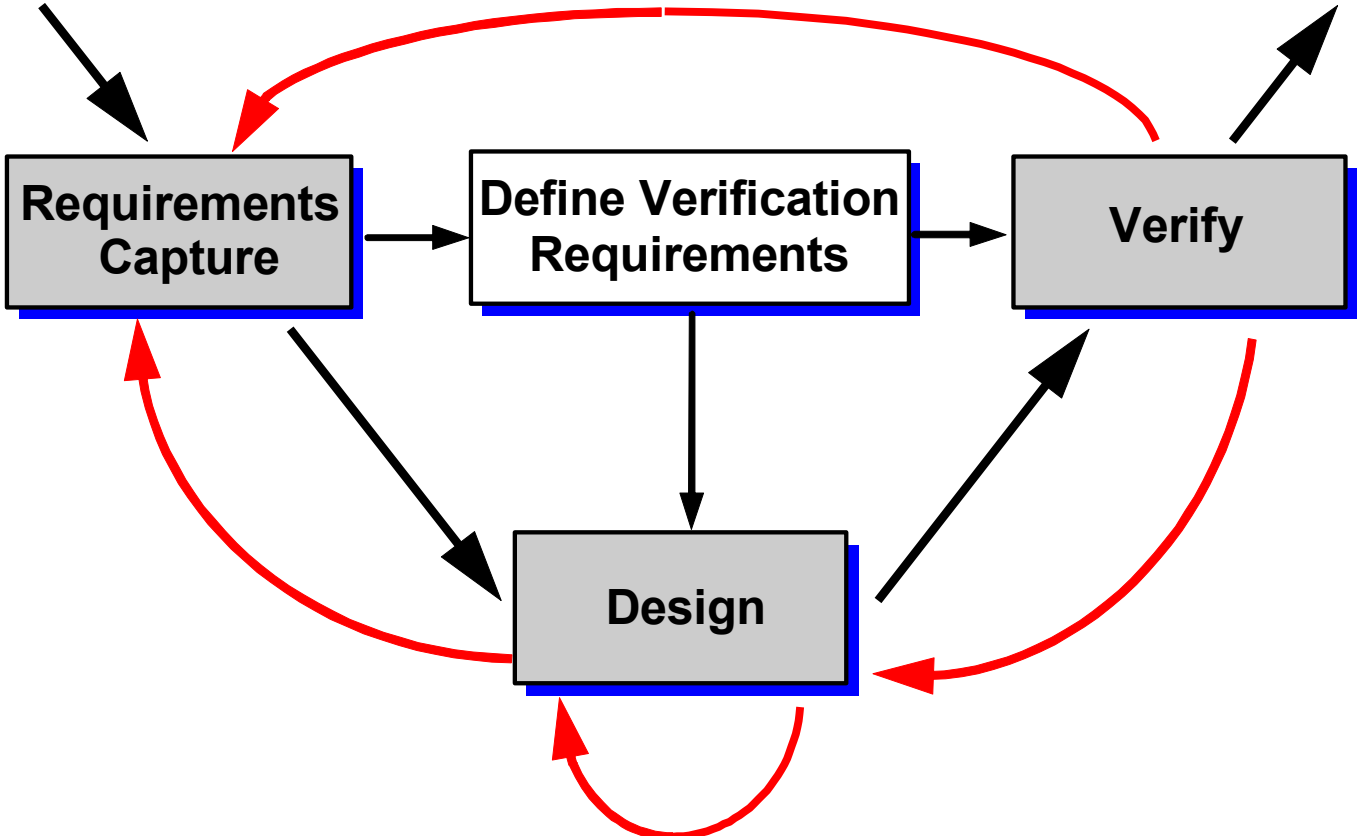
DESIGN TACTICS

3 Consider the effects of redesign on requirements

When redesign needs to be performed during design and test, the effects of that redesign on the initial requirements should be considered and taken into account. This requires clear tracking of requirements through design and test and repetition of hazard analyses as appropriate.

DESIGN TACTICS

3 Consider the effects of redesign on requirements



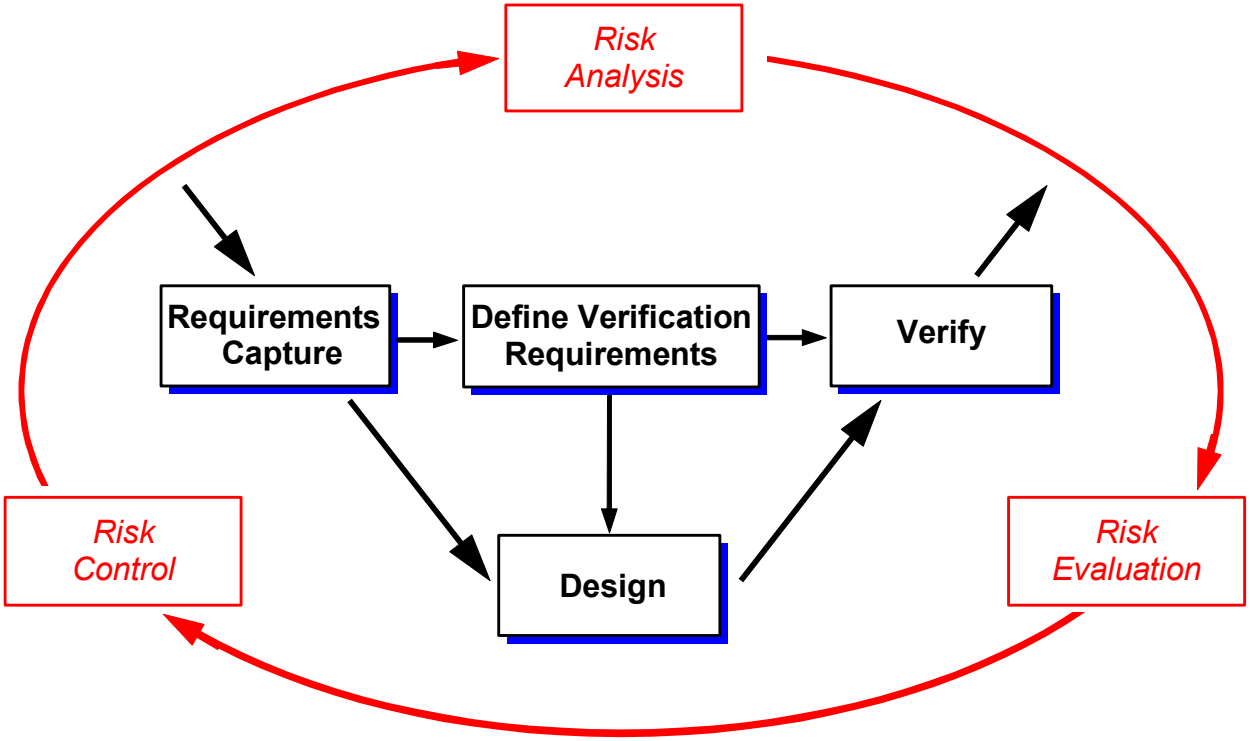
DESIGN TACTICS

4 Use a risk based approach to design and testing

Risk analysis should start during the requirements capture stage and continue through to detailed design. The risk analysis, along with the initial requirements, provide a basis for defining the test requirements.

DESIGN TACTICS

4 Use a *risk based* approach to design and testing



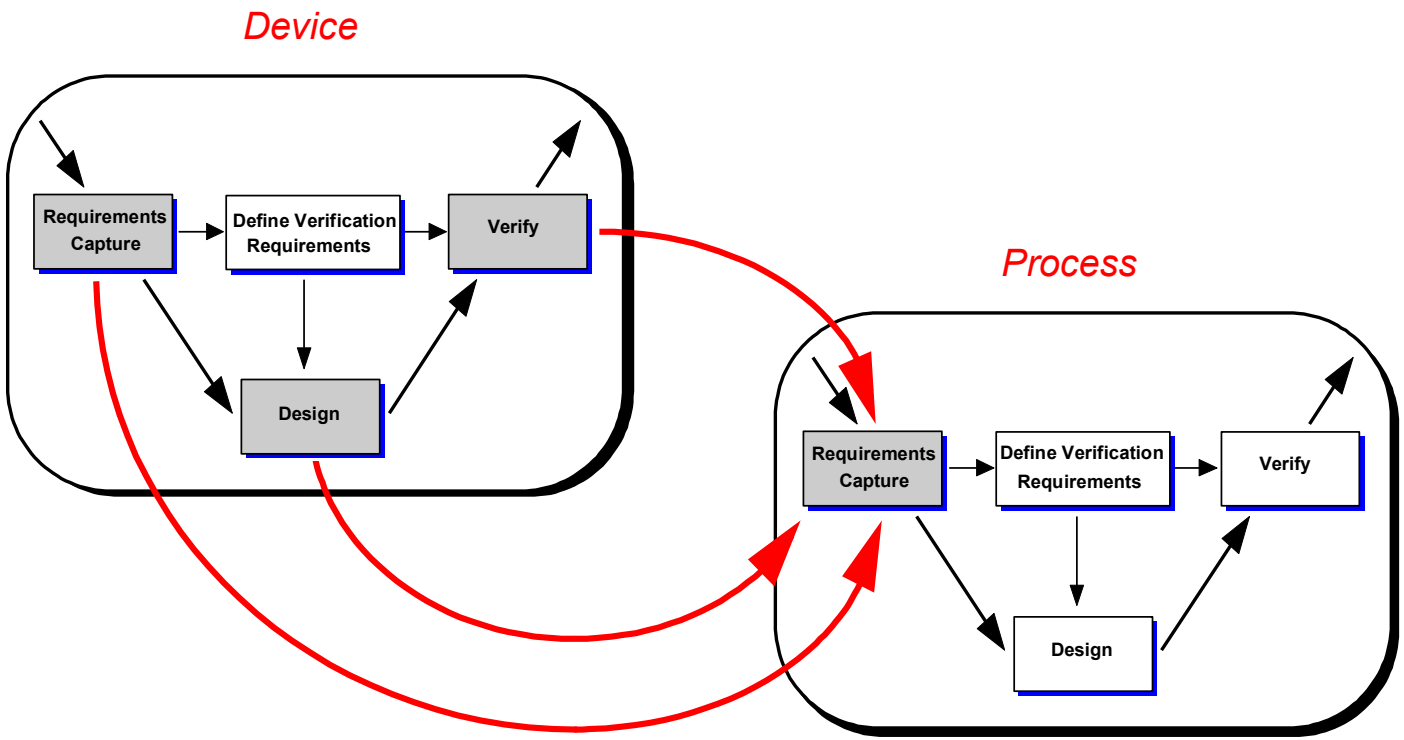
DESIGN TACTICS

5 Consider the effects of product requirements, design and testing on process requirements

Decisions made during the product requirements capture, design, and test phases must be explored to understand their impact on the requirements for the related process equipment.

DESIGN TACTICS

5 Consider the effects of product requirements, design and testing on process requirements



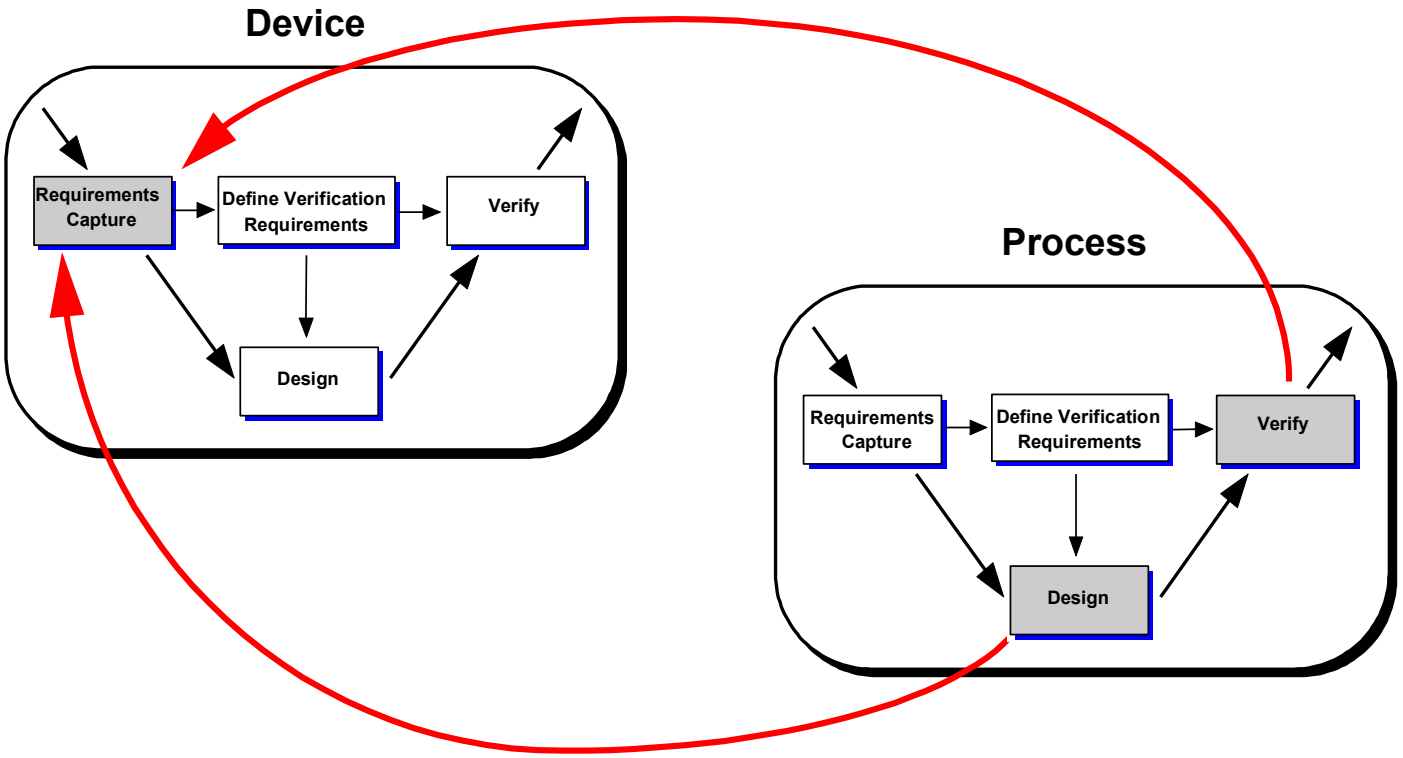
DESIGN TACTICS

6 Consider the effects of process redesign on product requirements

The effects of redesign performed during process design and test must be understood and reflected in the product requirements.

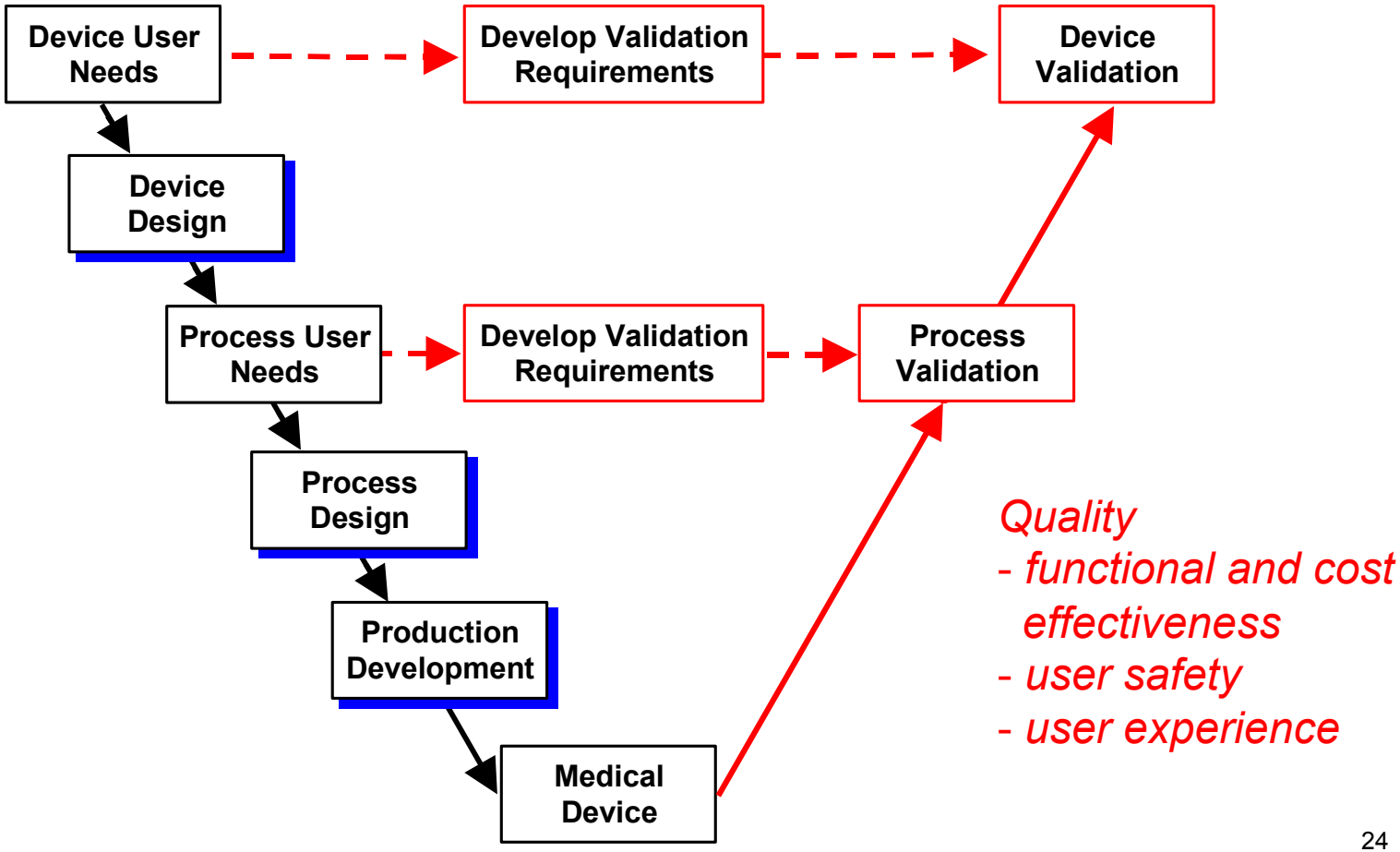
DESIGN TACTICS

6 Consider the effects of process redesign on product requirements

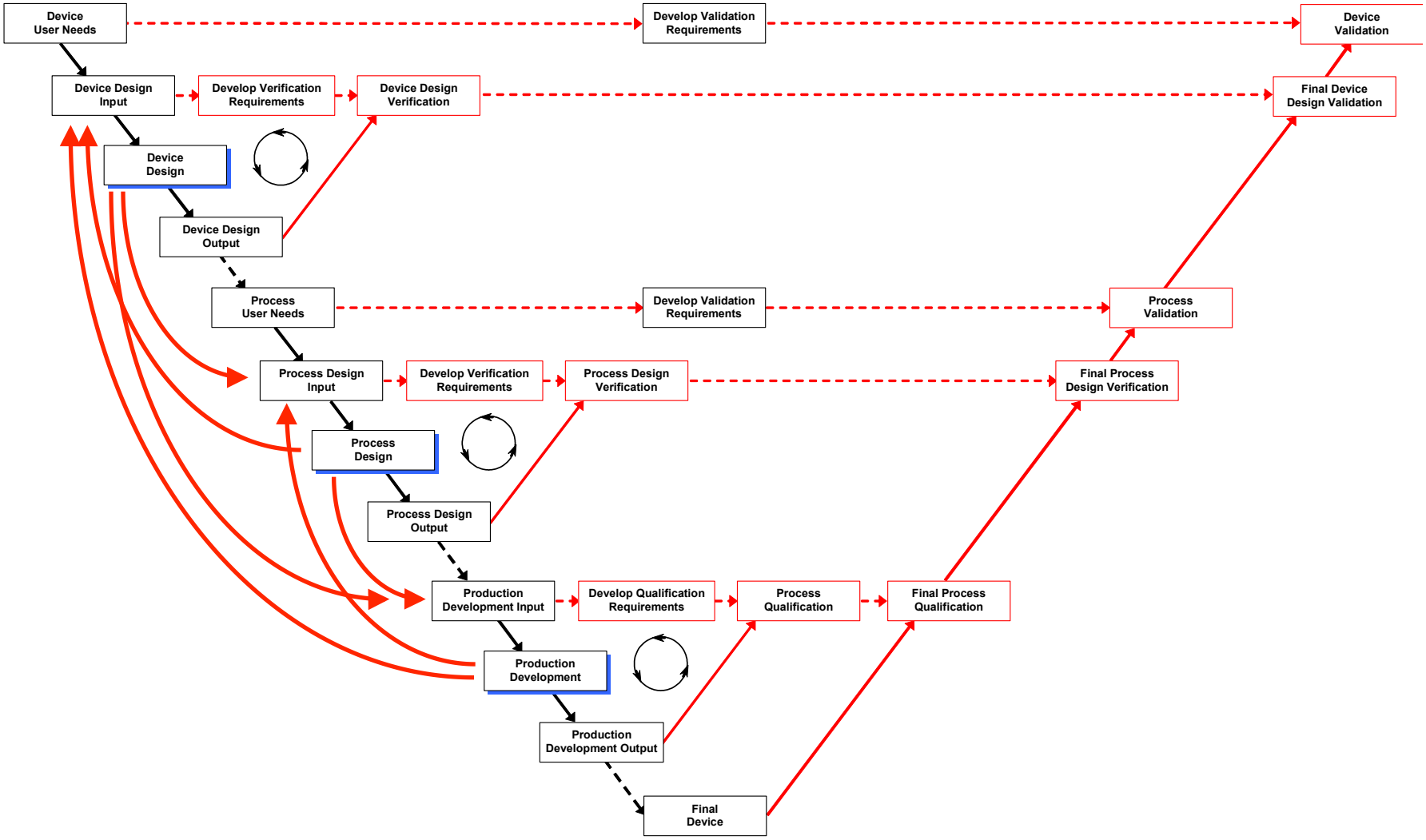


GOOD PRACTICE

- An integrated approach to product development



GOOD PRACTICE



GOOD PRACTICE

- Does your system have the activities shown in the V-Model?
- Does your design team understand the difference between verification and validation?
- Do you attempt to capture all of the user needs and all of the intended uses of the device before commencing with the design and development?
- Have you set up a validation strategy?
- Have you set up verification requirements for each design input?
- Have you verified each design output against a design input?
- Have you set up a process validation strategy?
- Have you set up process qualification requirements?
- Have you qualified the final process equipment?
- Have you proven that the final device meets its initial device requirements (is verification complete)?
- Have you proven that the final device meets all of the user needs and all of the intended uses (is validation complete)?

GOOD PRACTICE

1 Capture implicit and explicit requirements

- ❑ Do you use a systematic method to capture requirements?
- ❑ Do you have a method in place to ensure that both implicit and explicit requirements are captured?
- ❑ Have you considered all users and stakeholders of the device?
- ❑ Have you considered the device throughout its lifecycle?
- ❑ Have you considered the requirements for regulatory approval?
- ❑ Have you considered the requirements for validation?
- ❑ Have you defined a procedure for reviewing and changing requirements?
- ❑ Do you perform the above for both device and process?

GOOD PRACTICE

2 Requirements should be testable

- ❑ Do you have a systematic procedure for ensuring that requirements are verifiable?
- ❑ Does every requirement have quantitative performance targets?
- ❑ If it is not possible to set quantitative targets, have you identified alternative methods of verification?
- ❑ Are specifications and verification requirements formulated, where
- ❑ possible, before design and verification are carried out?
- ❑ Are the verification requirements communicated to the design team?
- ❑ Do you perform the above for both device and process?

GOOD PRACTICE

3 Consider the effects of redesign on requirements

- ❑ Do you have a systematic risk management programme in place?
- ❑ Do you have representatives from the users and stakeholders involved in the risk management process?
- ❑ Do you use the cycle of risk analysis, risk evaluation and risk control throughout the design and development project?
- ❑ Do you use risk management to drive design and verification of the device and process equipment?
- ❑ Do you perform a preliminary hazard analysis on the user requirements?
- ❑ Do you consider the lifecycle of the product in your risk management?
- ❑ Do you identify critical device/user interfaces?
- ❑ Do you communicate the results of the risk management process to the product development teams?
- ❑ Do you perform the above for both device and process?

GOOD PRACTICE

4 Use a risk based approach to design and testing

- ❑ Do you have a re-design strategy or procedure in place at the beginning of a project (change management system)?
- ❑ Do you have a systematic procedure for considering the effects of redesign on all requirements?
- ❑ Do you revisit the hazard, fault and risk analysis when conducting redesign?
- ❑ Do you conduct design reviews to investigate the effects of re-design?
- ❑ Do you re-verify changes in requirements?
- ❑ Do you perform the above for both device and process?

GOOD PRACTICE

5 Consider the effects of product requirements, design and testing on process requirements

- ❑ Do you have a systematic procedure to encourage communication between device design, process design and production development personnel?
- ❑ Do you design the device and process equipment in parallel?
- ❑ Do device designers think ahead to process design issues?
- ❑ Do device designers think ahead to process verification and qualification issues?
- ❑ Do device designers think ahead to process validation issues?
- ❑ Are device designers aware of the limits of the process equipment?
- ❑ Are device designers aware of the limits of the materials?
- ❑ Does the device risk management process activity influence the process?
- ❑ Are process flow diagrams used early in the device design and developed as the design of the product becomes more detailed?
- ❑ Are process flow diagrams used as a basis to develop process specifications?

GOOD PRACTICE

6 Consider the effects of process redesign on product requirements

- ❑ Is there a systematic procedure to explore the effects of process redesign on device requirements (change control)?
- ❑ Do you conduct design reviews to investigate the effects of process redesign of device design?
- ❑ Do you revisit the hazard, fault and risk analysis on the process and/or device as appropriate?
- ❑ Do you re-verify changes in process and/or device requirements as appropriate?

EXAMPLE: LAWN MOWER

- Verification –

  functions as expected

  safe

  meets standards

  colour

- Validation –

  profitable

  safe

  cut grass

EXAMPLE: ASTHMATIC INHALER

- Verification –

  dosage

  spray

  structural integrity

- Validation –

  ergonomics / ease of use

  user trials

  alleviate symptoms

EXAMPLE: DRAUGHT BEER IN A CAN

- Verification –

  number of bubbles
  safe
  quality
  weight
  shelf-life

- Validation –

  taste / experience
  safe

EXAMPLE: FEMALE CONDOM

- Verification –

  strength

  flexibility

  no holes

- Validation –

  barrier to conception

EXAMPLE: FIRE-FIGHTER TRAINING UNIT

- Verification –

  module testing – *software and hardware*
  integration testing – *software and hardware*
  system testing – *pre-installation*
  system testing – *post-installation*
  acceptance testing – *customer sign-off*

- Validation –

  quality of training
  user experience

GOOD PRACTICE

- Two product manufactures develop different multi-dose dry powder inhalers.
- One designs a device which stores the powder in sealed pockets which have been pre-dosed under factory clean room conditions by a well maintained machine.
- The other device stores the powder in bulk from which doses are extracted when required under the prevailing local conditions.
- Validation of the first device was straightforward and product sales are brisk.
- Validation of the second device is incomplete since dosing cannot be demonstrated to be consistent during summer heat and winter rain, so the product in not yet on the market.
- This real example shows how validation can impact upon product development time and cost.