VERIFICATION & TESTING STRATEGIES FOR COMPLIANCE WITH ISO 13485:2016, IEC 62304 / 60601-1 / 82304-1

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Rook Quality Systems

MAKE EVERY MOVE COUNT

Rook Quality Systems is a consulting firm dedicated to helping startup to mid-sized medical device companies develop and maintain effective and efficient quality systems.

Experience
Over a decade working with class I-III devices, SaMD, and IVDs. Supporting companies in the very early stages of QMS and device creation, from design through commercialization and post-market monitoring.

Expertise
Rook's team of eighteen quality engineers and certified auditors are experts in FDA regulations, MDSAP audits, ISO 13485:2016 compliance, and MDR conformity and provide support during an external or regulatory audit.

Efficiency
We leverage experience and best practices to help build the QMS so that clients can get their devices to market faster than standard methods, and use these systems to continue producing effective, quality devices.

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We provide specialized and custom consulting services for all classes of medical devices, including medical software and combination devices.

- Quality System Design
- DHF/ TF Creation
- Audit Support
- Software Validation
- Design Control
- Risk Management
- Regulatory Submission Support (Int'l)
- Quality System Training

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Webinar Outline

1. Overview of Medical Device Testing
2. How to Identify Testing
3. External Testing Laboratories
4. IEC 60601 / 61010
5. Software Testing IEC 62034
6. Internal Bench Testing
7. What To Do If You Fail
8. Ongoing Testing / Questions

Overview of Medical Device Testing

Design and development verification

Design and development verification shall be performed in accordance with planned and documented arrangements to ensure that the design and development outputs have met the design and development input requirements.

The organization shall document verification plans that include methods, acceptance criteria and, as appropriate, statistical techniques with rationale for sample size.

If the intended use requires that the medical device be connected to, or have an interface with, other medical device(s), verification shall include confirmation that the design outputs meet design inputs when so connected or interfaced.

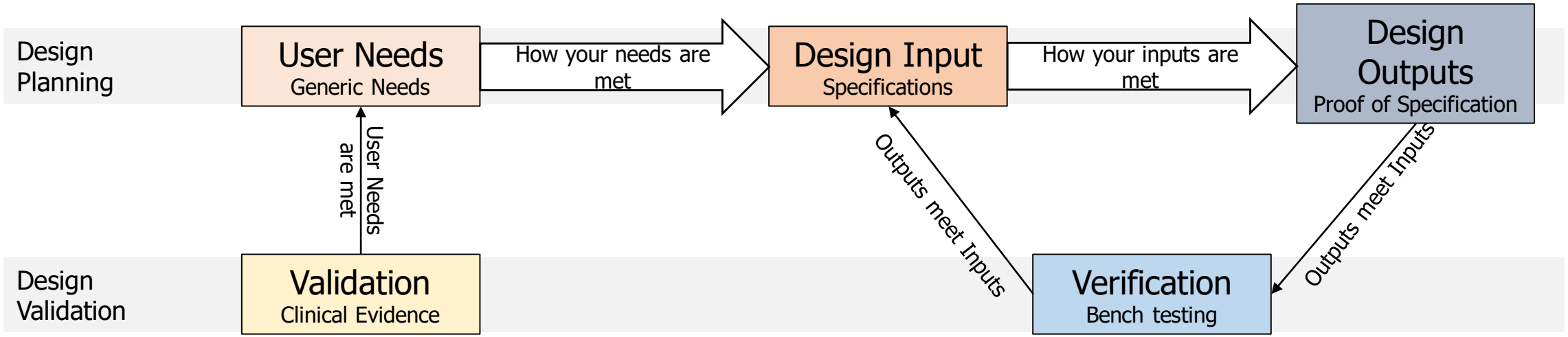
Overview of Medical Device Testing

FDA 21 CFR 820.30

Design verification

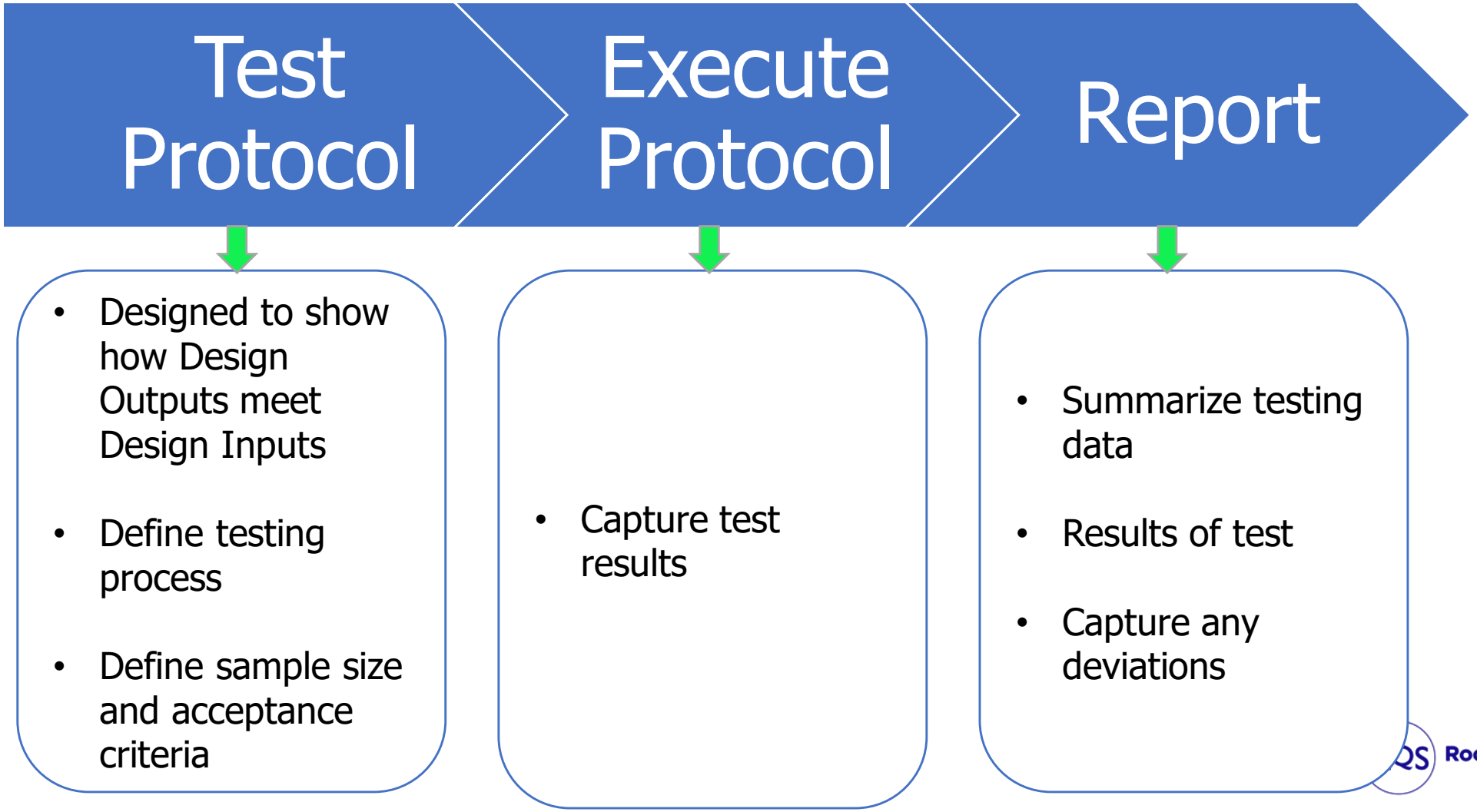
Each manufacturer shall establish and maintain procedures for verifying the device design. Design verification shall confirm that the design output meets the design input requirements. The results of the design verification, including identification of the design, method(s), the date, and the individual(s) performing the verification, shall be documented in the DHF.

Design Control



21 CFR 820.30
ISO 13485:2016 section 7.3

Overview of Medical Device Testing



How to Identify Testing

- Design Traceability Matrix - Verify Inputs meet Outputs
- Determine regulatory requirements for specific device
- Identify if the regulatory testing applies to your device
- Discuss with testing lab
- Confirm testing plan if unsure (pre-submission meeting)

How to Identify Testing

Design Traceability Matrix - Verify Inputs meet Outputs

Create design inputs/software requirements for your device

If you are unsure of the specifications or tolerances create testing protocols to determine specifications

Ensure the inputs/requirements can be tested or verified

How to Identify Testing

- **Regulatory Requirements**
  - Identify the product code for your device
  - Search product code on the FDA website and identify consensus standards.
- **Purchase Standards – Review the standards in detail**
  - Review FDA website to identify any FDA Guidance documents related to your device
  - Review Predicate Devices

How to Identify Testing

Regulatory Requirements

- Review Consensus Standards, Guidance Docs, and Predicates to determine if the standard applies to your device
- There may be situations where you can justify not doing testing using various methods
  - Risk Review
  - Materials/components already tested to standard

External Testing

Discuss with Testing Lab

- Determine if any of the testing will require external laboratories to complete
  - 60601/61010
  - FCC/Wireless Co-existence testing
  - Biocompatibility
- Discuss strategies and requirements of testing with the test lab
- Confirm sample size

External Testing

- Get multiple quotes from testing labs
- Compare quotes and discuss timelines
- Confirm if possible that all testing will be completed at the same facility
- Determine timelines for testing and document review
- Implement testing

IEC 60601 Testing

- Requirement for electrical medical devices
- Multiple components of the 60601 standard that need to be reviewed
- Testing is just part of the certification
- Risk Management File reviewed in detail
- IFU and Label reviewed in detail

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IEC 60601 Testing

- Review to see if additional sections of the standard are required for your device
  - 60601-1-11 Home Use Device
  - 60601-1-3 X-Ray Systems
  - 61010-1,2 Electrical Lab Equipment (Diagnostic Devices)
  - 80601-2-56 Clinical Thermometer
  - 60601-2-66 Hearing Aids

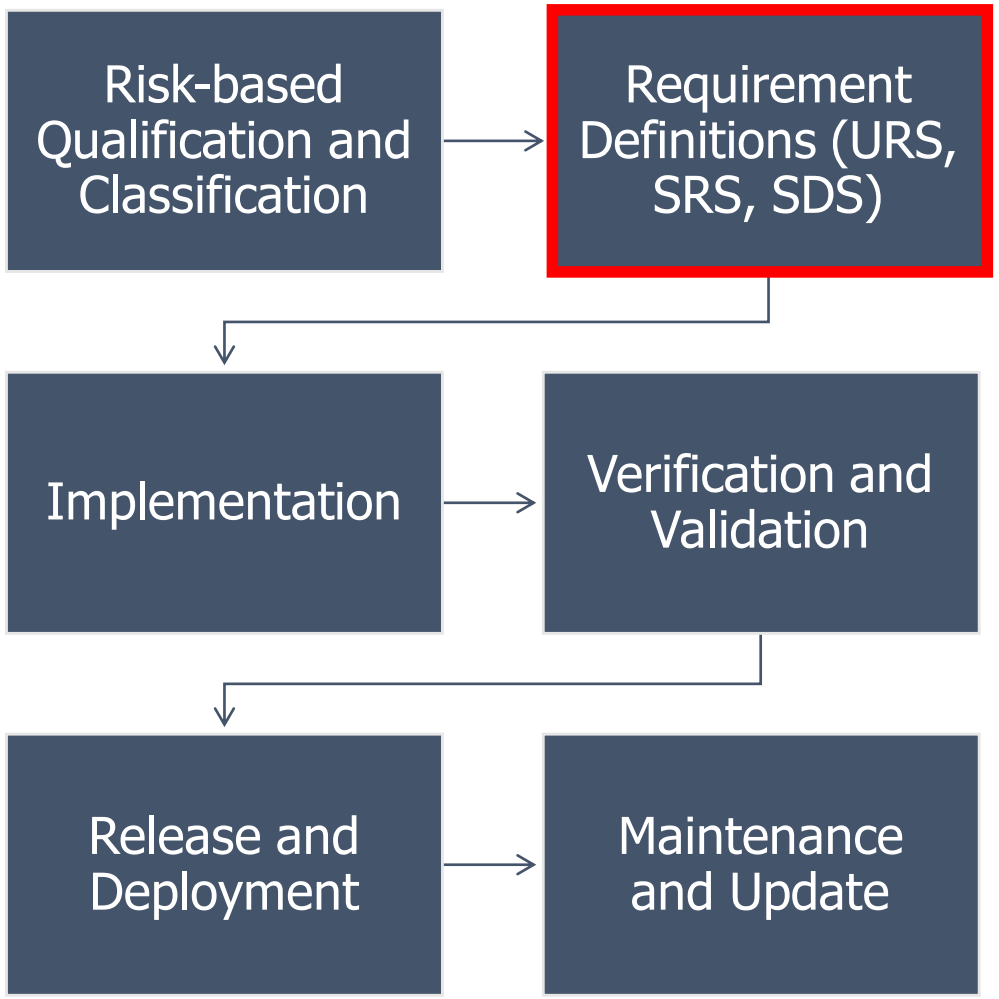
IEC 60601 Testing Process

- Review quotes and agree to tests to be completed
- Ship devices for testing (multiple, may be destructive)
- Submit RMF, IFU, Label
- Submit documentation for device components, data sheets, material specifications, antenna

IEC 60601 Testing Process

- Complete required paperwork to begin testing
  - insulation diagram
  - essential performance
  - classification
  - risk checklists
- Begin testing
- Review Report

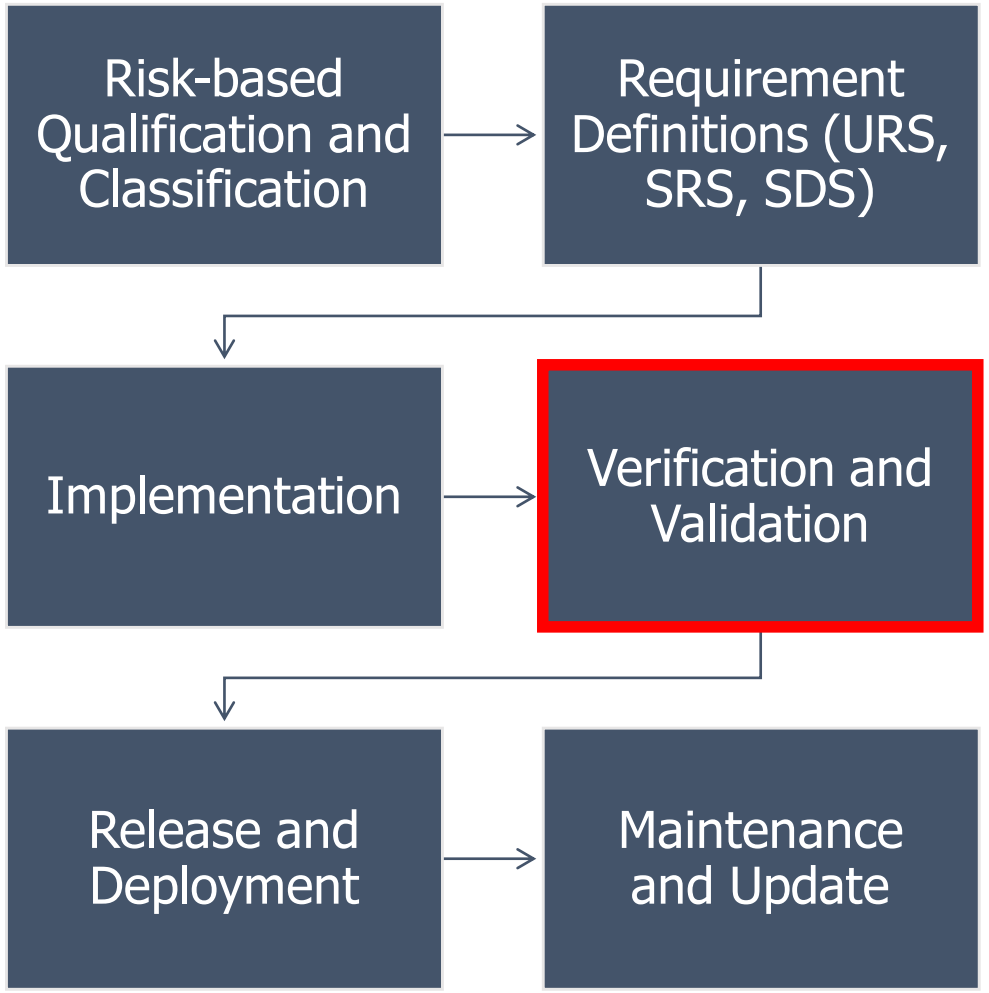
Software V&V: How it fits into the Software Lifecycle



Create Requirement Specifications

- User Requirement Specifications
  - Describe how software integrates with clinical workflow
- Software Requirement Specifications
  - Frontend
  - Backend
  - Risk control measures
  - Non-functional
  - Algorithm performance
  - Data requirements
- Software design Specifications
  - Architecture design decisions based on URS, SRS, and risks.

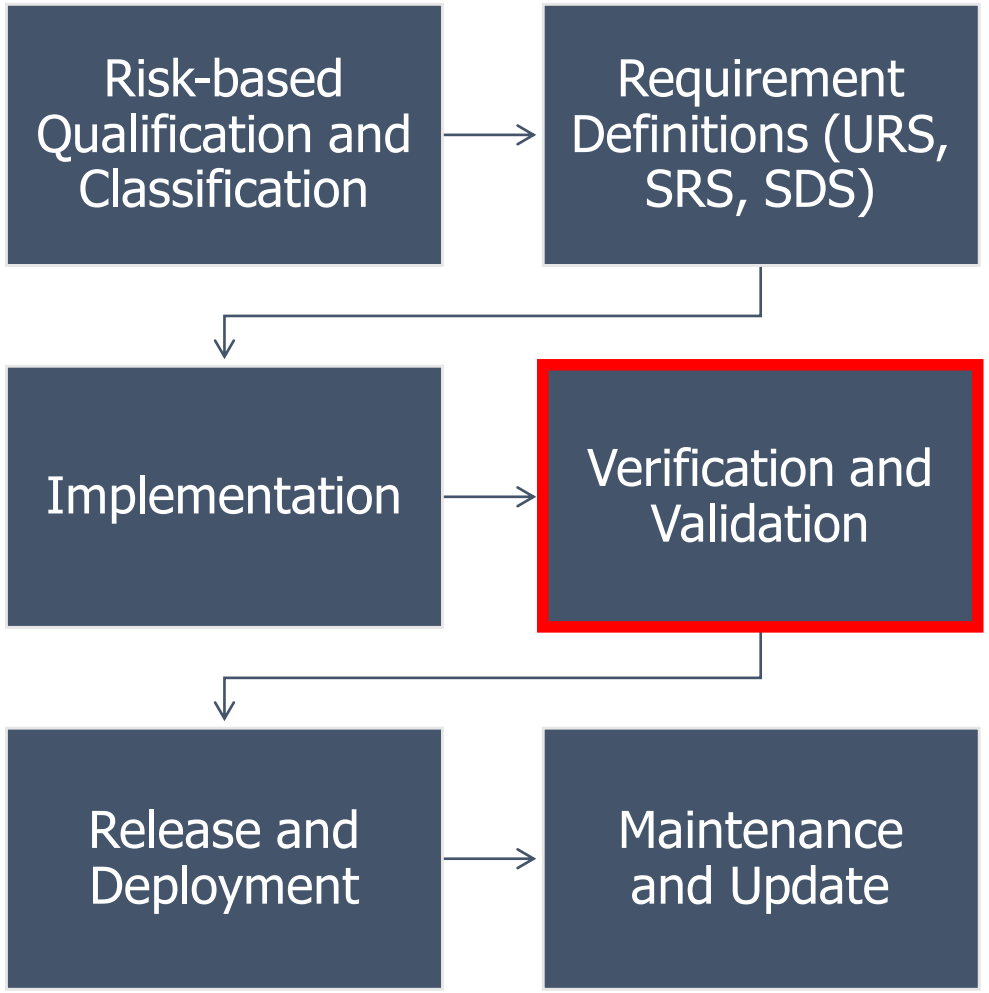
Software V&V: Verification Planning



- Structured such that the developed software meets the defined requirements
- Verification should be considered when requirements are being developed (high-level)

- **IEC 62304 Testing**
  - Identify Risk Classification per IEC 62304
  - Test coverage driven by risk profile
    - Unit, integration & system level
- **Verification Planning**
  - Primary purpose to look into defects
  - Defect tracking method needs to be identified up front
  - Acceptance criteria clearly laid out for each test case planned

Software V&V Execution



- Ideally, requirements should be implemented before beginning software verification

- **Test Cases**
  - Establish entry and exit criteria to define when test execution can begin and end
  - Test Environment should be detailed to capture intended use scenario
  - Test assumptions should outline any preparation steps needed to produce the expected results in the test case
- **Validation**
  - Scenarios cover the clinical user and environment
  - Acceptable failure behavior

Internal Bench Testing

Perform all identified testing on a finished device design, or an accurate prototype of the device, not on a device that is still under development and subject to design changes

Determine Master Testing Plan

- Testing of your device's design outputs/specifications
  - Such as: Mechanical and Bioengineering performance
    - Example: Fatigue, wear, tensile strength, compression, and burst pressure; bench tests using ex vivo, in vitro, and in situ animal or human tissue; and animal carcass or human cadaveric testing
  - Testing identified through Risk Assessments
  - Testing per applicable device specific regulatory standards/guidance doc

Testing Documentation

- Test Protocols & Test Report Templates to be used during testing
- Final Test Reports & Summaries to be included in your premarket submission

Internal Bench Testing Elements

Define your Test Objectives (specifications or compliance to a regulatory standard/guidance)

Determine Sampling Parameters

- Sample: Entire device/a part or component/attribute of the device
- Is it the final/finished device subjected to all manufacturing processes?
  - If not, justify why this approach is appropriate given any differences that may impact performance of the tested device
- Sample Size: Based on Test Objectives, Risk Analysis, Sampling Plan or as described in the standard/guidance
- Describe sample configuration, how samples represent a clinically relevant scenario and how inter and intra lot variability are accounted for

Determine Pass/Fail Criteria (when applicable)

- Should be Pre-Defined: Based on performance needs & intended use of the device
- For characterization tests without an acceptance criteria, determine assessment criteria

Internal Bench Testing

Determine Data Analysis Plan

- Planned Qualitative and/or Quantitative Assessments

Test Results

- Present data collected for all samples (including outlying results) in data sheets or tables
- Accompanied by summaries, statistical information, additional images, rounding methods

Data Analysis

- Conclude with if acceptance criteria were met and describe potential reasons of failure
- Determine if re-testing is required, describe test protocol deviations and assess impact on test results

Discussion/Conclusions

- Discuss conclusions drawn from test results with respect to stated objectives
- Whether pre-specified acceptance criteria were met

What To Do If You Fail

- Summarize failure in the test report
- Determine the root cause of the failure
- Identify how to edit device or software for a better result
- Capture changes in design file (Design Input/Output changes)
- Conduct re-testing
- Repeat as necessary

Ongoing Testing/Design Changes

- Capture changes in design file (Design Input/Output changes)
- Utilized design traceability matrix and a risk assessment to determine if additional verification testing is needed
- Justify reasons for not testing
- Update DHF with new outputs and testing
- Track changes in ECO, Software Change process
- Release new design

Questions

www.RookQS.com
Make sure to visit our website to learn more about our services and consulting team.

Contact **info@rookqs.com** for more questions, comments, or to set up a meeting. One of our consultants will be sure to reach out to assist!

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