



# Top 3 Testing Tips for Successful Verification

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**Trisha Bouthot, Director of Quality & Test, Sunrise Labs**  
**Dave Hibbard, Director of Programs, Sunrise Labs**



## Attendees will learn

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- Best practices in development and execution of verification plans and protocols
- Tailoring verification plans based on project needs, risk profile and regulatory strategy
- Strategies to help mitigate schedule impact and risks when verification start is delayed
- The benefits to planning for verification early in a project
- Implementation of Agile methodologies with continuous code review/integration testing



# Verification is a Partnership

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## Quality Assurance & Development

At its core, Verification is confirmation that the device was designed right

Verification considerations should be made early and often throughout development

Verification isn't just the responsibility of the test engineers

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# Best Practices



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## Verification Plans

“Planning” is more than just a plan

## Protocols

Strategize to ease your pain

## Tools

Choose the right tool for the job

## Reports

A Summary Report is your friend

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# Verification Plan

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## Project Needs

Device Use - Emergency Use, Human Factors Studies, Clinical Trial, Commercialization

## Risk Assessment

Safety Class: FDA vs IEC 62304  
IEC 60601  
Schedule Risk

## Regulatory Strategy

IRB, 510(k), PMA  
Release Regions

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# Protocols

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## Test Case Development

Strategy to breakup requirements into Protocols

Dry Runs

Match test strategy to Class of product

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# Tools

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## Tools

Requirements and Test Management Tools

Agile Methodologies

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# Execution and Reporting

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## Test Execution

Hold off in favor of dry runs

Goal is for smooth issue free execution

Redline minor protocol issues

## Test Reporting

Rationale for open anomalies

Create summary document



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## Key Takeaways

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- **Tip 1: Start planning for test early on in project**
    - Review requirements for testability
  
  - **Tip 2: Match test strategy to Class of product**
    - Organize Protocols with rerun/regression in mind
  
  - **Tip 3: Dry run, dry run, dry run**
    - Ensure smooth execution of verification

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**Questions?**

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# Thank you!

Every Great Project Starts With A Thoughtful Conversation

## RESOURCES

[Podcast - Continuous Integration & Automated Testing](#)

[White Paper - Managing Requirements](#)

[White Paper - Medical Device Commercialization 101](#)

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## Contact Us

**Laurin Noel**

VP Business Development

[lnoe1@sunriselabs.com](mailto:lnoe1@sunriselabs.com)

[SunriseLabs](#)