

Accelerating a Predictable Validation Process



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Agenda

- **Validation process**
- **Discuss hardware design, manufacturing processes and software considerations**
- **Tips for increased success and schedule reduction**

Overall Validation Process

- **Early requirements, with test methods**
- **Concept development (division of design activities)**
- **Risk management**
- **Detailed design (and development testing)**
- **Integration testing (confirmation tests)**
- **Validation**

Validation begins at Conception

Key Areas Requiring Validation

- **Hardware Design**
- **Manufacturing Processes**
- **Software**

Validation Themes

- All areas have similar concerns:
- Approach
- Requirements
- Inputs
- Understanding
- Improvement/ risk reduction
- Confirmation prior to final system validation

Hardware Design Differences

- Bench/ lab testing must be representative of final use environment
- Methods to evaluate design need to be anticipated
 - Clay, cardboard, SLA, non-functional, etc.
- At what level can we validate?
 - Some could be relevant at a lower level and not need repeated

Manufacturing Process Differences

- **Test and inspection methods need developed**
 - Potential to leverage design tests, yet these need to be applicable for high volumes. Don't use exact versions of design tests, but don't ignore them either.
- **Lower risk exists if design and components are frozen before process validation is executed**

Software Differences

- **Tends to depend on hardware, thus lags to a certain degree**
 - As functions are added, software needs to adapt
 - As sensors are added, software needs to adapt
- **Easier to do incremental "integration" testing compared to hardware design**
 - Develop new code and then evaluate with prior code
- **Use environment is still important here**
 - Computer, operating system, quantity of users (bandwidth)

Component versus System Test

- **Understanding components (internally or at a vendor) is a good way to reduce risk**
 - Include component testing early
- **Finding a root cause during a system test is extremely complex**
- **Component exposures (manufacturing processes, sterilization, packaging/ shipping) can impact performance and reliability**
- **Important to have a strategic test plan. Ability to reduce potential errors at system level, yet allow time for resolving system level issues.**
 - If first system level test is for validation, then there is a lot to understand and explain
 - I prefer a quick, high priority system level confirmation. Not for every requirement, but enough to have reasonable confidence prior to “for the record” testing

Characterization Testing is Essential

- **Designers (of hardware, processes and software) need time to play**
- **However, at some point this needs to be structured to understand what is going on**
 - This helps accelerate any root cause analysis that may be needed during system level testing
- **Good documentation can be used for validation purposes**
 - To justify approach
 - To resolve failures

This is also called sensitivity testing and limit testing

Final Validation

- **Begins when characterization is completed**
 - Validation not started because we ran out of time
 - Raises confidence in passing validation test
 - What is acceptance criteria for knowing we completed it?
- **Test for the Record/ Transparency**
 - Learning should be done during characterization only
 - Any failures or deviations during validation should be communicated with management and customer. Avoid glossing over these items.
 - Nothing new is ever perfect. A clean report will appear suspicious.

Additional Validation Process Insights

- **Create tolerance limits for acceptable performance**
- **Determine critical components**
- **Understand material options**
- **Determine use conditions/ use cases**
- **Understand environmental sensitivities**

Special Situations

- **Process control limits (time, temperature, pressure, line speed, setup conditions, etc.)**
- **Process operating procedures**
- **Short term stability and capability of the process**
- **Test methods**
- **Software parameters and validation**
- **Material handling requirements**
- **Potential failure modes, action levels and worst-case conditions**

Conclusion

- **Doing upfront work prepares for validation, versus making validation strategy decisions at end of the project**
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 - www.PerrysSolutions.com
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 - Newsletters are all archived on our publications page