



SIMPLIFYING SUT INTEGRATION AND DEPLOYMENT

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SESSION OVERVIEW AND OBJECTIVES

Simplifying SUT

Cross Functional Panel

Overview

- > Provide relevant and targeted guidance on how to simplify SUT integration and deployment from both end user and supplier perspectives
- > During this session, each Panel Member will cover their Top 3 Technical, Business and Quality means to simplify new or existing SUT implementation/Deployment
- > Panel Exists of the Following Expert Level End Uses and Suppliers
 - » **Mark McElligott**: Partner/Principal Process Engineering from PDS Sandbox
 - » **Mark Maselli**: Process Engineering Manager from Homology
 - » **Jay Harp**: Single-Use Product Manager from VWR/Integra Companies
 - » **Bill Devine**: Process Engineer and Single Use Lead from Pharma-Tech Services
 - » **Polly Hanff**: Global Regulatory Affairs and Quality Director from Saint Gobain



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Simplifying SUT

Cross Functional Panel

Session Goal

- > Provide targeted and relevant “take-home” strategies for all attendees to implement into current or future SUT integrations
- > Remove or Reduce unnecessary complexity, mysteries and confusion around real/relevant requirements versus “nice to haves”
- > Provide a cross functional panel of industry experts with direct/hands-on experience inclusive of SUT end users who have implemented both stand alone and hybrid solutions

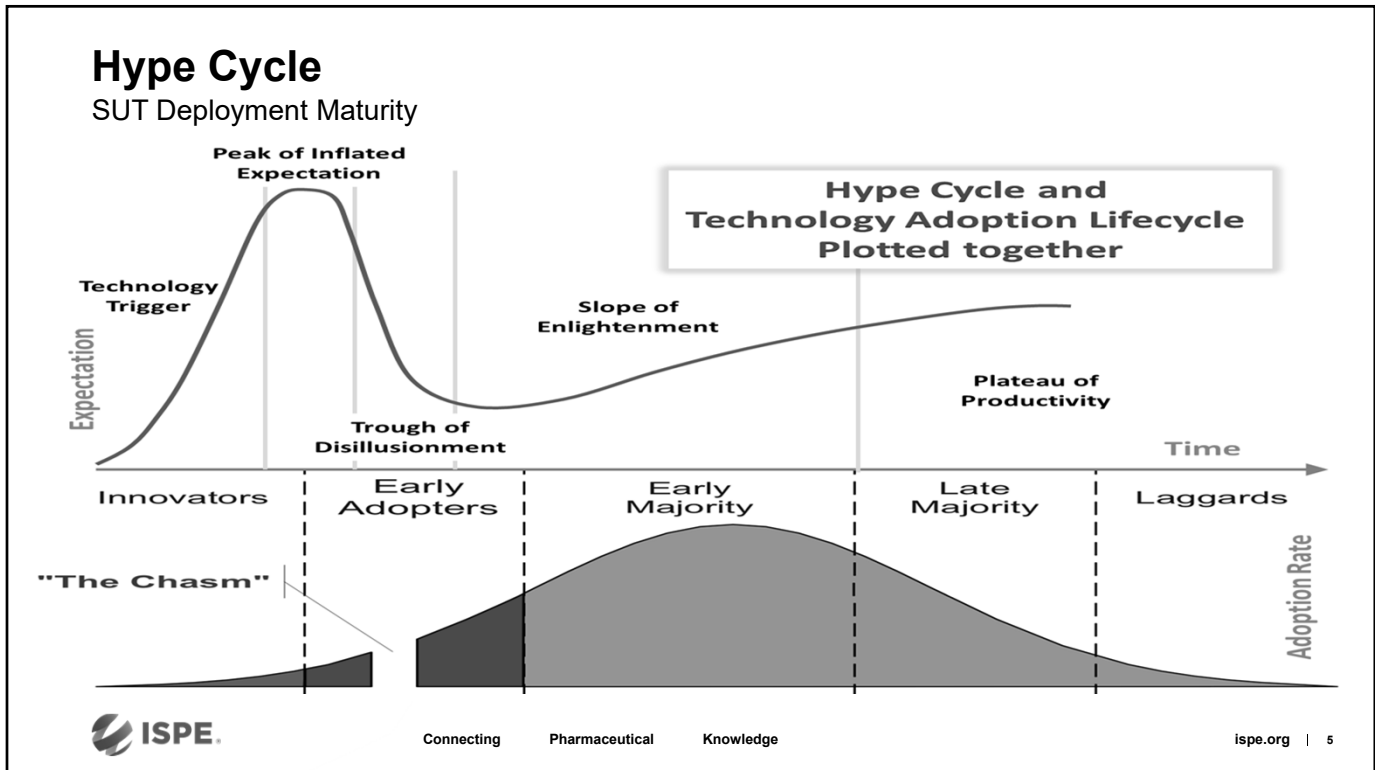


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KEY ELEMENTS FOR SIMPLIFYING SUT

MARK MCELLIGOTT

PARTNER/PRINCIPAL PROCESS ENGINEER-PDS SANDBOX

Top 3 Technical Ways to Simplify SUT

1. Minimize MOCs downstream of leachables clearance step for all processes
2. Facilities should be designed around the SU parts, instead of designing SU parts to fit the facility. This will lower the total number of unique parts
3. SU Component selection should be "platformed" and stepping outside of the exiting platform must be supported by value proposition/business case that outweighs the associated costs. (End User)



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Top 3 Business Ways to Simplify SUT

1. Select SU suppliers that act as "Partners" that have your patient in mind
2. Select SU suppliers who have technical expertise to help in ensuring relevant requirements have been established and they align with process requirements.
3. Track VCNs and ensure QTA's regarding supply chain changes to SU materials closest to the patient have security built in to allow for adequate testing



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Top 3 Quality Ways to Simplify SUT

1. Select SU suppliers that have a centralized Quality Program between all sites involved in manufacturing SU components used in manufacturing
2. Ensure SU Supplier QA Department demonstrates control over testing instead of leaving the acceptance criteria to the testing lab
3. Ensure SU Supplier manufacturing controls and sampling methodologies are statistically relevant



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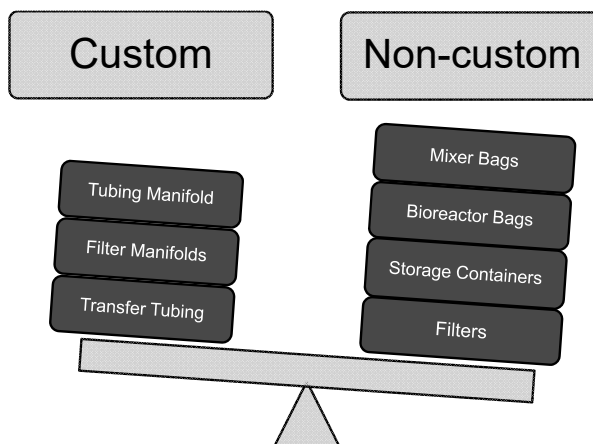
KEY ELEMENTS FOR SIMPLIFYING SUT

MARK MASELLI

PROCESS ENGINEERING MANAGER-HOMOLOGY

Top 3 Technical Ways to Simplify SUT

1. Establish a platform process
2. Find a balance between custom and non-custom SUTs
3. Constantly monitor and control process performance of SUT and work with suppliers to improve



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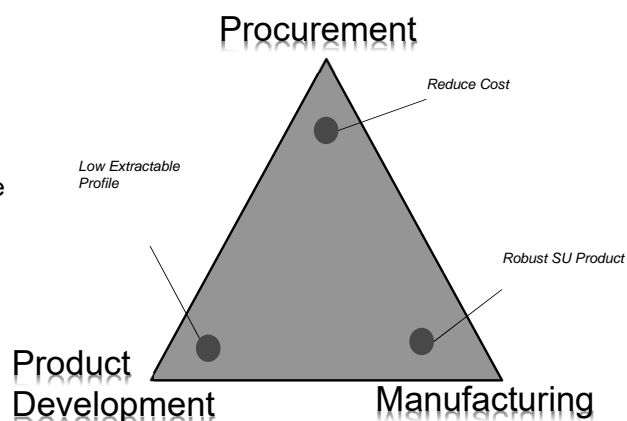
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Top 3 Business Ways to Simplify SUT

1. Define a strategy with key stakeholding departments within the organization
2. Collaborate with select suppliers throughout the development process to ensure streamlined process scale-up
3. Manage a single-use technology roadmap



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Top 3 Quality Ways to Simplify SUT

1. Select SU suppliers who have characterized their materials and understand the criticality of their components within the end-users process
2. Establish an efficient process to manage and control material and design changes
3. Develop a modular qualification strategy to expedite change



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KEY ELEMENTS TO SIMPLIFYING SUT

JAY HARP

SINGLE-USE PRODUCT MANAGER: VWR/INTEGRA COMPANIES

Top 3 Technical Ways to Simplify SUT

1. Maximization custom flexibility with responsible designs
2. Provide manufacturer/integrator complete process stream rather than just segmented unit of operation
3. Use appropriate/characterized/proven components for the appropriate application



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Top 3 Business Ways to Simplify SUT

1. Select SU suppliers that act as "Partners" that have your patient in mind
2. Transparency from manufacturer/integrator to end user & end user to manufacturer/integrator
3. Supplier that is devotion to the industry



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Top 3 Quality Ways to Simplify SUT

1. End user expectations between manufacturing and quality
2. Proper/robust/auditable relationship with L1 & L2 component manufacturers/suppliers
3. End user's regulatory requirements that are unified site to site.



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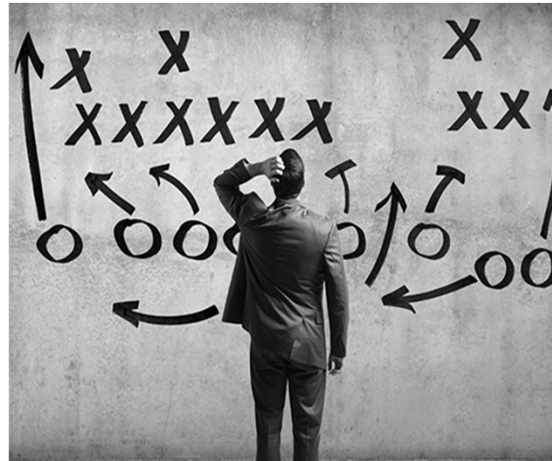
KEYS ELEMENTS TO SIMPLIFYING SUT

BILL DEVINE

PROCESS ENGINEER SINGLE USE LEAD
PHARMA-TECH SERVICES

Top 3 Technical Ways to Simplify SUT

1. Project Execution Planning – Replace or supplement traditional Cleaning/Sterilization Validation Master Plans with a Single Use Implementation Master Plan.
2. Identifying real world, tangible technical User Requirements based upon science and risk based principles for which the SUT must provide. (pressure, flow, temperature, connection types, etc.)
3. Communicate SUT PEP and User Requirements to all stakeholders especially, SUT suppliers to ensure alignment and applicability of requirements. Be Transparent!



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Top 3 Business Ways to Simplify SUT

1. Identify and communicate real world, tangible Business User Requirements based upon required business practices. (Payment Terms, Quotes, QTA's, POs, Lead Times, etc.)
2. Recognize and align to the business work flows of SUT suppliers. Be nimble, avoid rework
3. Stop buying SUT like stainless steel. Develop purchasing strategies for continuous supply chain of SUT vs one time capital purchase of stainless steel systems.



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Top 3 Quality Ways to Simplify SUT

1. Identifying and communicate real world, tangible quality User Requirements based upon science and risk based principles. (regulatory, E&L, SAL, Release testing, etc.)
2. Alignment/Audit of Quality Management Systems to deliver upon requested quality User Requirements
3. Stop qualifying SUT like stainless steel. Revise outdated standards, SOPs, and guidelines to appropriate reflect advances with SUT. (Process closure methods, environmental backgrounds, etc.)



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KEYS ELEMENTS TO SIMPLIFYING SUT

POLLY HANFF

GLOBAL REGULATORY AND QUALITY DIRECTOR
SAINT GOBAIN PERFORMANCE PLASTICS

Top 3 Technical Ways to Simplify SUT

1. Align Supplier Technical Support with End User Technical decision makers – early engagement to minimize part by part requirements
2. Designing the End User Facility and Process in coordination with the Supplier to optimize usage of standard offerings
3. BPOG guidance on extractables testing is not practical when time and cost are considered with testing using 6 model solvents across the range of time/temperature for a SU supplier with a large portfolio of products. Alignment on the “base” need (e.g. ethanol & water)....



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Top 3 Business Ways to Simplify SUT

1. End User Industry Standardization of Quality and Technical Requirements
2. Intellectual Property:
 - Consider IP developed that relate to SUT could be leveraged by suppliers to gain efficiency. Examples: ad hoc equipment developed for manipulating SUS at the end user, shipping systems, cryopreservation systems.
 - Clarification on IP when it comes to SU designs. Where can custom designs be leveraged for different customers vs what is proprietary.
3. Improved forecasting and demand visibility



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Top 3 Quality Ways to Simplify SUT

1. Standardize on cleanroom expectations for SUT such that the process step is considered.
 - What parts of the SUT need to be manufactured in a cleanroom?
 - What particulate levels are achievable depending on the manufacturing type (extrusion, molding, assembly)?
 - Should end-users be treating these all equal in terms of requirements?
2. Alignment on where in the bioprocess a sterile label claim is required vs bioburden reduction via gamma irradiation. Where is fluid path sterility required vs full immersion.
3. BPOG/BPSA Change Notification decision tree – can we bring risk-based thinking into this as a first step as this is what ISO, ICH, and health authorities all require.



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**CONCLUSION
AND
PANEL DISCUSSION**

Simplifying SUT Conclusion

Cross Functional Panel

Session Goal Re-Stated

- > Provide relevant and targeted take aways for all attendees to implement into current or future SUT strategies
- > Reduce unnecessary complexity and confusion around real/relevant requirements versus “nice to haves”
- > **SUT** Implementation and Deployment can be simplified and streamlined through the establishment of targeted, specific, and most importantly relevant requirements

Panel Discussion



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