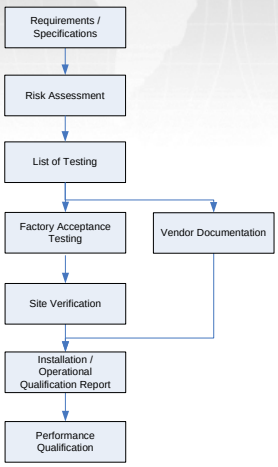
Bristol-Myers Squibb
Devens Facility
Verification / Qualification Approach

Michelle Whipple



Risk Assessment

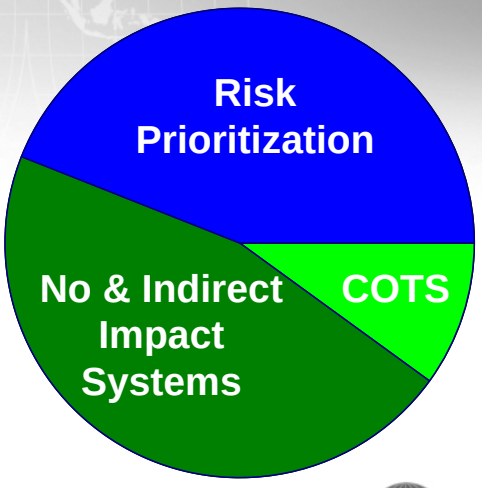
- Three Part Process
  - Impact (Direct, Indirect, No Impact)
  - Degree of Customization
  - Risk Prioritization Assessment (Against Product and Regulatory Requirements)
- Product Impact Tests are Quality Approved
- All Other Tests Approved by SME

Overall Risk Assessment Results

Total of 85 systems required a full 3 part risk assessment

Performed according to process groupings (Media Prep, Cell Culture, etc)

Completed in ~2 months

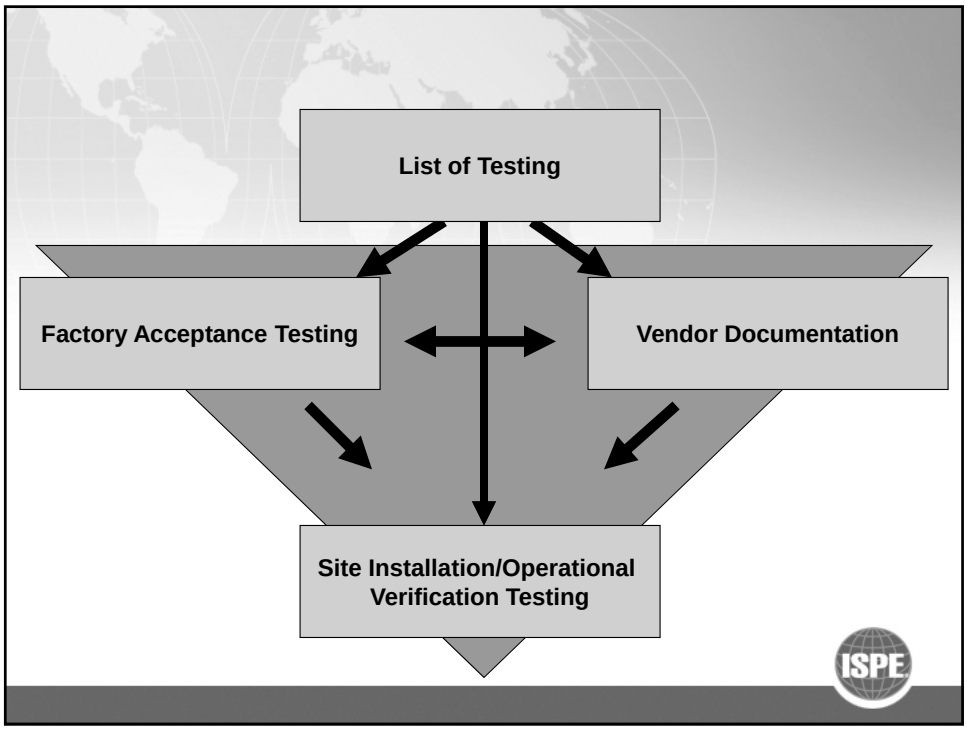


Media Preparation Example

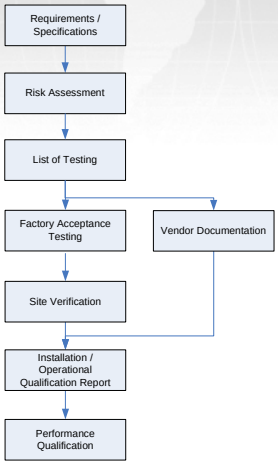
- Impact – Direct
- Customization – Some Customization
- Product Requirements
  - Agitation Control - Agitator Motor
  - Temperature Control – Vessel RTD
  - WFI Addition Control – Flow Transmitter
  - pH Measurement – Vessel pH Meter
  - Osmolality Measurement – Offline Sample

Media Preparation Example

- Other Requirements
  - CIP of Tank and Transfer Line CIP – Skid Controls
  - Only Transfer Line post filters is SIPd – RTDs
  - Process / Hold Times – Recipe Timers

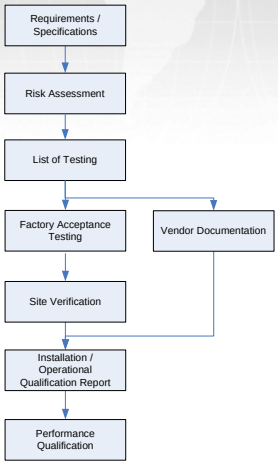


Vendor Documentation



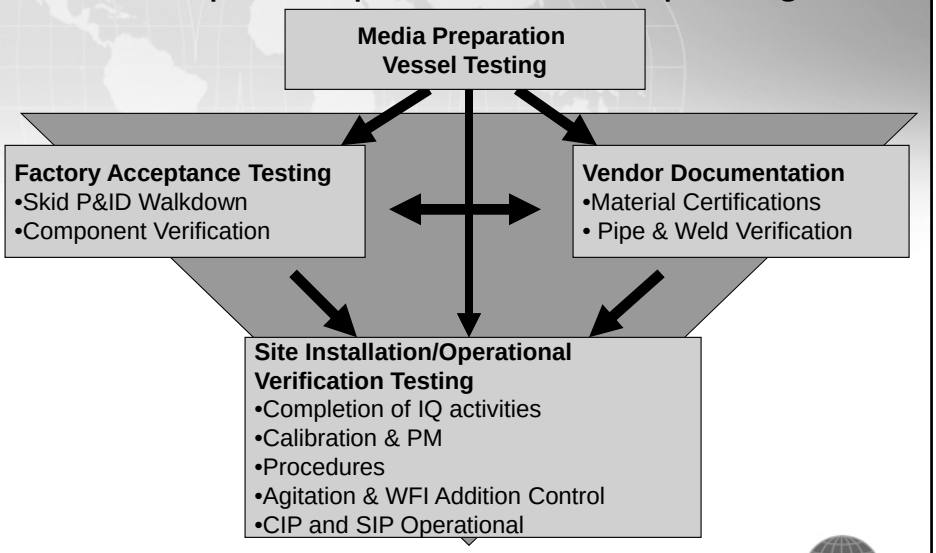
- Vendor Audits for Direct Impact Systems
- Review by BMS SME's
- Audit of documents by QA

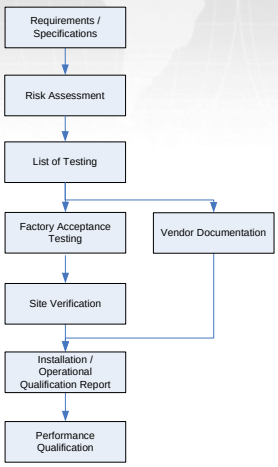
Factory Acceptance Testing



- Risk Assessment completed prior to FAT
- Consideration of impact to tests due to transportation, utility limitations at the vendor
- Good Documentation Practice training to groups performing testing

Media Prep Example – Product Impacting





Performance Qualification

- Focus on Process requirements
- Simulated batches may be run using procedures and automation functionality in the fully integrated system
- Steam in Place and Clean in Place functional challenges are included

Media Preparation Example – PQ's

- Mixing Study
- Various Hold Time Studies
- SIP with BI's for transfer line only
- Cleaning Validation

Summary

Science and risk based approach to focus testing on impact to patient safety, product quality, and data integrity

Provides traceability between equipment testing and product requirements and identification of critical instruments