Pfizer's Science and Risk Based Approach to C&Q

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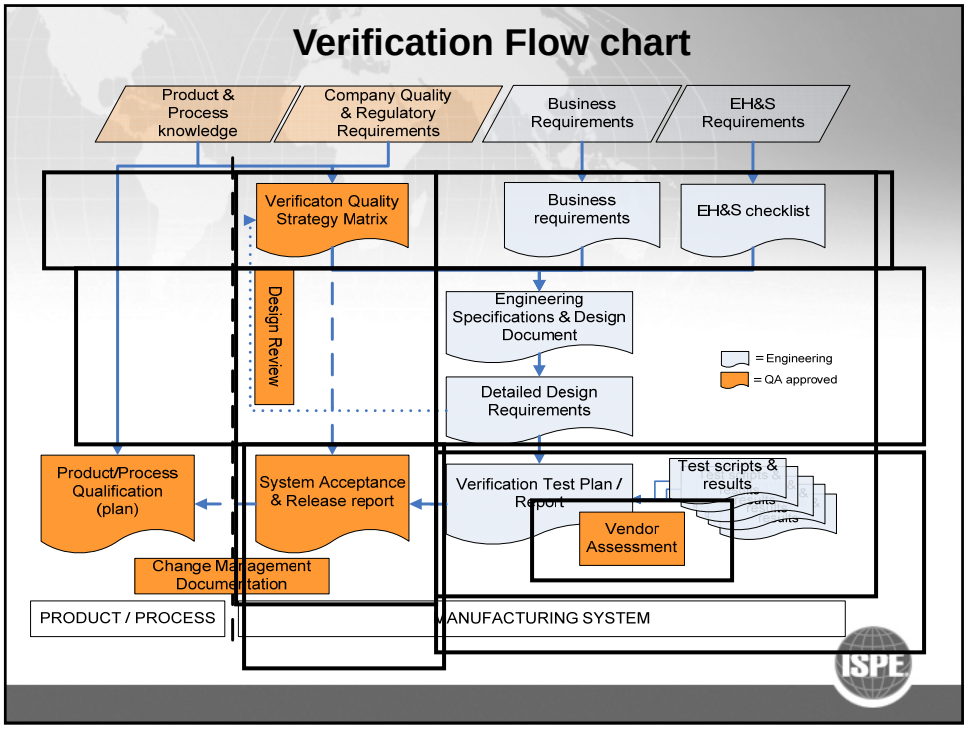
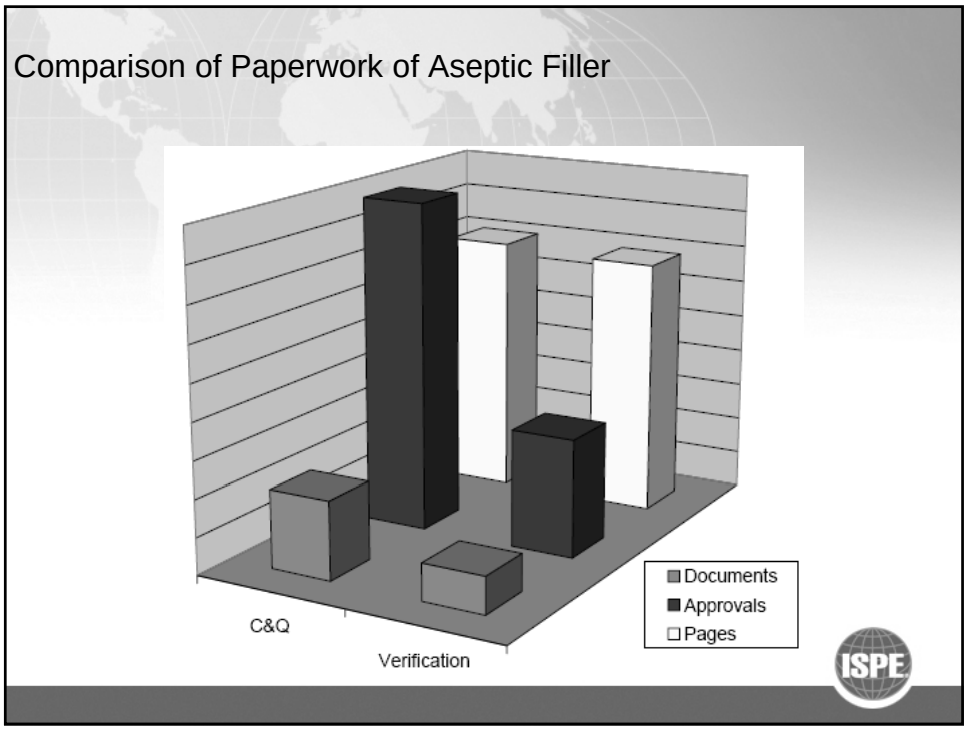
Armen Nahabedian
Pfizer Global Engineering
Andover, MA

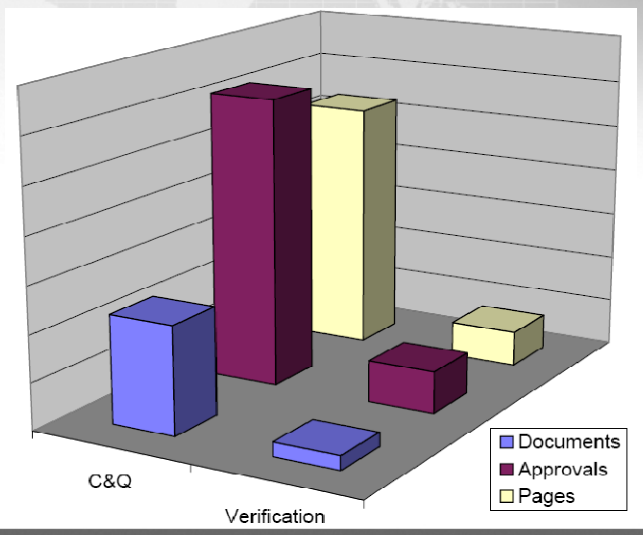
Organizational Scope and Status of Verification Program

Status	Pfizer Sites
Total	**>70**
Newly implemented (< 1 year experience)	**9**
In planning and implementation	**16**
Future Opportunities	**>45**

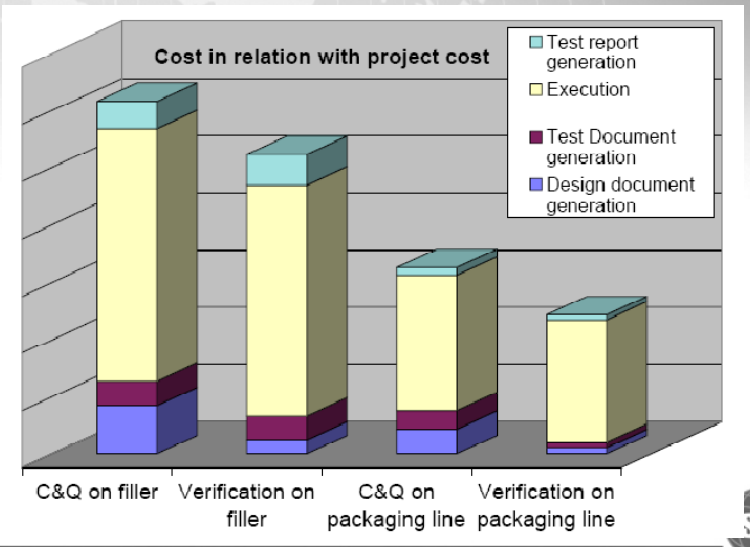

Verification Flow chart
Product & Process knowledge
Company Quality & Regulatory Requirements
Business Requirements
EH&S Requirements
Verificaton Quality Strategy Matrix
Business requirements
EH&S checklist
Design Review
Engineering Specifications & Design Document
= Engineering
= QA approved
Detailed Design Requirements
Product/Process Qualification (plan)
System Acceptance & Release report
Verification Test Plan / Report
Test scripts & results
Vendor Assessment
Change Management Documentation
PRODUCT / PROCESS
MANUFACTURING SYSTEM
ISPE


Comparison of Paperwork of Aseptic Filler
C&Q
Verification
Documents
Approvals
Pages
ISPE

Comparison of Paperwork of Packaging Line



Compare C&Q cost data



Some Common Notions about Verification Seen at the Sites

The Verification Program = Req-Spec/Design and Testing

The Verification Program = A testing program

Verification = Sufficient Testing to Show Fitness for Use

Verification = Lots of Testing

GEPs take Engineering Management's Commitment

GEPs are a No Brainer

The SME is responsible for testing and evaluating the results

Engineering Hands off to the Verification Group

Engineering is Responsible to Assure Fitness for Use

"Who checks the quality of our work if QA does not"?

Document Example

- Requirements Document
- Design Review Summary