620 Cranbury Road, Suite 202
East Brunswick, NJ 08816
Tel 732.257.9033
Fax 732.257.9044
www.stsv.com

Lifecycle Quality Solutions

STS Federal Government Consulting Practice IV&V Offering

WBE Certified
GSA Contract GS-35F-0108T

For information
Please contact:
gsa70@stsv.com

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Outline

- Background on STS
- What is IV&V?
- STS IV&V Service Offering
- STS IV&V Methodology
- Summary

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Background on STS

- Founded in 1998
- Privately held company, WBE Certified, Classified as Small Business
- Total Revenue: $13.5M (2005)
- Total number of employees: 100+
- Consulting Practices:
  - Life Sciences
  - Telecommunications
  - Financial Services
  - Government (GSA Schedule 70 effective November 2006)
- Full Life Cycle but with specialty in Testing, Quality, and Compliance
- Relevant IV&V Experience: Testing, QA, Compliance, Auditing, Project Management, FDA Computer System Validation
- Credentialed, trained, experienced consulting staff certified in STS Methodologies
- Staff includes specialists with hard to find skills such as enterprise architecture, security, and program management

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What is IV&V?

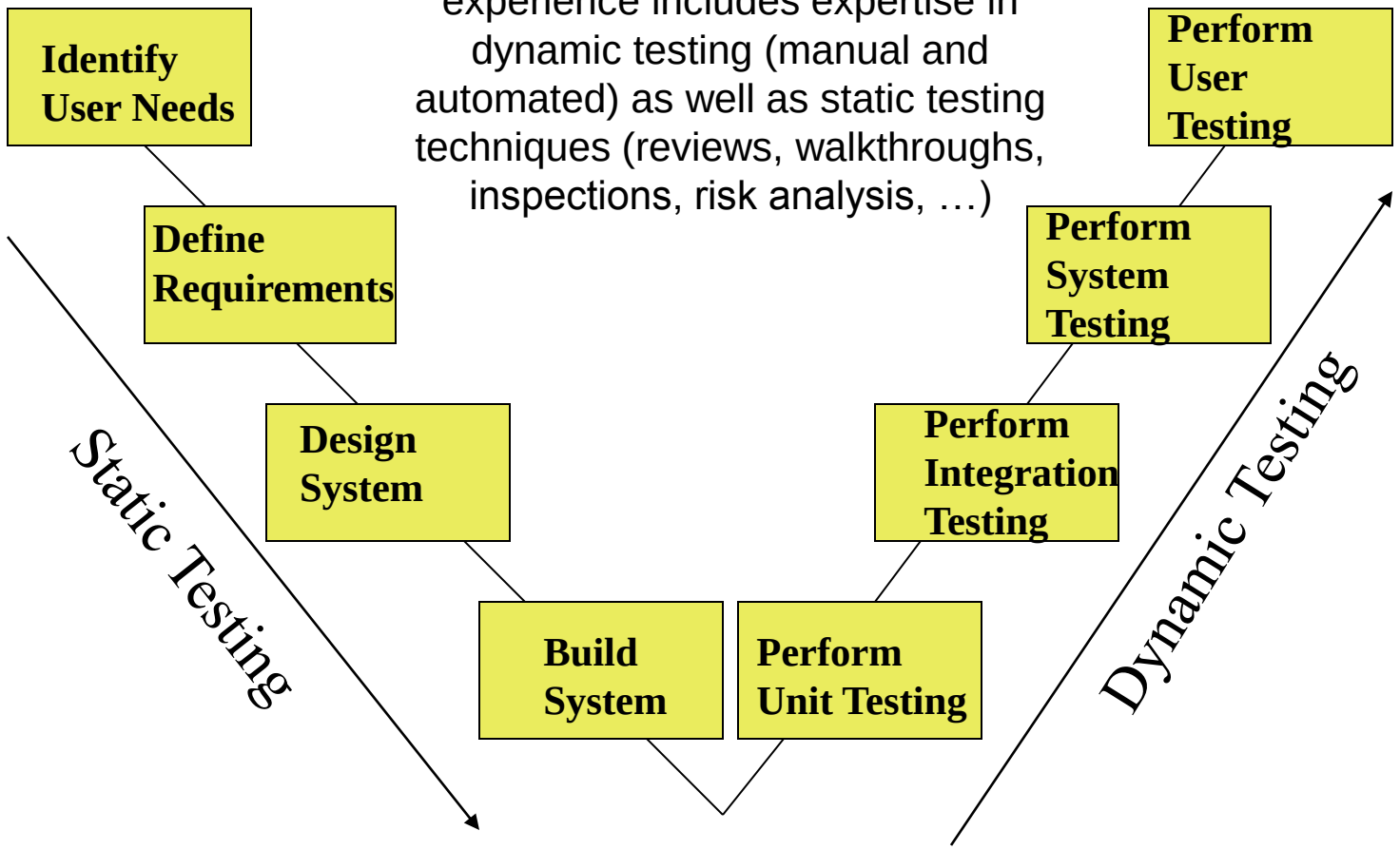
- IV&V refers to a spectrum of QA, compliance, and testing functions ranging from quality and project delivery oversight responsibilities to full SDLC, rigorous static and dynamic testing
- Performed by a team independent of both System Owners and System Developers

IV&V as QA Oversight

- Establish quality system (if quality system doesn't exist)
- Drive conformance to quality system and project constraints (e.g. budget, schedule, deliverable acceptance)
- Performed by a team independent of both System Owners and System Developers

“V” Diagram of Software Development Life Cycle (SDLC)

STS’s full life cycle experience includes expertise in dynamic testing (manual and automated) as well as static testing techniques (reviews, walkthroughs, inspections, risk analysis, …)



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Rigorous IV&V

- Verification and Validation activities performed by IV&V team throughout SDLC
- Consistent with international standards and industry best practices (e.g. IEEE standards for IV&V)
- Consistent with most stringent regulations and guidelines (e.g. FDA Computer System Validation and 21 CFR Part 11)

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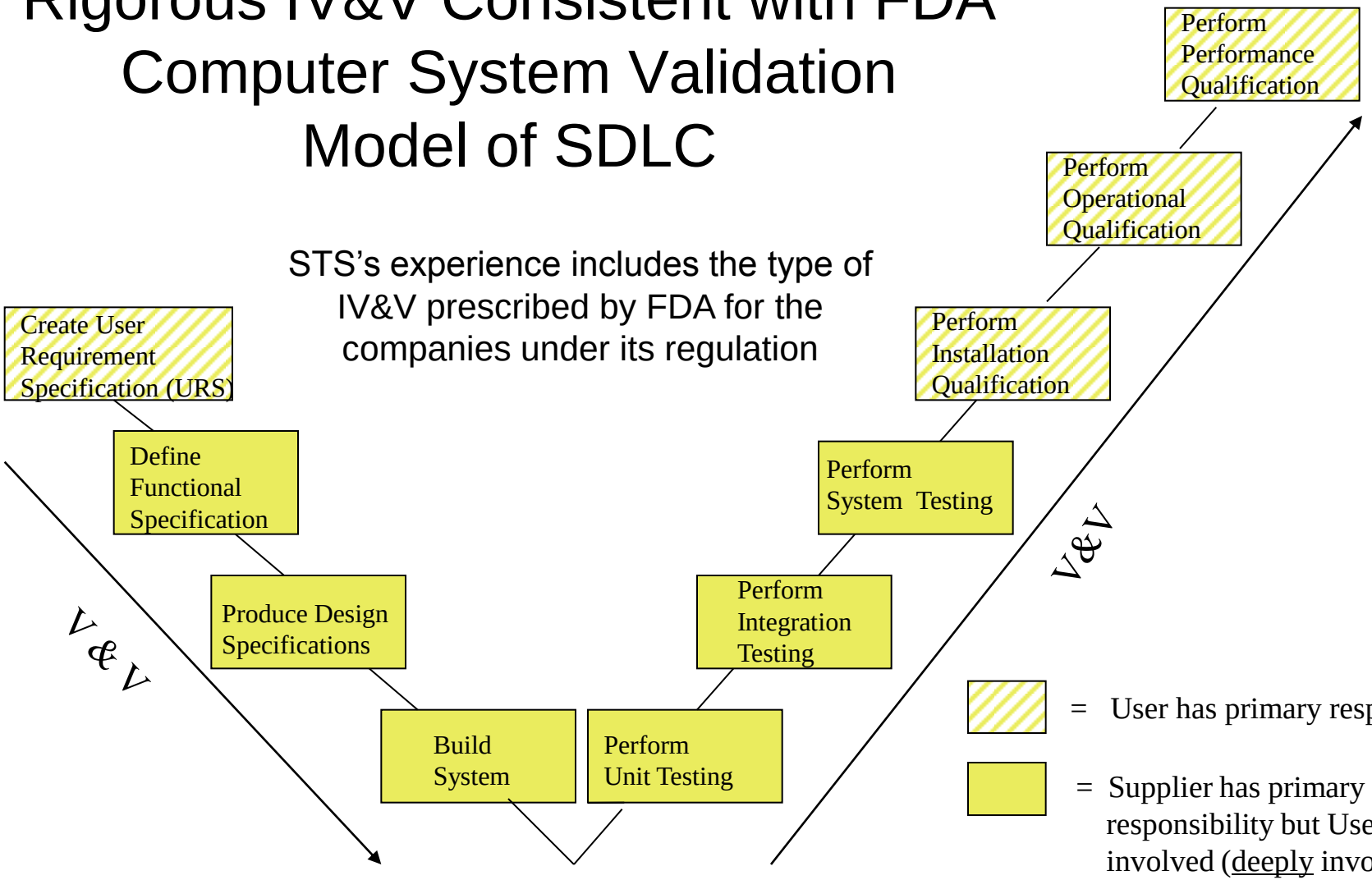
Rigorous IV&V Consistent with FDA Computer System Validation Model of SDLC

STS's experience includes the type of IV&V prescribed by FDA for the companies under its regulation



= User has primary responsibility

= Supplier has primary responsibility but User is involved (<u>deeply</u> involved for custom development) and User is responsible for ensuring that documented evidence of quality is accumulated.

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STS IV&V Service Offering

- Verification and Validation activities performed by STS IV&V team throughout SDLC
- Level of IV&V activities consistent with client needs
- Services and deliverables range from QA and project oversight to producing IV&V documents consistent with international standards, industry best practices and most stringent regulations and guidelines

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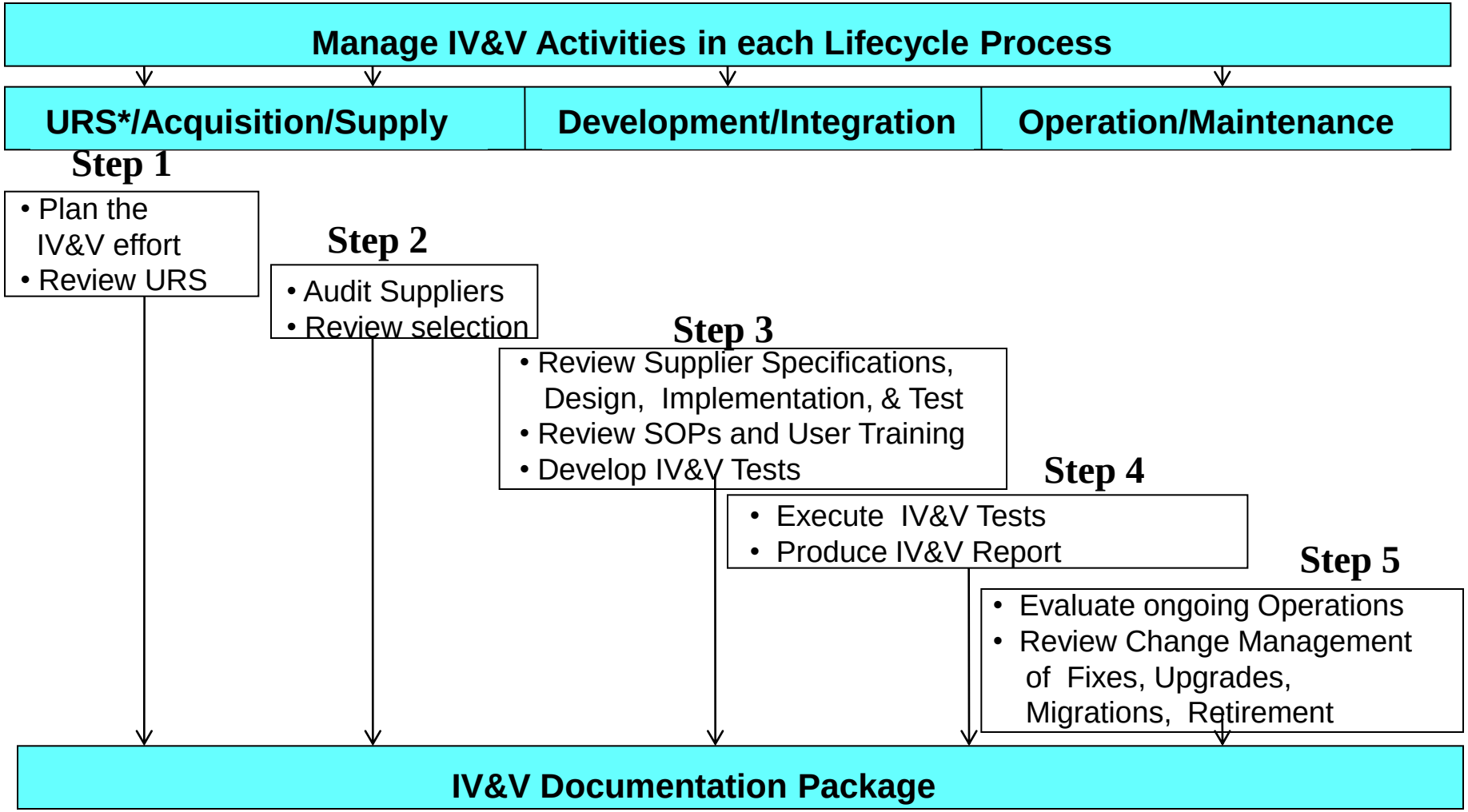
High Level View of STS IV&V Methodology



* URS stands for User Requirements Specification

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Outline of IV&V Plan

- Purpose
- Referenced documents
- Definitions
- Validation overview
  - organization
  - master schedule
  - resources summary
  - responsibilities
  - tools, techniques and methodologies
- Life cycle validation
  - management of validation
  - acquisition
  - supply
  - development
    - concept phase
    - requirements phase
    - design phase
    - implementation phase
    - test phase
    - installation and checkout phase
  - operation
  - maintenance

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Outline of Validation Plan (continued)

Software validation reporting

Validation administration procedures

- anomaly reporting and resolution
- task iteration policy
- deviation policy
- control procedures
- standards, practices and conventions

Validation documentation requirements

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STS Can Meet Your IV&V Needs

- Significant experience in Testing, QA, Compliance, Auditing, Project Management, Independent Computer System Validation
- Flexible IV&V service offering ranging from QA oversight to stringent IV&V deliverables consistent with international standards, industry best practices and most stringent regulations and guidelines
- Credentialed, trained, experienced consulting staff certified in STS Methodologies

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