Trinity Consultants Life Sciences' Approach to ASTM E2500 Rev 25

(Focus: HPAPI)

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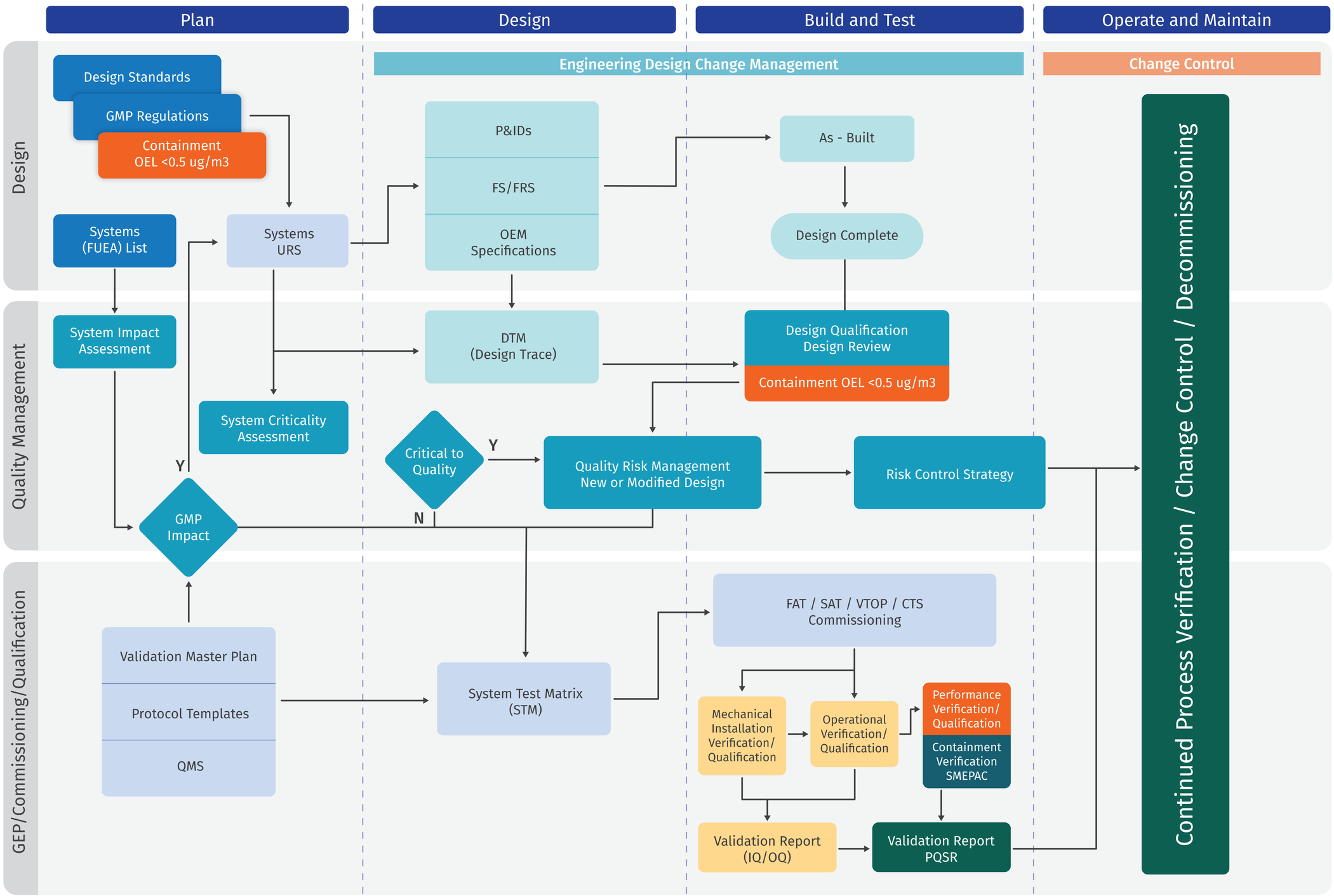

LEGEND

- Inputs
- Engineering
- QRM Elements
- CQV Elements
- HPAPI Impact
- Quality Approval
- QA Oversight

ACRONYMS

CTS – Controlled Temperature Systems

DTM – Design Trace Matrix

FAT – Factory Acceptance Testing

FS /FRS – Functional (Requirements) Specifications

FUEA – Facility Utility Equipment Automation

GMP – Good Manufacturing Practices

IQ – Installation Qualification

OQ – Operational Qualification

PQSR – Performance Qualification Summary Report

P&IDs – Piping & Instrumentation Drawings

QMS – Quality Management Systems

SAT – Site Acceptance Testing

URS – User Requirements Specifications

VTOP – Virtual Turnover Packages