ISA Delhi Section

Setting the Standard for Automation™

Computer System Validation- Practical Aspects

Anand iyer

Innovative Consulting Inc.

sales@iconsultingcorp.com

ISA-D: “Fertiliser , Food and Pharma Symposium-2022”

Anand Krishnan Iyer,
Principal Consultant, Innovative Consulting Inc

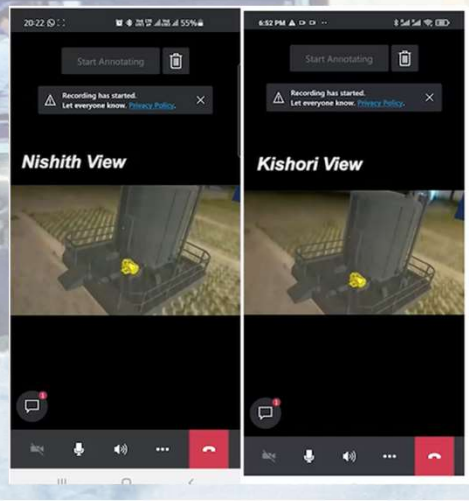
B.E.(INSTRUMENTATION),
Computer System Validation
TUV CFSP, Ex-PMP.,
Industrial Cybersecurity Competency- Abhisam

Active in ISA-ACARD, ISA-Pune & ISA-Bengaluru
Global Incharge Fieper project ISA-ACARD

Innovative Consulting Inc
ISA Delhi Don’t Miss trying out our AR with Hololens -2

1. **Operator training in Virtual environment.**
2. **Step by step guidance in Virtual environment.**
3. **Virtual Walkthrough**
4. **Digital Signature via remote collaboration.**
5. **Full Validation package possible**

SOP: Three Pump Operation



Our Company: Overview

Innovative Consulting Inc. provides professional support and companionship for **consulting services, project governance, and accelerating customer solutions** in Automation, Manufacturing Systems & IT.

Our team works closely with clients to deliver expertise to **plan, design, implement, and maintain client projects** in alignment with industry standards and design specifications.

Locations:

United States (OR & CA), Canada, Estonia and India

Our Mission

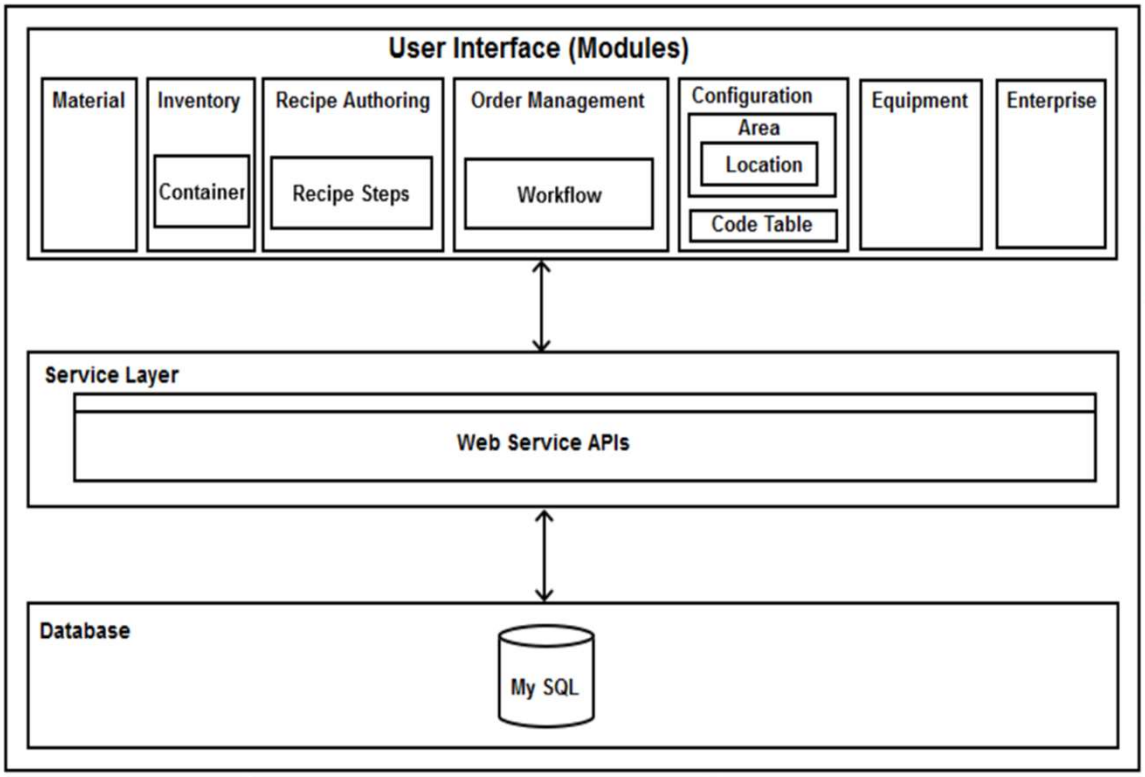
- Customer Satisfaction is High Priority
- Accurate / Precise Engineering
- On Time Commissioning/ Startup
- Highest ROI
- Rapid Deployment
- Experience in FDA Regulated Industries
- Virtual Support for Remote Activity
- Close Coordination with Teams

Anand Krishnan Iyer,
eWIS MES

eWIS stands for electronic Work Instruction System is the Manufacturing Planning and Execution System for managing the Manufacturing operations and Enterprise management. There are seven modules integrated together for the successful planning and execution of the manufacturing process.

- Material Module
- Inventory Module
- Recipe Authoring Module
- Order Management Module
- Configuration Module
- Equipment Module
- Enterprise Module

Anand Krishnan Iyer,
eWIS MES Architecture



Clients

ICI

CSV- Practical Aspects
ALCOA +

- Attributable – Who?
- Legible – Easily readable / understandable
- Contemporaneous – At the time of happening
- Original – The original record and not a true copy
- Accurate – error free and accurate
- +
  - Complete – all data including repeats
  - Consistent – date time stamped- in sequence
  - Enduring - Storage medium will last lifecycle … read retention period +
  - Available – can be brought for audit/review/inspection

CSV- Practical Aspects
What is Computer System Validation (CSV)?

- What is the Computerized system designed to do?
- Can it do this consistently, repeatedly (so that it can be proven) and is it compliant to standards?
- This requires establishing standards, procedures, verification documents, that can prove all this.
- Plus once systems are in place, records –deviations-mitigations- change management happen.
- CSV is the documented process that the computerized system does all the above.
- CSV is a lifecycle process. Starts from conceptualizing a project and lasts till disposal of all elements of that project. (maybe replaced by another system and its CSV)

CSV- Practical Aspects
Where to begin

- Standards.
  - GMP Standards / Guidelines
    - FDA 21 CFR 11, 210, 211, 820
    - EU GMP Eudralex Anex 11
    - ISPE GAMP5
    - WHO/ ICH/PICS GMP Guidelines
  - ISA S88
  - ISA S95
  - ISA S99 / IEC 62443
  - NIST Cybersecurity Framework
  - Corporate Global Standards (developed over time)
  - Consultant provided Specs and standards (for greenfield)

CSV- Practical Aspects
Where to begin-Know your outfield

- Type of Project - Greenfield or Brownfield
- Scope of Project
  - Systems PAS-LIMS-MES-SAIL-Historian-SAP connectivity – Others
- Automation Qualification Plan
  - All encompassing – referencing different plans (PAS Plan / MES Plan / Integration plan)
- Documentation System
  - Manual – All documents are generated manually. E.g. Traceability is generated manually
  - Automated – Documentation System has templates and Traceability and other derived documents created automatically.
- Organization Maturity
  - Global Standards available and established and updated
  - Obsolete Global standards.
  - No Global standards
  - Fully Digitized VS lots of paper based records

CSV- Practical Aspects
Where to begin-Know your outfield

- Templates
  - Templates for documents are established and available
  - Templates to be development.
- Experts
  - Experts Available inhouse
  - Consultant hired / responsible for all Documentation activities.
- List of Deliverables
  - Clearly defined.
  - Room for additions in future
- Preferably have Separate Development – Verification and Production environments.

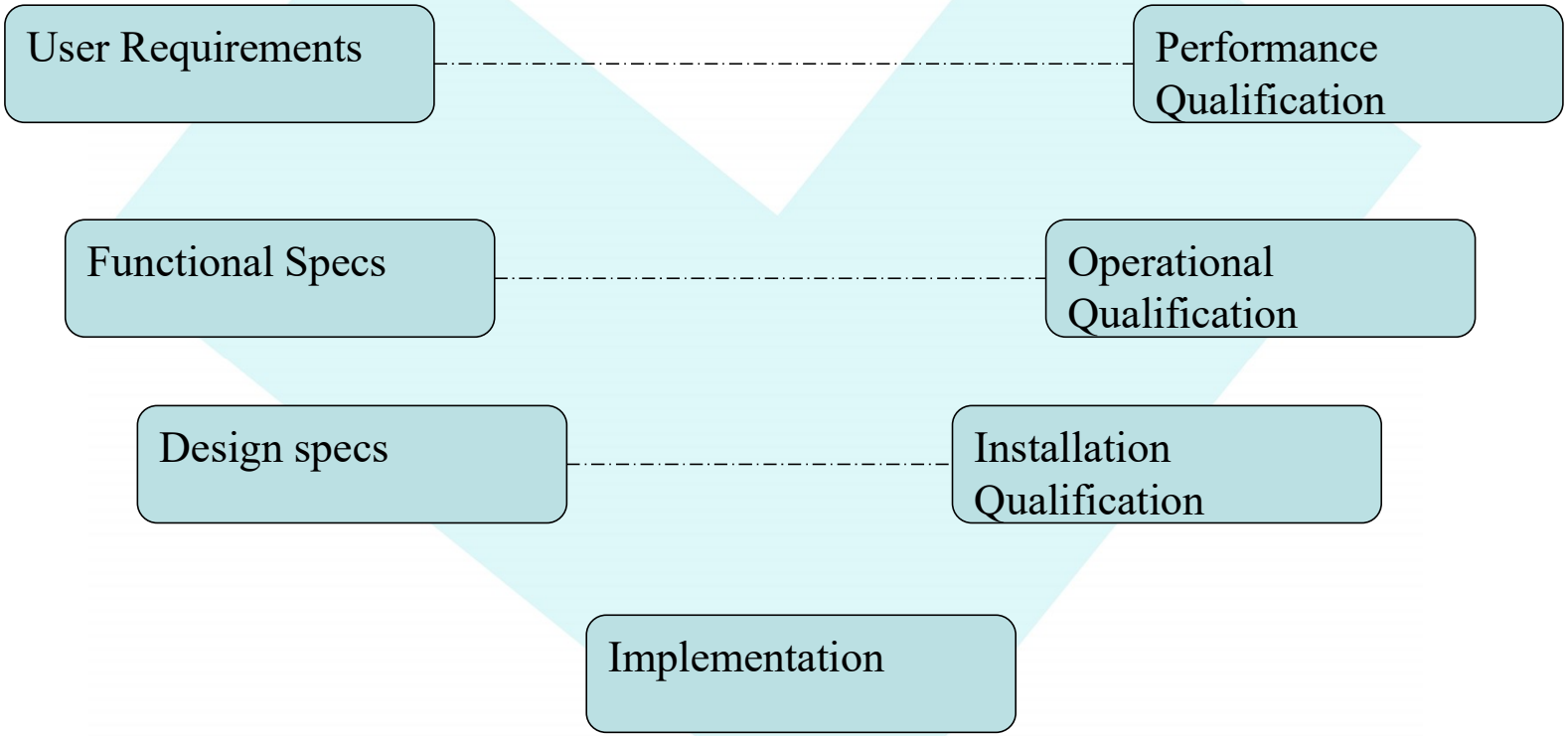
CSV- Practical Aspects
Get Going – Start-Luv-all

- Look at the exercise positively. Like a tennis tournament. Its exciting-entertaining- lots of tense moments and eventually the game wins! You have a compliant facility.
- URS as a starting point!
- RISK assessment
- Partner Evaluation
  - Automation Integrator selection
    - Subcontractor evaluation / selection
  - CSV consultant selection.
  - Automation Systems selection.
  - Documentation System Selection.
  - Local installation contractor selection.

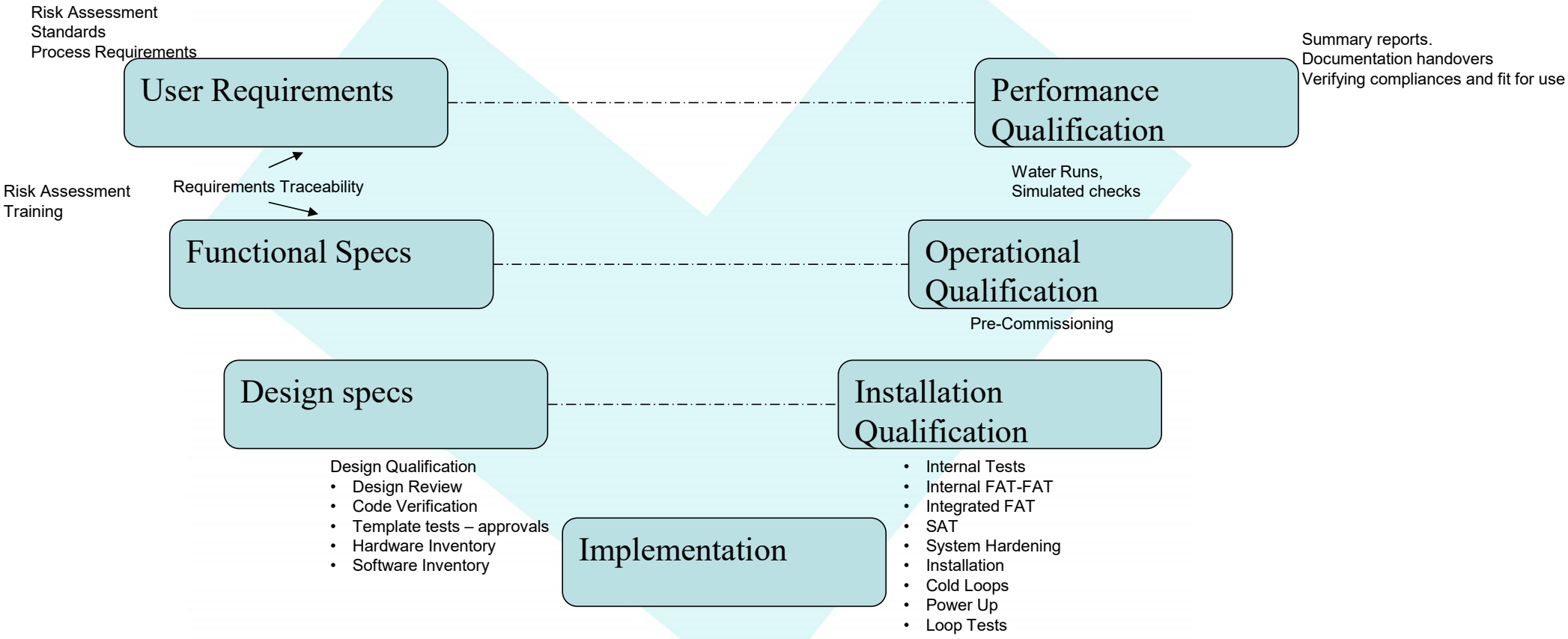
CSV- Practical Aspects
GAMP

- Good Automated Manufacturing Practice.
- CGMP – Current Good Manufacturing Practice
- GxP Generic Good Practice or Good (x) Practice
- COTS- Commercial off the Shelf Software
- GAMP – 4 Category
  - Configured software
    - SCADA
    - DCS
    - PLC
    - PAS (Process Automation Systems)
    - LIMS (Laboratory information Management System)
    - SAIL (Standard Automation Integration Layer)
    - MES (Syncade, eWIS, Werum etc.)
    - Historian (PI / Aspentech etc)

CSV- Practical Aspects
The V Model



CSV- Practical Aspects
V Model Steps (system-equipmentwise)



CSV- Practical Aspects
Supporting Activities / Documents

- Training
- Backup – Recovery Procedures
- Disaster Management Procedures
- Zero Day Recovery – Separate or part of Disaster Management
- Audit Trail retrieval – checking procedures
- Software Development Lifecycle
- Cybersecurity – Access related procedures.
- Change Management Procedures

CSV- Practical Aspects
Maintenance to Disposal

- Maintain system in Validated state.
- Manage Change.
- Maintain / audit Maintenance records as required by GMP.
- Perform Gap Assessments as needed.
- Perform Risk Assessments as needed.
- Perform/verify IQ-OQ-PQ as needed for changes.
- Maintain HW and SW Inventory. Check and update regularly.
- Update Anti-Virus-maintain records.
- Manage Users (Add-Delete-Restore). Update records.
- Maintain/verify Cybersecurity logs.
- Perform maintenance – maintain records.
- Have deviation management processes. Remedy deviations
- Update Standards. Update systems-documentation as needed.
- Maintain backups. Test restore at regular intervals.
- Slowly we come to End of Life and then Obsolescence plan, decommissioning and disposal needs to be planned and replaced with new system.

CSV- Practical Aspects
Future Developments

- Automated derived document generation.
- IIoT- cloud based system Validation is a challenge
- AI-ML, Validation challenges.
- Integrated supply chains- integrated CSV?
- Use of AR in Validation (remote verifier, virtual presenvce)
- Use of AR in virtual walkthroughs / virtual IQ-OQ-PQ

CSV- Practical Aspects
Q&A

- Sales@iconsultingcorp.com