T&ID, The Single Use Facility P&ID

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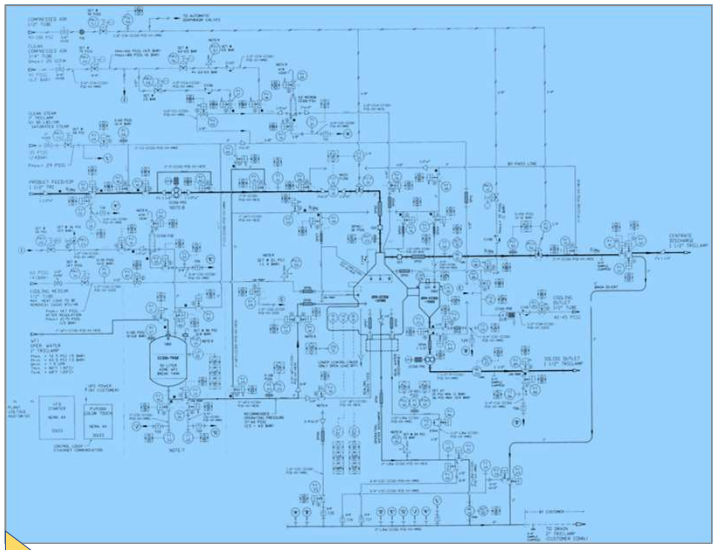
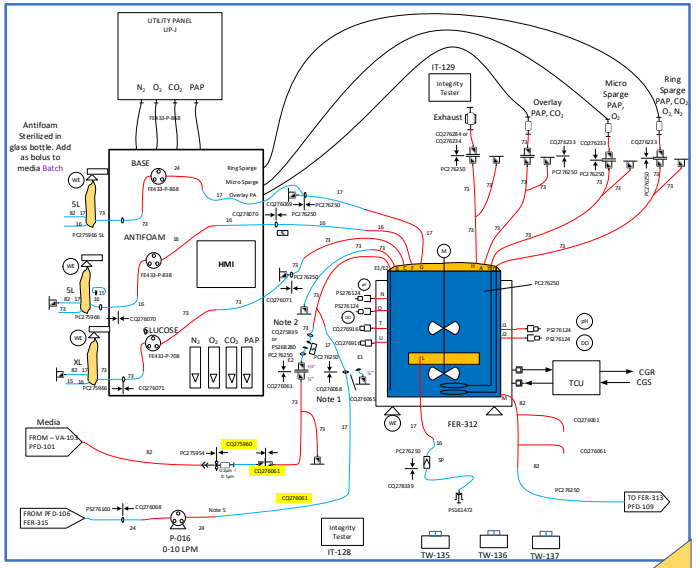


ABSTRACT

Pharmaceutical process conceptualization, design, and construction, has driving factors to establish a production process that is in a state of control regardless of the facility type. With Stainless Steel plants, the requirements for cleaning validation establish many design constraints for a stainless steel production process. SUT on the other hand, have only the in-process cleaning steps to be concerned with (Chromatography, Ultrafiltration). After processing, SUT plants will dispose of process fluid path and set up new flow paths for the next run. Unlike SS plants, detailed process fluid path documentation is missing. Through the use of Process T&IDs, single use process flow path documentation can be provided with additional benefits. These are: Risk Assessment Platform, A training tool, Documented Bill of Materials and a platform for hazard analysis.

Ref: A Structured Tool for SUT Implementation Pharmaceutical Engineering: August 2015 Vol. 35 No 4



STAINLESS STEEL(SS) OPERATIONAL RISKS

- Very complex and not forgiving of change
- Design evolution, final outcome impacts licensed process
- Flexibility increases Qualification time

P&ID CHALLENGES

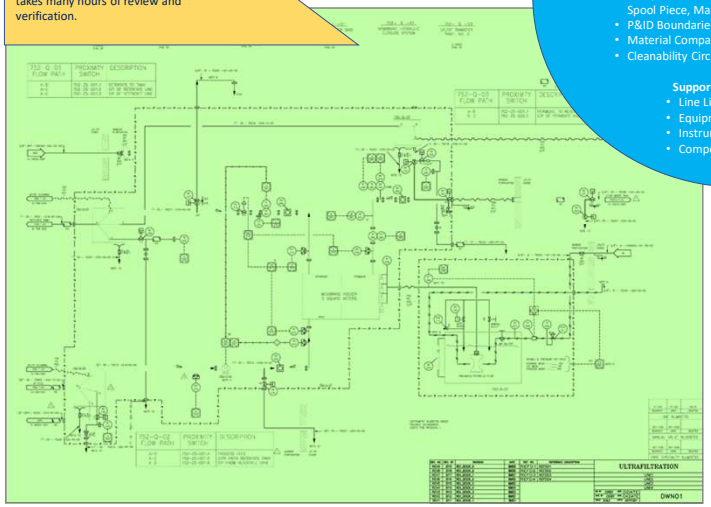
Many of the challenges of P&ID development comes with the As-Built completion. True representation of the final design takes many hours of review and verification.

SS- P&ID KEY POINTS

- Equipment (Type, Capacity, Size, Number)
- Line Numbers (Size, Service, Number, Specification, Insulation, Slope)
- Automated Valves (Size, Connection Type, Control Logic, Drainability, Interlocks)
- Transfer Panels, Valve Assemblies
- Instruments (Connection Types, Loop Numbers)
- Components/Numbering, (Sight Glass, Hose, Spool Piece, Manual Valves)
- P&ID Boundaries (On/Off Tags, Vendor Packages)
- Material Compatibility
- Cleanability Circuits Drainable

Supporting Lists:

- Line List
- Equipment List
- Instrument List
- Component List



P&ID BENEFITS

- Reproducible and Pre-tested during IQ/OQ
- Robustness in design can extend operational pressure limits for processing
- Provides process documentation (As-Built P&IDs)
- Automation adds to system reproducibility as documented on P&ID

SUT- T&ID KEY POINTS

- Equipment (Type, Capacity, Size, Asset Number)
- Hose Asset Numbers (Size, Specification)
- Valves (Pinch Valve, Specialty Valves)
- Hose Connections (Connectors, Sterile Connectors, Luer Lock, Thermal Welds, Gender Specific, Genderless)
- Instruments (Connection Types, Loop Numbers)
- Components/Numbering, (Sight Tube, Hangers, Manifold Attachments),
- T&ID Boundaries (On/Off Tags, Vendor Packages)
- Material Compatibility (Product Contact, Support Systems)

Supporting Lists:

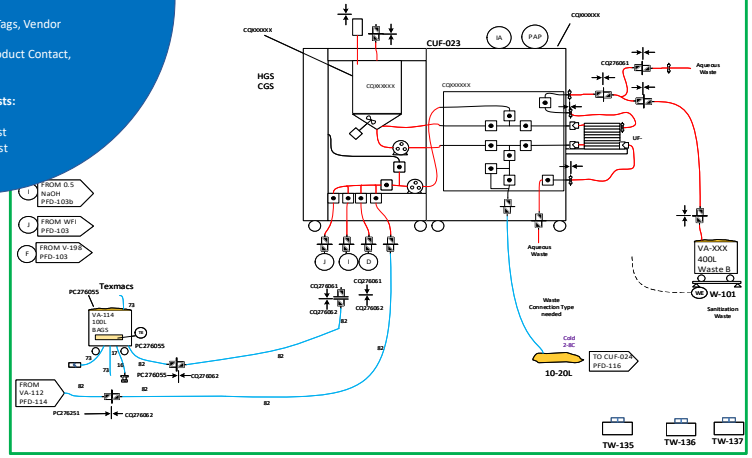
- Asset List
- Equipment List
- Instrument List

SINGLE USE TECHNOLOGY(SUT) OPERATIONAL RISKS

- Multiple Connections - Operator Dependent - Every Run
- Vacuum / Pressure conditions introduce Risk
- Material Handling Mistakes should drive Standardization
- Performance Information should be part of the Batch Record

T&ID CHALLENGES

- Pinched hose avoidance
- Connection access and ergonomics
- Operator training and consistency
- Waste handling
- Consistent materials and performance



T&ID BENEFITS

- Design is captured and part of training
- Documented Design that improved consistency
- Clear outline of process flow paths
- Assistance in installation Qualification
- Process Modifications and Qualifications are more easily documented

CONCLUSION

SUT design is best accomplished through standardization and documentation. Component installation is dynamic, and efforts should be employed to reduce potential mix ups. Use of process T&IDs can provide clear direction and sign off for repeated set ups that are required to maintain a state of control of critical operations. Stainless Steel facilities benefit from rigorous installation and operational qualifications. SUT facilities are easily changed and configured for production so extra care must be given to the repeated set up and tear down of production trains to meet the IQ, OQ intent, and FDA regulatory requirements.