

# Calibration And Validation Services

## Thermal Validation

### Thermal Mapping

### Cold Chain Management

### Freeze Dryers

### Warehouse Management



Autoclave



Lab Incubator



Lyophilizer



Warehouse



DHS



Cold Rooms



Tunnel



Cold Chain Management

### We Follow...

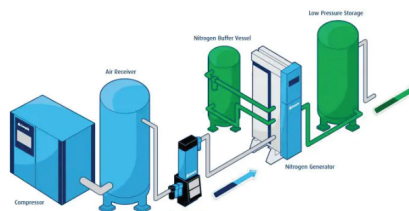
- ★ ISPE Good practice guide-Cold chain management
- ★ WHO TRS 961-Annex 9, Supplement 8
- ★ 21 CFR 211 cGMP for finished Pharmaceuticals
- ★ EN 285:2015
- ★ PDA Technical report No.1 Validation and Verification

## Compressed Gases -CA, N2 & Stream Quality

### COMPRESSED AIR SYSTEM



Compressed air  
We follow ... ★ ISO 8573-1

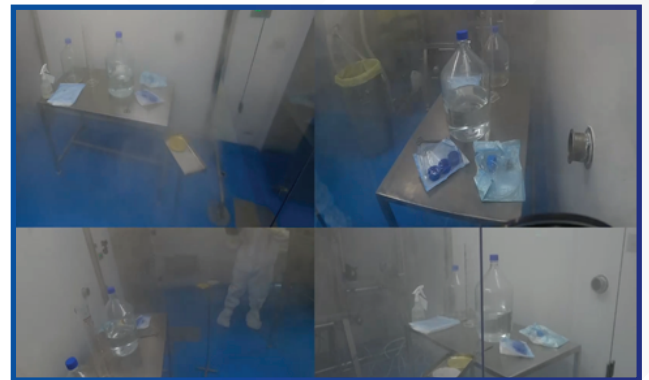


Nitrogen Gas  
★ USP/BP/EP



Stream Quality  
★ HTM 2010 / EN285

# Cleanroom Validations



**Go Pro Camera  
with Manifold Systems**

## We Follow...

- ★ ISO 14644: Part 1, & Part 3
- ★ WHO Annex 8: Guideline for heating ventilation & air Conditioning system for Non Sterile dosage form
- ★ USFDA: Guidance for Industry Sterile Drug Products
- ★ EU Annex 1
- ★ 21 CFR 211 cGMP for Finished Pharmaceuticals
- ★ ISPE: Good Practice Guid, Heating Ventilation and Air Conditioning (HVAC)

# Calibration Division

Thermal Discipline

Mechanical Discipline

Electro Thermal Discipline

Flow Discipline



## We Follow...

★ NABL accredited lab ID : C-1729, Certificate No: 3497

In-House Calibration of master Instruments

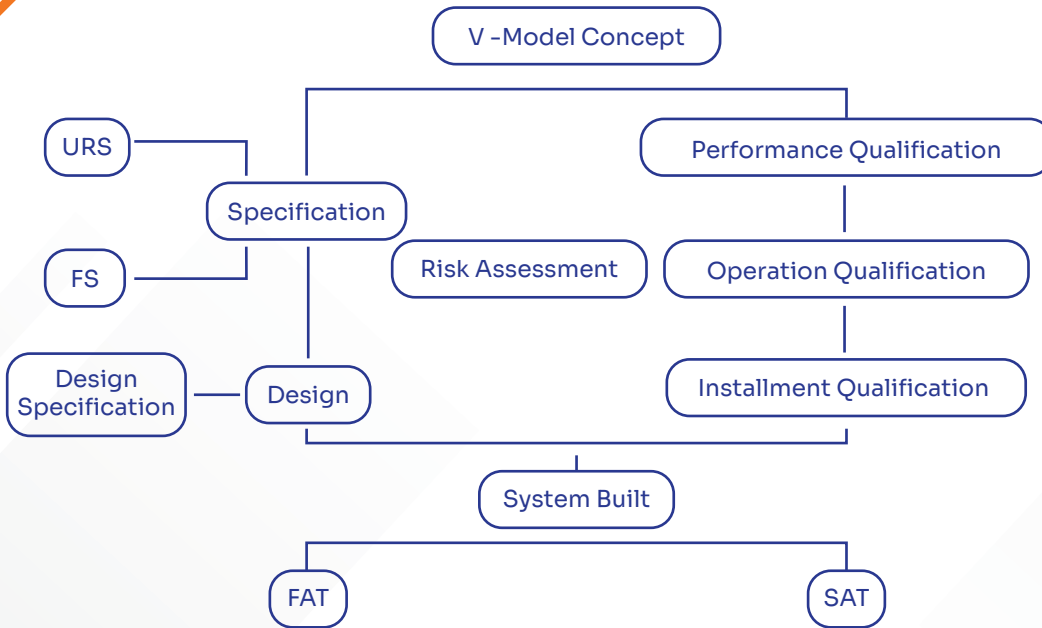
AMC based services - On site Services

Use Calsynbuf software for calibration certifications and we will get alerts for schedule calibration

Connecting Lives to Life

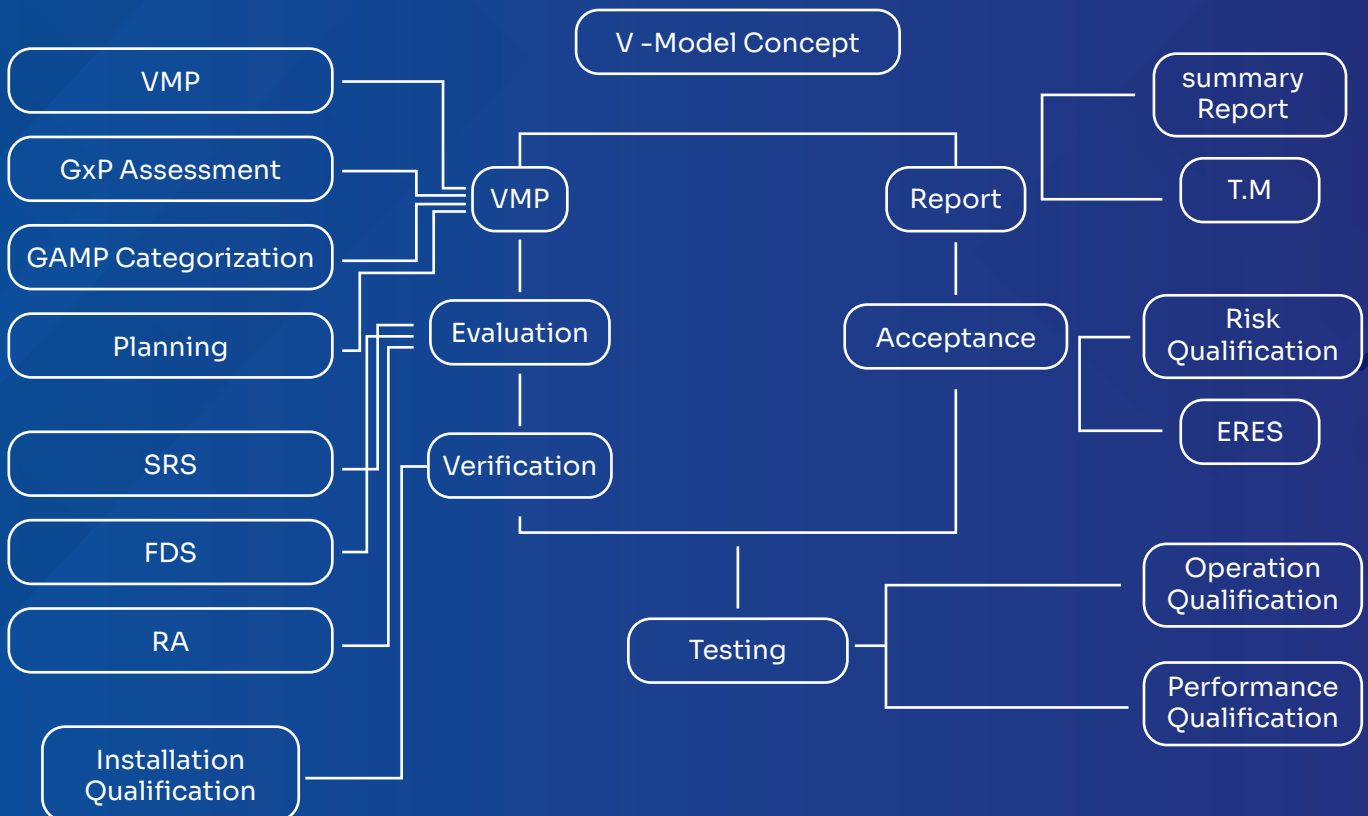
# Qualification Approach

## Equipment/Utilities



### We Follow...

- ★ ISPE GAMP 5 A risk-based approach to compliant GxP Computerized Systems Second Edition
- ★ FDA Title 21 CFR Part 11 Electronic Records; Electronic Signatures
- ★ EU GMP Volume 4, Annex 11: Computerised Systems
- ★ ISPE Baseline: Commissioning and qualification, Volume 5.



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