

# LIFECYCLE MANAGEMENT OF STABILITY CHAMBER WITH COMPUTERIZED SYSTEM USED IN PHARMACEUTICAL INDUSTRY

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## Original research



## ABSTRACT

*For the pharmaceutical industry to ensure product quality, operational efficacy, and regulatory compliance, effective lifecycle management of computerized systems. The following crucial phases are included in a systematic lifecycle approach: decommissioning, operation, maintenance, validation, and planning. Validation processes confirm that the system is reliable and that it complies with Good Automated Manufacturing Practices (GAMP) and legal standards. Risk-based methods are employed to identify and resolve any problems that can compromise a product's efficacy or safety. Examples of cutting-edge technology that enhance data integrity, speed up procedures, and lower regulatory hurdles include automation and digital workflows. The pharmaceutical business depends significantly on the lifecycle management of computerized systems to guarantee data integrity, operational effectiveness, and regulatory compliance across crucial processes like engineering, testing, production, warehousing, and planning. Lifecycle management is further improved by modern tools like automation, artificial intelligence, and machine learning, which accelerate regulatory submissions, simplify processes, and improve decision-making.*

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## 1. INTRODUCTION

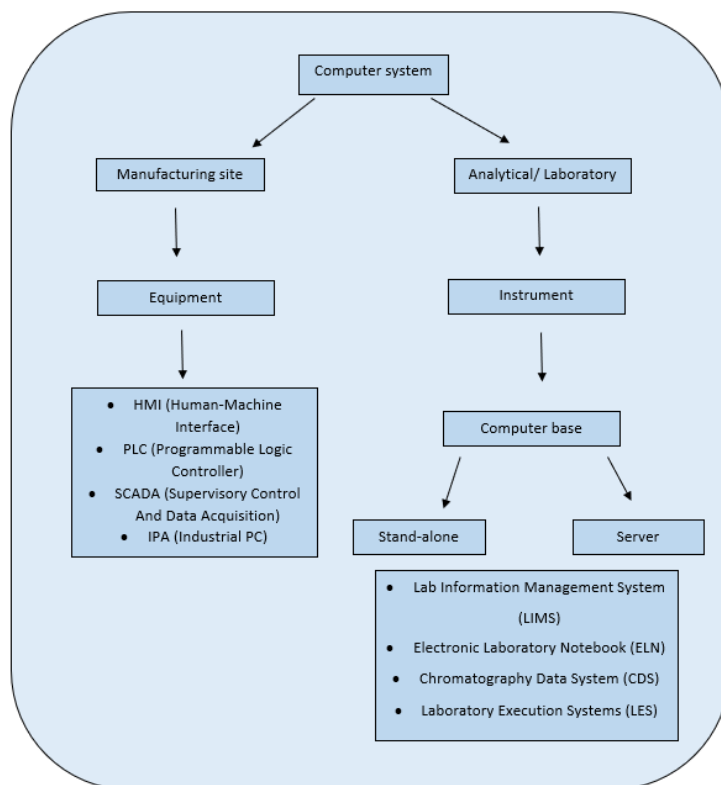
This paper documents were superseded via electronic records created with PLC, SCADA, and HMI platforms used for automation (Chukwunweike et al., 2024). While batch records are commonly, as of now, stored in an electronic fashion, several other processes which include documentation, sampling, and production procedures have been still in the process of undergoing full digitalization. Although many companies may still rely on paper records, electronic records offer meaningful advantages. These digital forms are helpful in lowering

the chance of human error, in addition to minimizing the potential for data manipulation. The true value for electronic records is realized by companies that implement industrial automation systems such as with HMI, PLC, and for SCADA software, which enable recording of actions at every operational level (Akande, 2023). This PLC-SCADA system ensures data integrity through preventing forbidden data manipulation after its recording. One key advantage of the SCADA and HMI software is to eliminate gaps in data for better accuracy and reliability (Ramdass & Balaraman, 2025). Additionally, HMI/PLC SCADA software can

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automatically capture and store critical events, while also allowing users to configure alerts or notifications when specific parameters exceed predefined limits. This functionality enables real-time detection of deviations within the industrial automation process, supporting proactive decision-making and enhancing process control (Sharma, 2024; Sofcon Training, 2018). The integration of computers with analytical gear has really streamlined analysis work and really lifted up performance and abilities of those instruments too. Now advanced analytical processes are fully integrated into computer systems and so many top manufacturers are developing software and having those ready for use on labs and industry (Eisen et al., 2020). These systems

typically include data acquisition and control functionalities. With automation, scientists and labs are using standalone computers and also networked computers more and more. They're using those computers to perform all sorts of things like lots and lots of data handling very efficiently and doing complex statistical stuff too (Cooper et al., 2025). They're also sharing information effortlessly and wonderfully amongst each other. It's making the work much smoother. This integration not only improves operational efficiency but also facilitates better data management and collaboration across laboratory environments (Almutairi et al., 2025; Effendi & Hendriyani, 2023).



**Figure 1.** Classification of Computerized System in Pharmaceutical Industry

Achieving and preserving compliance with relevant GxP rules and computerized systems' suitability for their intended use involves the following steps (Kawarkhe, 2025): a) Adapting concepts, methodologies, and life cycle activities within the parameters of validation plans and reports. b) Throughout the system's life cycle, the proper operational controls are applied. Computerized System Validation (CSV) adheres to the principles of Good Automated Manufacturing Practices, or GAMP. Manufacturers and other automation users adhere to GAMP (good automated manufacturing practices) as a set of rules to preserve operational dependability and efficiency (Rathod et al., 2025). GAMP 5 is centered on a lifecycle-based, structured validation approach that prioritizes risk management and documentation. The framework, now in its fifth revision, was first published in 1994 by the International Society for Pharmaceutical Engineering (ISPE) (Pedro et al., 2023). GAMP 5's

historical developments. In 1995, a few pharmaceutical specialists in the UK took the initiative to improve GxP compliance management, leading to the publication of the GAMP guideline. Together, they eventually published the GAMP guideline with the International Society for Pharmaceutical Engineering (ISPE). Following their initial publication in 1995, the guidelines underwent numerous changes. The most recent three modifications were GAMP4 (2001), GAMP5 (2008), and GAMP 5 (second edition, 2022). The most important change to the GAMP 5 standard in the previous 14 years is the second edition (SciencePharma. 2025). GAMP 5 is widely used in industries such as biotechnology, pharmaceuticals, and medical devices to ensure compliance with regulatory standards for computerized systems. System categorization: GAMP5 must be used to group all computerized systems that are important to GxP, and this classification must be used to define the

validation deliverables. The following GAMP5 software and hardware categories are used to establish the validation approach and determine the deliverables: Category 1- Infrastructure software, Category 3- Non-configured products, Category 4- Configured products, Category 5- Custom applications, Hardware category 1- Standard Hardware Components, Hardware category 2- Custom Build Hardware Components. Software category: Software under Category 1: Infrastructure: components of infrastructure that are connected to provide a unified environment for executing and sustaining applications and services. These are software layers or operating environment management programs. Operating systems, programming languages, network monitoring software, security software, and antivirus software are a few examples. Category 2: Eliminated Firmware was involved. During that period, the firmware released by GAMP4 was thought to be suitable for basic instruments. But as technology has developed, it has been acknowledged that sophisticated software, or firmware, may be integrated into systems. Non-configured products (category 3): these are off-the-shelf items utilized in commercial settings. It encompasses both systems that are adjustable but only employ the default configuration and systems that cannot be modified to validate business processes. COTS, firmware-based applications, for instance. Configurable software solutions fall under

category four. They offer standard interfaces and functions that allow users to customize business processes. Software is frequently extremely complex, but it may be customized to fit a given purpose. A few examples are SAP, LIMS, SCADA, and building management systems. The fifth category is bespoke applications, which are subsystems or systems created to specifically address the requirements of the regulated business. The software is specifically created and built to fit the business process of the user. During validation following first deployment and at every stage of system modification, such systems must pass a thorough evaluation of their performance and quality (Fortier & Michel, 2003). Category of hardware: Category 1: they are commercially accessible, standard hardware components that don't require any alteration. For instance, conventional computers and servers. The second category consists of hardware components that are either tailored to meet specific needs or configured in addition to conventional hardware. A typical computer with an extra communication card, for instance (Mehare et al., 2023).

Software used in manufacturing equipment's are: HMI [Human Machine Interface], PLC [Programmable Logic Controller], SCADA [Supervisory Control and Data Acquisition], IPC [Industrial PC].

**Table 1.** Difference between HMI/PLC/SCADA/IPC (Autocal 2025; Basu et al., 2023; IndMALL Automation 2024; Pharmastate Academy 2017)

Features	HMI	PLC	SCADA	IPC
Function	User interface for monitoring/control	Real-time control of machinery	Centralized monitoring/control	Rugged computing platform
Data Handling	Displays real-time data	Process inputs/outputs	Collects and analyzes data	Processes data like a PC
User Interaction	Direct interaction via GUI	No direct user interface	Indirect through HMI	Can serve as an HMI
Flexibility	Limited to specific tasks	Fixed programs	Highly flexible with multiple systems	Highly flexible, can run various software
Environment	Typically, less rugged	Designed for industrial use	Requires stable environment	Built to withstand harsh conditions
Summary Of Roles	Serves as the operator's dashboard, providing visual feedback and control capabilities.	Executes automated tasks based on sensor inputs, ensuring machinery operates correctly.	Oversees multiple PLCs and other devices, providing a broader view of operations across a facility.	Combines features of both HMIs and PCs, offering robust performance in demanding environments while allowing for software flexibility.

Software used in analytical laboratories: Lab Information Management System [LIMS], Electronic Laboratory

Notebook [ELN], Chromatography Data System [CDS], Laboratory Execution Systems [LES]

**Table 2.** Difference between ELN/LIMS/CDS/LES (Argento, 2020; CloudLIMS, 2018; Rubacha et al., 2011; SCION Instruments, 2023)

FEATURE	ELN	LIMS	CDS	LES
DATA TYPE	Unstructured	Structured	Chromatographic	Structured & Unstructured
FOCUS AREA	Experiment documentation	Sample management	Data processing	Procedure execution
USER INTERFACE	Flexible	Sample-centric	Instrument- focused	Procedure-centric
AUTOMATION LEVEL	Moderate	High	High	High
TYPICAL USE CASES	R&D environments	Routine testing	Chromatography labs	Quality control

## 2. METHODOLOGY

Methodology includes: Risk assessment, User Requirements Specification (URS), Vendor Identification and Assessment, Functional Specification (FS), Configuration Specifications, Design specification, Design qualification, Pre installation checks, Installation Qualification, Operational qualification, Performance qualification, Reference Traceability Matrix.

A semi-quantitative risk assessment approach was applied to identify and evaluate potential failure points within the stability chamber system. Each critical component, including temperature sensors, control units, communication modules, and alarm systems, was assessed based on severity, likelihood of occurrence, and detectability.

The risk priority was assigned qualitatively to ensure that system validation efforts were focused on the most critical functional areas. Particular attention was given to communication integrity between PLC and SCADA systems, as any interruption in this interface could directly affect data integrity and regulatory compliance. Mitigation measures, including redundant communication pathways and system recovery protocols, were verified during validation testing.

## 3. RESULT AND DISCUSSION

Cooling chamber or Stability chamber: A stability chamber simulates different real-world conditions to help determine the effects of temperature, pressure, oxygen levels, light, and humidity on a product.

In addition to the descriptive qualification approach, a quantitative performance evaluation of the stability chamber system was carried out under controlled operating conditions. Temperature stability was monitored over a 24-hour and 72-hour period using calibrated external data loggers placed at critical locations inside the chamber.

The analysis showed that the system maintained a stable temperature profile around the setpoint of 5.0°C, with observed fluctuations remaining within  $\pm 0.3^\circ\text{C}$  under normal operating conditions. The alarm response system demonstrated a fast reaction time, typically between 2 and 5 seconds after threshold deviation, confirming reliable real-time monitoring and control capability. These results indicate that the system not only meets validation requirements but also provides a high level of operational consistency suitable for regulated pharmaceutical storage conditions.

### 3.1 KPI Framework and Statistical Evaluation (Integrated for This Study)

To further strengthen the validation of the stability chamber system equipped with ICDAS 3.1 software, a quantitative performance assessment was introduced in addition to the descriptive IQ/OQ/PQ validation approach. The objective was to establish measurable

performance indicators aligned with computerized system validation principles and regulatory expectations.

#### 3.1.1 Key Performance Indicator (KPI) Analysis

##### (a) Deviation Detection Time

The response time of the system to detect and report deviations from the predefined setpoint (5.0°C) was evaluated as a critical performance indicator.

The results showed that the ICDAS 3.1 system, integrated with PLC and SCADA layers, generated alarms within 2 to 5 seconds after threshold violation. This confirms rapid real-time monitoring capability and ensures immediate operator notification.

KPI outcome: High-performance real-time deviation detection

##### (b) Temperature Variance Analysis

Temperature stability was assessed over 24-hour and 72-hour monitoring periods using calibrated data loggers positioned at critical chamber locations.

The system maintained a stable thermal profile around the setpoint of 5.0°C, with observed fluctuations limited to  $\pm 0.3^\circ\text{C}$ .

This indicates low system variance and confirms effective thermal regulation and uniform air circulation within the chamber.

KPI outcome: High temperature stability with minimal variance

##### (c) System Uptime Performance

System availability and operational continuity were evaluated based on uninterrupted monitoring and data acquisition capability of the ICDAS platform.

The system demonstrated continuous operation without data loss during monitoring cycles, supported by PLC-based control and SCADA redundancy mechanisms. Recovery after power or communication interruption occurred automatically as per system configuration.

KPI outcome: High system availability and automated recovery capability

#### 3.1.2 Statistical Evaluation of Temperature Stability

##### (a) Mean and Standard Deviation (SD)

Temperature data collected during validation cycles (24 h and 72 h) were analyzed to determine statistical stability.

- Mean temperature remained close to the setpoint of 5.0°C
- Standard deviation was low, corresponding to the observed fluctuation range of  $\pm 0.3^\circ\text{C}$

This confirms that the system operates within a narrow dispersion band, indicating high precision in environmental control.

Interpretation: Low variability and high process stability

##### (b) Statistical Process Control (SPC) – Control Chart Analysis

A Statistical Process Control (SPC) approach was applied to evaluate process behavior over time.

The temperature data points remained consistently within the predefined upper and lower control limits, with no observed trend shifts, cyclic patterns, or out-of-control signals.

This confirms that the stability chamber operates under a statistically controlled process state.

Interpretation:

- No process drift detected
- No out-of-control conditions observed
- Stable long-term performance verified

### 3.1.3 Integrated Interpretation

The combined KPI and statistical evaluation confirms that the ICDAS 3.1-based stability chamber system provides:

- Rapid deviation detection (2–5 seconds)
- Tight temperature control ( $\pm 0.3^{\circ}\text{C}$ )
- High operational continuity and uptime
- Statistically stable process behavior (SPC compliance)

These results significantly enhance the traditional IQ/OQ/PQ validation approach by introducing quantifiable performance metrics, thereby improving compliance with modern expectations for data integrity, computerized system validation, and risk-based pharmaceutical quality systems.

The pharmaceutical industry uses these chambers to understand how their products will behave over time, ensuring that they are safe not only upon manufacture, but also after transport and storage. Stability (cooling) chamber: make: newtronic, model: nlcc34si, software: software name: ICDAS 3.1. It is very effectively complying to the requirements of 21 CFR Part 11. Qualification of Stability Chamber: Pre-installation Qualification- Starts with pre-installation check of equipment. Checklist is prepared and verified accordingly (Table 3).

The ICDAS 3.1 system operates as an integrated industrial IT architecture combining PLC-based control, SCADA supervisory functions, and centralized data acquisition. Sensor data from PT-100 probes are first processed at the PLC level, where primary control decisions are executed.

This information is then transmitted via Ethernet TCP/IP communication to the SCADA layer, which provides real-time visualization, alarm management, and audit trail recording. The SCADA system further ensures compliance with regulatory requirements such as 21 CFR Part 11 by maintaining secure user access control and complete traceability of all system actions.

At the highest level, the ICDAS platform acts as a centralized data management system, enabling long-term storage, retrieval, and analysis of operational and environmental data.

**Table 3.** Prepared list with descriptions

S.no	Description	Checked by\date	Verified by\date	Remarks
1.	Physical condition of equipment			
2.	All the welding joints are grounded to a smooth finish and meeting the requirements as per purchase order specification.			
3.	Equipment pre-installation cleaning done.			
4.	All the related required spares/components are received and made available for installation as per packing list from supplier.			
5.	All the related drawings, operation manual, test certificate provided by the supplier for installation.			
6.	Sufficient room for installation provided.			
7.	Equipment position marking done as per drawings.			
8.	Foundation for equipment installation made as per manufacturer's recommendation.			
9.	All the supporting utilities are put in place			
10.	Electrical points are provided as per the requirements.			
11.	The cutout positions are matching with the machine.			
12.	Others, if any.			

All the documents status should be checked- URS attached, FAT/SAT Documents, User Manual attached, Supplier Protocol attached, Drawings (Equipment, Lay out...). Hardware Qualification: installation qualification- The contents of IQ- Protocol pre approval, Brief description, Purpose, Test procedures, Test rules, System functional, Verification of test system details, Machine details, Master document verification, Scope of equipment, Warning symbols, Control system hardware components, Safety devices as per physical installation, Utilities verification, Deviation report, Appendix,

Approval of test results. Annexures: 1- Training certificate, 2- Design document (DQ), 3- Operation manual file (user manual), 4- Electric wiring diagram, 5- General assembly diagram, 6- SOP, 7- Certified component of chamber, 8- Warranty certificate of chamber. Tests: Verification of test system details, Machine details- Describes the details of machine, which is being qualified. Master document verification- The listed documents must be available with their reference number, revision number, date, etc. Annexure-3, 4, 5: Scope of equipment- The listed documents must be

available with their reference number, revision number, date, etc. Warning symbols: All the warning symbols must be provided and visible. Control system hardware components- Verify control system components properly mounted and as per electrical wiring diagram and general

assembly drawing. Annexure-7: Safety devices as per physical installation  
 Safety devices are provided for components and undershoots. Utilities verification- For proper functioning of the chamber, the utilities to the equipment must be supplied/ connected properly (Table 4).

**Table 4.** Technical compliance and acceptance test results

S.NO	TECHNICAL DATA VERSION		TEST RESULT MET		COMMENTS/ DEVIATIONS
	Test/acceptance	System operation manual: operation manual ver 3.1	yes <input type="checkbox"/>	no <input type="checkbox"/>	Annexure-03
	Test/acceptance	General assembly drawing	yes <input type="checkbox"/>	no <input type="checkbox"/>	Annexure-05
	Test/acceptance	Electrical wiring diagram	yes <input type="checkbox"/>	no <input type="checkbox"/>	Annexure-04
	Test/acceptance	Combined temperature sensor Make: PURN SANKET Model: PT-100	yes <input type="checkbox"/>	no <input type="checkbox"/>	Annexure-07

Operational Qualification and Performance Qualification- Annexures: Test of equipment functions: 1- Newtronic service engineer training certificate, 2- Communication with ICDAS 3.1, 3- Cooling test, 4- Standby cooling test, 5- Low temperature alarm test, 6- High temperature alarm test, 7- Utility alarm test, 8- Safety device test, 9- Conditions setting, 10- External sensors certificate, 11- Empty sensors position photo, 12- 1-hour calibration (data logger and chamber), 13- 24-hour calibration (data logger and chamber). Test of equipment functions, Healthiness of control system, If you activate the UPS for controller and main switch, the system will go into operation, Communication with ICDAS on Ethernet. Give the IP address to equipment and connect it to Ethernet. From ICDAS user should be able to program the settable parameter such as set values, alarm limits and data recording interval.

Annexure-02: Air circulation system/ventilator, After the system is started on, the ventilator will rotate and must suck the air over the evaporator unit. Cooling: To check the cooling function set the temperature set point 3~4°C below the ambient temperature. The set value should be within the range as per manual. Annexure-3, 4: Temperature alarm testing- the alarm hooter is installed in the panel, it is activated in case of exceeding temperature alarm limits and the same alarms get transfers to ICDAS software. Annexure-5, 6: Utility alarm testing- the alarm hooter is installed in the panel; it is activated in case of mains failure, door kept open and the same alarm get transfer to ICDAS software. Annexure-7: Safety device testing for temperature- Various safety device is installed in the chamber to

protect chamber from under shooting of conditions (temperature) inside the chamber. Annexure-8: Conditions settings- The system is set to following final required conditions: 5.0°C. Annexure-9: System/controller power failure condition- The controller should not be affected by power failure and should start automatically as per user settings after power has resumed. Qualification procedure for distribution study of temperature in empty chamber: Positions of the sensors (Annexure-10), Placement of the external sensors (Annexure-11), Result of tests (Annexure-12, 13). Annexure-1: External sensors certificate, Annexure-2: Loaded samples photography, Annexure-3: 24-hour calibration (data logger and chamber), Annexure-4: Door open recovery test, Annexure-5: Power failure recovery test. To check the distribution of temperature in loaded chamber: Positions of the sensors (Annexure-01), Placement of the external sensors (Annexure-02), Result of tests (Annexure-3, 4), Evaluation of the loaded mapping tests and conclusion (Annexure-3, 4). Qualification procedure: recovery study for temperature: Results of the door open recovery tests (Annexure-4), Results of the power failure recovery tests (Annexure-5), Evaluation of the loaded mapping and recovery tests and conclusion (Annexure-4, 5).

A comparative evaluation between traditional manual monitoring of stability chambers and the computerized ICDAS 3.1 system highlights significant improvements in operational efficiency and data integrity. In manual systems, data recording is performed intermittently, which increases the risk of delayed detection of deviations as well as transcription errors

during documentation. This lack of continuous monitoring often leads to gaps in traceability and slower response to out-of-limit conditions.

In contrast, the ICDAS 3.1 computerized system provides continuous real-time monitoring with automated data logging and immediate alarm generation whenever predefined limits are exceeded. This ensures faster detection of deviations, improved response time, and significantly reduced dependency on manual intervention.

Based on operational observations during system qualification, the implementation of the computerized system resulted in improved consistency of documentation, reduction in manual recording errors, and enhanced speed of deviation detection and corrective actions. Overall, this demonstrates a clear operational advantage of IT-integrated validation systems compared to traditional manual monitoring approaches in pharmaceutical stability chamber environments.

Computer System Validation: Installation Qualification and Operational Qualification- System policy: Unique user account name, Unique user password, Passwords expire, Limit of entry attempts. Application user levels configuration: Each user level permission. Date and time: Cannot be changed (system administrator can only change). Password integrity: Wrong password will not be accepted. Control of equipment: Shall acquire the testing parameters and execute the same. Date acquisition and evaluation: The computer shall acquire the data from equipment. Evaluate the acquired data, limits and results should be within the acceptable limits. Printing of data: Print out should match with displayed results. Data storage and retrieval: Acquired data should store in respective selected folder and retrievable. Audit trail: The changes made shall be recorded in to the audit trail along with date and time. Software Qualification: Installation

Qualification- Software IQ starts with verification of test system details: Includes computer system details, Software details, Master document verification, Ethernet communication verification, Utilities verification. All the tests are done and results are attached as annexure.

**Table 5.** Configuration requirements and actual system parameters

Configuration	Minimum required	Actual availability
Processor	Intel Core i5, clock speed 3.2 GHz	12 <sup>th</sup> Gen intel® core™ i5-12500 3.0 GHz
Rom	12GB	8.0 GB
Hard disk	500GB	500 GB
Number of USB ports	4	8
Operation system	Windows 7or Higher version	Windows 10 Pro

Annexure 1,2,3 - describes the details of computer system on which the software will be installed and qualified. Annexure-1- training certificate. Annexure-2- Contains system details which includes Computer system make, System lag number, Location, Model number, Serial number. Common group name in ICDAS 3.1, The test defines the system software configuration: updated Anti-Virus, the test defines the system hardware configuration, Operator system (Table 5).Annexure-3- The test defines the system configuration: Power setting disabled (sleep, hibernate, hard disk), Firewall port enabled (502 & 1433). Annexure-4- describes the local service software must be installed properly at the defined path properly.

**Table 6.** Software functionality test results for equipment configuration and communication module

Technical data version		Observation
<b>Annexure 01</b>		
Click on the equipment configuration option in the configuration window	the equipment configuration page opens	ICDAS 3.1 software installing and usage pages opened and total software screenshots attached.
<b>Annexure 02</b>		
Click on add/edit to add a new equipment	The equipment config window must open for adding of new equipment	Window opened
<b>Annexure 03</b>		
Check the communication status for all connected chambers.	Must display the online/offline status of the equipment along with process values	Real time summary, real time display, I/O status and running hours open.
<b>No annexure</b>		
Enter the following details Equipment name IP address Log interval Door access type Click save button	the details entered gets saved and the equipment gets added and displayed in the equipment configuration window	details entered equipment name: IP address: Log interval: Door access type:

During installation of ICDAS3.1 local service server URL, PORT & Server IP address is available? Is client Local Software ICDAS 3.1 installed properly? Annexure-5&6- description the listed documents must be available with their reference number, revision number, date, etc. Annexure-5- software activation key, Annexure-6- paper license details, Annexure-7- description the above computer system & the equipment must be connected via ethernet for communication between the software and the logger. Computer system Ethernet IP configuration: IP address, Subnet address, Gate way address, Connection speed, totally 17 equipment's can be added to a single system: Equipment-1, Equipment name, Equipment type, EQP IP address. No annexure attached for utilities verification. The utilities to the computer system must be supplied or connected properly. Electrical supply for computer: UPS supply: 200~240VAC, Software: ICDAS 3.1 Local service, Supplier name: Newtronic Lifecare Equipment Private Limited. Operational Qualification: Equipment addition- Equipment number 1 addition (Table 6). Performance Qualification: Verification of software functionality- Annexure-1- Contingency testing: Alarms contingency testing- Description- the ICDAS 3.1 software must be able to download alarms logged by every equipment to the software. Test procedure- generate the alarms as mentioned below and check whether it gets transferred to the software (Table 7).

**Table 7.** Functional Test Results for Alarm Logging and Data Transfer from PLC to Software

Description	Expected result	Observation
Does the logged alarms from equipment get transferred to software	The logged alarms in PLC must get transferred to software	Alarms downloaded properly

Annexure-2 - Network failure testing/data logging test- Description- the ICDAS 3.1 software must be able to download stored readings and alarms in the memory of PLC to ICDAS 3.1 software of every connected

equipment. Test procedure- set the log interval for recording of data as 5 minutes in the chamber. Shut down the local client PC for 30mins. Generate alarms for door open/close, mains fail/resume and water level fail/OK. Restart the client PC and cross check whether the data and alarms are download or not. Once test over reset the log interval to original set log interval (Table 8, Table 9).

**Table 8.** Data and Alarm Transfer Test Results for ICDAS 3.1 System

Description	Expected result	Observation
Does the data and alarms stored from equipment get transferred to software	The stored reading and alarms must get transferred to ICDAS3.1 software once network is connected or OK	Network working fine

**Table 9.** Report generation test results

Description	Expected result	Observation
Reports	The software must print the records in PDF and with highlights (bold) in case of deviation	PDF data will be attached

Reference Traceability Matrix (Table 10): High Priority: Features or requirements that are essential for the system's basic functionality. These are typically system requirements that need to be implemented first to ensure the product operates as intended. Medium Priority: Important features that enhance system functionality but are not vital for the initial launch or operation. These can be implemented in later phases. Low Priority: Non-essential features or enhancements that don't affect the core system functionality and can be implemented last or in future releases

**Table 10.** System requirements, design and test verification matrix

S.NO	REQUIREMENTS	DESIGN	SYSTEM TEST	PRIORITY
<b>Operational requirements</b>				
	Electricity supply of 50Hz and in to 240V range without interruption.	In utility requirements, chamber (equipment supply), voltage-230 VAC ± 10 VAC, and frequency: 50Hz mentioned.	In IQ, under verification of test system details, in control system hardware components it is mentioned that supply voltage for cooling system and stand by cooling system is 220 ~ 240 V, 50 Hz. In IQ, under verification of test system details, in utilities verification electrical supply for cooling chamber supply 230±10vac is mentioned.	Medium
	Equipment shall operate in the room condition ambient (0-55°C).	In surrounding of equipment, temperature should be within 15°C TO 30°C mentioned.	In IQ, under verification of test system details, in utilities	Medium

S.NO	REQUIREMENTS	DESIGN	SYSTEM TEST	PRIORITY
			verification, temperature 15 to 30°C mentioned.	
	Warning symbols shall provide.	In operation manual file, safety warnings are mentioned.	In IQ, under verification of test system details, in warning symbols it is mentioned that electrical symbols on the electrical panel visible.	Medium
	USP cone connection with sufficient backup.	In user manual, SMPS under technical specification of components is present.	In IQ, under verification of test system details, in utilities verification, USP supply for controller/SMPS supply 230 VAC mentioned.	Medium
<b>Functional requirements</b>				
	SS 304 interior and exterior finish.	In user manual, MOC it is mentioned that inner and outer chamber is made of stainless steel graded 304.	In IQ, under verification of test system details, in material of construction it is mentioned that inner and outer chamber is made up of stainless steel 304 grade.	Medium
	Stainless steel trays.	In user manual, MOC it is mentioned that trays are made of stainless steel graded 304.	In IQ, under verification of test system details, in material of construction it is mentioned that perforated trays are made up of stainless steel 304 grade.	Medium
	PT-100 or suitable probe for temperature monitoring	In technical specification, sensors: 4no's mentioned.	In IQ, under verification of test system details, in scope of equipment it is mentioned that temperature sensor's 4 no's are present.	Medium
	PUF insulator	Under scope, insulation: PUF		Medium
<b>Safety requirements</b>				
	Safety devices: Low and High temperature cut off thermostats.	In DQ, introduction it is mentioned that the equipment as alarming and safety systems. Alarms: temperature deviations, utility failure.	In IQ, under verification of test system details, in safety devices it is mentioned that high temperature safety thermostat present. In OQ and PQ, under test of equipment functions, safety device testing for temperature done and passes the test	Medium
	Alert system	In technical specification, audio and visual alarms for temperature variation and utility failures provided.	In OQ and PQ, under test of equipment functions, utility alarm test done and passes the test In OQ and PQ, under test of equipment functions, temperature alarm test done and passes the test	Medium
<b>Other requirements</b>				
	Single software platform incorporates all of the functions required for cooling chamber.	ICDAS software version 3.1	ICDAS software version 3.1	Medium
	Capable to work in Ethernet communication environment.	Under scope, PC communication: Ethernet (TCP/IP) is mentioned.	In IQ, under verification of test system details, in utility verification, it is mentioned that Ethernet communication for chamber with ICDAS software: CAT-5\CAT-6 cable for LAN connected to PLC.	Medium

S.NO	REQUIREMENTS	DESIGN	SYSTEM TEST	PRIORITY
	Cooling chamber should comply with 21 CFR 11 compliance.	In user manual, it is mentioned that the system is 21 CFR 11 ready with facility of User access control Data backup/ restore facility Log data/alarm capture and report generation Audit trail for all the user activity History report User creation Real time display facility Input output status for better trouble shooting in case of system failure	User access control Data backup/ restore facility Log data/alarm capture and report generation Audit trail for all the user activity History report User creation Real time display facility Input output status for better trouble shooting in case of system failure	Medium
	Capable to configure different user access levels based on their individual responsibilities.			
	Software should have data backup and restoration provision.			
	All the creations, modification, deletion details should capture in audit trial log.			
	Compatibility: Data acquisition system shall run on windows operating system.			
	Capable to connect with back up storage system.			
	Software shall have automated running program with running history details			

### 5. CONCLUSION

Computerized system lifecycle management improves supply chain transparency, speeds up problem solving, and maintains product quality when backed by a strong traceability matrix. Pharmaceutical businesses can lower operational risks, show adherence to quality standards throughout the system's lifecycle, and expedite compliance with FDA and EMA regulations by integrating the RTM into documentation workflows. This organized method reduces recalls and rework, which minimizes expenses and guarantees patient safety. Beyond procedural compliance, the study highlights the importance of integrating analytical performance evaluation with computerized system validation in pharmaceutical environments. The combination of lifecycle-based validation and IT-enabled monitoring

systems enhances not only regulatory compliance but also operational transparency and decision-making efficiency.

This approach contributes to the broader digital transformation of pharmaceutical manufacturing by demonstrating how traditional validation frameworks such as GAMP 5 can be effectively extended with IT-driven performance analysis and system-level data integration.

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