ISO 9001:2015 CERTIFIED

ARIZONA AUTOMATION & TECHNOLOGIES

COMMITTED TO DELIVER EXCELLENCE WITH INTEGRITY

REGULATORY COMPLIANCE SERVICES IN LIFE SCIENCE INDUSTRIES

Compliance to the regulations is becoming a global and complex scenario putting increasing demands on a company's time and resources. Pharmaceutical, biotechnology and medical device manufacturing must observe national and international legislation to increase product safety and ensure the health of consumers.

HURDLES IN THE WAY OF COMPLIANCE

- How to balance the on-going changes in the industry and the implementation of New technologies with the need for Compliance?
- How to find time and resources to stay up to date with regulatory developments and to be constantly prepared for an Inspection.
- How to meet consumer demand for high Quality standards at good prices in Soughed economies.

Our Engineering team is taking care of:

- ✓ **GxP/GAP/Risk assessment**
- ✓ **Validation Project Management**
- ✓ **Validation Strategic Planning**
- ✓ **Specialized Validation Training**
- ✓ **Regulatory Services**
- ✓ **HVAC Validation**
- ✓ **Process Validation**
- ✓ **Audit Compliance**

WHY ARIZONA???

Here in ARIZONA we provide Regulatory Compliance solutions to the life science Sector to enhance and maximize the Operational performance of its customers by helping clients to achieve their business Objectives in a professional, timely and cost Effective manner.

EFFECTIVE SOLUTION

Arizona specializes in IT Regulatory Compliance with focus on implementing Risk Based Validation solutions based On **GAMP5 & CFR Tittle 21 Part 11** principles & for Computerized System Validation.

OUR SERVICES

ARIZONA AUTOMATION & TECHNOLOGIES provides you full length of following services but it's not limited to:

❖ CSV VALIDATION SERVICES:

- PLC-HMI/ IPC, SCADA, DCS system validation
- Building Management System (BMS)& EMS system validation

- Analytic Software Validation like SAS, WinNonlin, Chromeleon
- Laboratory Software System Validation like HPLC, GC, LCMS
- ERP & SAP Software validation
- Plant Serialization/ Aggregation, TracLINK, Track and Trace, Warehouse management software validation.
- LIMS, Empower and Metlab, Specialty software validation.
- IT Infrastructure, Server and Network validation
- GAP Assessment and 21 CFR, Part 11, GXP Assessment
- Excel sheet Developments and Validation as per 21 CFR, Part 11
- CSV documents reviewer, CSV Audit and Audit support
- Data Integrity, ALCOA, Risk Assessment & CSV Training

❖ Clean Room Validation/ HVAC Services

- Air Flow Measurement
- Room Air Changes Hour.
- Filter Integrity Testing
- Pressure Differentials
- Particle Count Measurement.
- Recovery Test
- Temperature and Relative Humidity
- Air Flow Pattern
- Microbial Count

AUTOMATION & TECHNOLOGIES

ARIZONA AUTOMATION is established with an objective to provide complete Automation solutions from design, engineering, development, testing to successful commissioning of Project with quality Maintenance Services at all the time. Using the effective and efficient combination of PLC, DCS, SCADA, HMI, VFD, and other Industrial Automation products.

OUR SERVICESS:

- **SYSTEM INTEGRATION**

System integration services in most efficient, cost effective & timely manner. We provide Total System Integration like: PLC / PAC /Controller Programming, HMI-GUI Designing,
SCADA application Development & communication interface.

- **OEM Solution:**

Dependable Automation Partner Partnering in Conceptualization right from the machine / Equipment Design

Stage, Control System Design and Component Selection, Control System Manufacturing OR Control system component supply, Software development, System Integration to various third party devices.

- **AUTOMATION SOFTWARE**

We build customized software's based on Windows platform which can be hooked up to any PLC brand on open protocol and any third party device having its own dedicated protocol.

- **RETROFIT AUTOMATION**

Optimize ROI - Make the most out of existing investments Many Times Old equipment's though mechanically workable cease to operate because of outdated automation products. No need to discard and make fresh investments. We upgrade your existing Establishment with outdated automation products to latest technology.

- **We provide automation AMC in many pharma and kept their systems running healthy and hassle free with standard of compliance.**
- **Also providing backup support as well offline support to reach & fulfilled our client specification & needs.**

Computer systems facilitate the daily work of Life Sciences manufacturers. Computers are found more and more in research and development departments, in manufacturing sites, and in storage and distribution and quality control areas. They create, modify, maintain, archive, retrieve or transmit data.
Computer systems are a central factor determining work sequences; they are faster and less expensive than manual interventions.

Where a computer replaces a manual operation, there should be no resultant decrease in product quality or quality assurance.

Key challenges

Any computerized system that could influence the safety and quality of pharmaceutical products must be validated.
A validation program must verify whether

- The computer and its applications work as intended and according to specifications and regulatory requirements
- The computer data is protected from unauthorized access and changes, as well as unintended loses
- The quality management system works in sync with the computerized systems with regard to the good practices.

Comprehensive validation assistance

We focus on implementing internationally accepted GAMP 5 guidelines and its current interpretations for validation of computerized systems applying Risk Based Approach and Life Cycle Management Philosophy. Our validation program covers:

- Validation Master Plan
- Risk Assessment Plan and Report
- User Requirement Specifications
- Functional Specifications
- Design Specifications
- Infrastructure Qualification & Report
- Installation Qualification Protocol and Report
- Operation Qualification Protocol &Report
- Performance Qualification Protocol &Report
- Validation Summary Report
- Traceability Matrix
- Assessment for compliance with regulations pertaining to electronic records and signatures (e.g., 21 CFR Part 11)
- Supplier Assessment Report
- Periodic Review Report

Business systems and applications are increasing in complexity and integration, so that companies can deliver real- time manufacturing, engineering, sales and accounting information across the entire enterprise.

What is Enterprise Resource and Planning?

ERP systems are widely used by enterprises internally and externally to integrate activities like SCM, inventory management, manufacturing, accounts finance, HRM, quality management, sales, distribution etc. The configuration of an ERP depends on the operational requirements of the business and the software validation requirements are governed by the concerned regulations. Hence validating the ERP system becomes complex and challenging for the enterprises bound by the regulatory pressure.

Key challenges

The most troubling issues while validating the ERP systems are:

- The screening of the key processes for validation of the ERP which important from the regulatory point of view.
- The extent of validation to be carried out while considering a particular business process

Informed business decisions

Arizona Solutions adheres to a risk management and process analysis strategy which allows enterprises to identify key opportunities to manage and mitigate risks related to long term software validation costs working in accordance with the current GAMP guidelines. We make you understand the risks so that you can make intelligent business decisions while meeting your compliance requirements.

Professionals at Arizona have sound experience of validating wide range of ERP systems. Based on GxP and risk assessment of the processes of ERP systems with respect to the specifications, we deliver to you, the stepwise captured qualification results traceable, point to point, to the specifications.

Process control systems are used for the automation of manufacturing processes (data collection, data supply, monitoring and controlling of the manufacturing process [PLC], and linking superimposed systems for manufacturing control [MES]. Process control systems encompass a wide range of systems: from small controls, e.g. built into manufacturing devices or equipment, to large, distributed control systems, like those for the operation of plants for manufacturing bulk materials or APIs.

Key challenges

- Determining the critical quality parameters and attributes and having specified instruments for verification of the same
- For large and complex systems, determining the key attributes that affect the quality of product directly/ indirectly

Standardization through GAMP

One of the key benefits of GAMP is the life cycle documents, which have proven their effectiveness as communication tools along the entire validation and life cycle of drug products.

Arizona works with the customer to create a functional specification for the control system, a documented risk assessment to analyze potential hazards and existing mitigations, a design specification for the entire machine, and installation and operational qualification protocols.

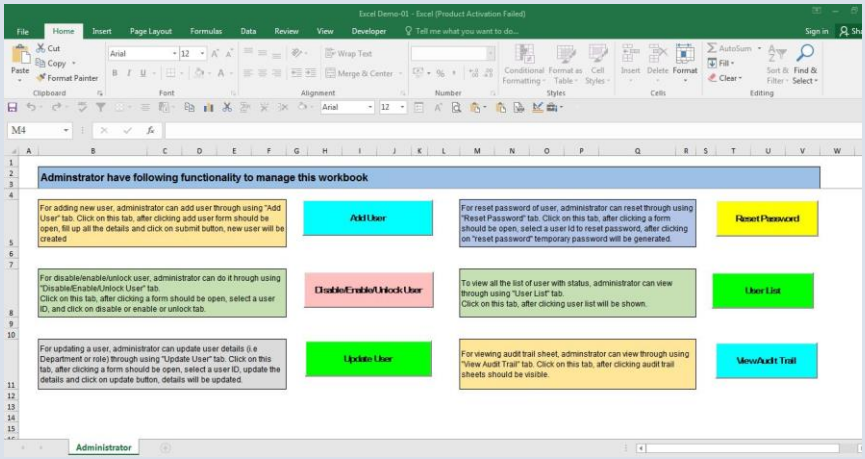
We provide validation services for following types of Process Control Systems: -

- PLC - SCADA
- PLC – HMI- IPC
- PLC - HMI -IPC- CAMERA SYSTEM
- BMS/ EMS System
- DATA LOGGER SYSTEM

Spreadsheets in regulated industries

Using spreadsheets in a regulated environment for GxP purposes whether as an operator interface, as a data manipulation tool or for data storage, it comes with a lot of responsibility though how so ever simple it may appear to use.

Log-on security for the application and spreadsheets, independent audit trail, electronic signatures, data security, authorizations are the key implications of the rule 21 CFR Part 11.



Warning letters are being sent that cite, for example, a company's "failure to use fully validated computer spreadsheets to calculate analytical results for in-process and finished product testing." Responding to such situations can impact your time-to-market.

We customize and simplify

The validation effort poses a significant challenge primarily because of the capabilities of the modern electronic spreadsheets; for example: excel spreadsheets with automated reporting and data manipulation and presentation through the use of forms, macros, modules driven by high-level programming language such as VBA

Various functionality we develop in Excel Sheet for Laboratory, Clinical, Research Centre, Pharma QC departments and many other areas Arizona provides spreadsheet development and validation services to help build authentic spreadsheets which can be used in the regulated environment and generated reliable and authentic data. We provide also you with the documented evidence of their correct functionality.

The process is designed to maximize efficiency and focuses on repeatability of the usage of the spreadsheets and helps its customers build confidence in the spreadsheets outputs both for regulatory compliance (21 CFR Part 11) and operational accuracy.

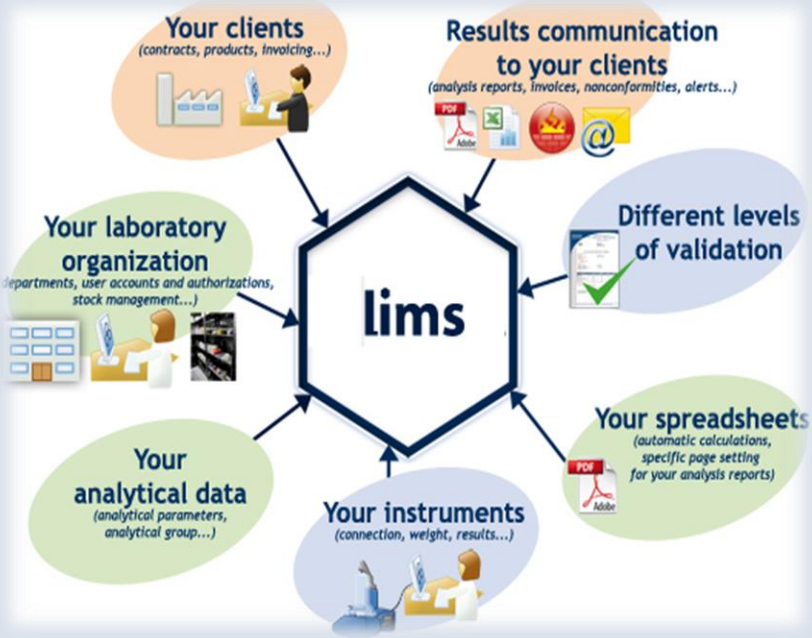
LABORATORY SOFTWARE VALIDATION

In January 2002, The FDA issued the General Principles of Software Validation. This guidance applies to any computerized system and software in the life science industry that is used to automate device design, testing, component acceptance, manufacturing, labelling, packing, distribution, or complaint handling for quality system. In addition, Computer system that are used to create, modify, and maintain electronic records and to manage electronic signatures are also subject to validation requirements.

Rules and regulation for Laboratory systems can be found in 21 CFR 211 (Good Manufacturing Practice), 21 CFR 58 (Good Laboratory Practice), 21 CFR 820 (Quality system regulation for Medical devices), 21 CFR, Part 11.

The FDA considers software validation to be "confirmation by examination and provision of objective evidence that software specifications conform the user needs and intended uses and that the particular requirements implemented through software can be consistently fulfilled."

Under OECD5, Validation is the responsibility of test Site Management. In GLP, it's the responsibility of the System Owner or Business Process Owner.



- We have an ability to enable a holistic view of compliance that aligns with multiple regulatory requirements by leveraging domain knowledge, quality and industrial standards, thereby reducing redundancies.
- Capabilities to validate software like Waters, Agilent and Shimadzu, highly complex configurable IT systems (Empower, LIMS), based upon Risk assessment, current regulations, Policies and Procedures. We mitigate risks by focusing on regulatory compliance and cost effectiveness.
- To assist in managing CSV proactively through the system's lifecycle design, development, implementation, and technologies that enable highly-regulated process in research and development, manufacturing, quality, supply chain, and commercial operations.
- Arizona provides outright solutions for Laboratory systems like: HPLC, GC, LCMS-MS, Spectrometer, FTIR, UV, PH meter, Stability chamber, TOC etc.

Temperature mapping is the process of mapping the differences and changes in temperature which occur within a single temperature controlled system due to influences like opening doors, proximity to cooling fans, personnel movement, the quality of products being stored at any given time.

Regulatory implications

As regulators increase their emphasis on GMP requirements for controlled thermal storage requirements, the definitive method to demonstrate that all controlled storage equipment, or storage areas, stay within the specified limits is through a thorough Temperature Mapping Study.

Why Temperature Mapping?

Clause 3.19 of the PIC/S GMP guide states:

"Storage areas should be designed or adapted to ensure good storage conditions. In particular, they should be clean and dry and maintained within acceptable temperature limits. “Where special storage conditions are required (e.g. temperature, humidity) these should be provided, checked and monitored."

A temperature mapping exercise is expected to collect the following information:

- The impact of interventions (door openings / power failures, etc.)
- Identification of hot and cold spots
- Variation of temperature at a single point
- Temperature variation across the area.
- Length of time of any temperature excursions

How we help you in this:

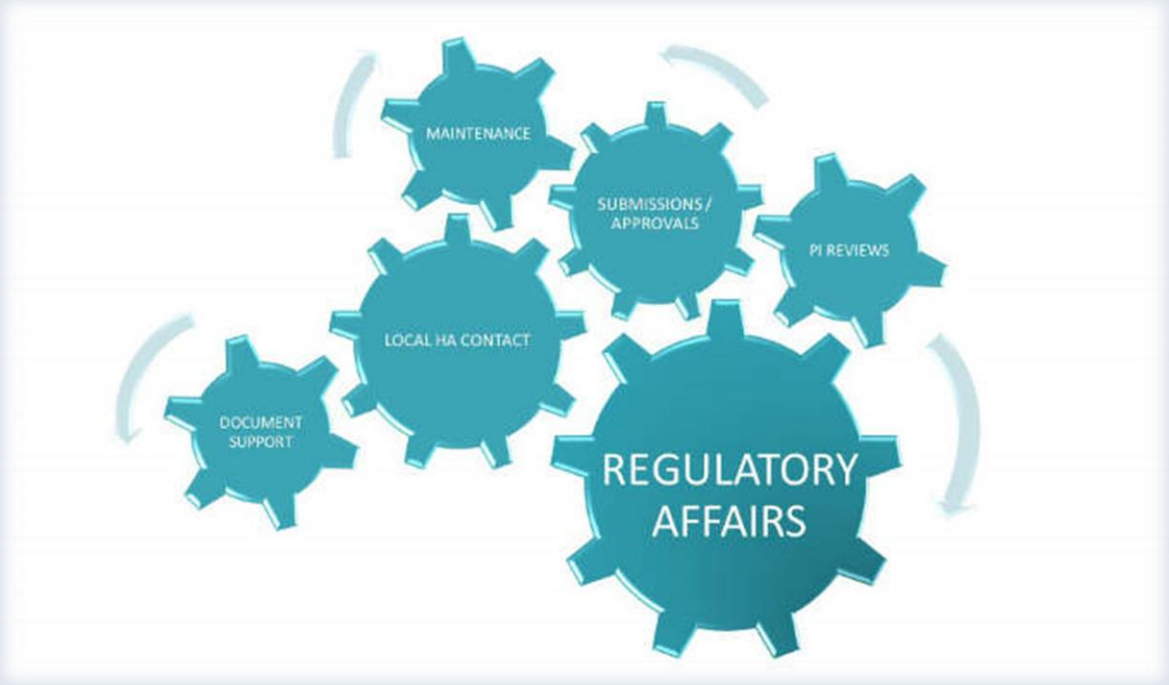
Temperature Mapping Study comprises four broad activities:

- Protocol development
- Trial execution
- Data analysis
- Reporting

Arizona serve you in:

- Freezers, Ultra Low Freezers, and Control Rate Freezers
- Refrigerators
- Incubators
- Cold Rooms
- Autoclaves
- Ovens
- Stability Rooms
- Stability Chambers
- Warehouse Storage Facilities and more


torrent
PHARMA
SAUDIBIO
الشركة السعودية لصناعات التكنولوجيا الطبية الحيوية
Saudi Biotechnology Manufacturing Co.
Zydus
Cadila
Alembic
Touching Lives over 100 years
PINNACLE
LIFESCIENCE
Akums
Windlas Healthcare
gsk
Panacea Biotec
Innovation in support of life
Acebright
ALKEM
WINDLAS
Biotech Ltd.
A WHO-GMP Certified Company
Centaur
SCOTT-EDIL
PHARMACIA LTD.
Emcure
SUCCESS THROUGH INNOVATION
MACLEODS
JUBILANT
LifeSciences
LUPIN
Cipla
SENTISS



COMPUTER SYSTEM VALIDATION

ARIZONA AUTOMATION & TECHNOLOGIES
E-mail: info@arizonaautomation.in /contact@arizonaautomation.in
Contact Number: 0091-9712648866, 9909786331
WWW.ARIZONAAUTOMATION.IN