

“OUR BELIEF
Committed to Deliver an Excellence with Integrity.”



› OUR SERVICES

• CSV VALIDATION

GxP computerized system validation (i.e. Process control system, Lab/Analytical software system, Customize & Enterprise software system) as per following regulatory guidelines like GAMP5, CFR Tittle 21 Part 11, EU Annex 11.

• IT-SOFTWARE DEVELOPMENT

Provide a customized GxP software solution that strictly adhere to regulatory guidelines like GAMP5, CFR Tittle 21 Part 11, EU Annex 11.

• COMPLIANCE SUPPORT

QMS support, GMP Consulting, FAT-SAT Support, Compliance training, Audit Consulting, Regulatory Compliance documentations (CQV & Data Integrity), Cleanroom Validation, Temperature Mapping.

• IT-GxP & IT-ADMINISTRATION SUPPORT

User Management Activities, Backup & Periodic Restoration Activities, Preventive Maintenance, Inventory Management of GxP Computerized Systems.

> ABOUT ARIZONA

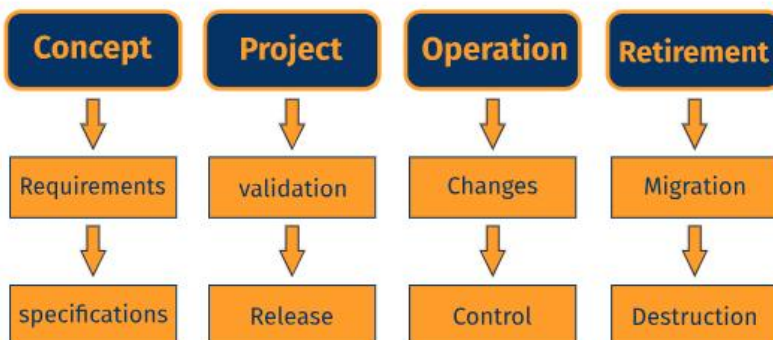
- Arizona Automation & Technologies, Provides One-stop Compliance Solutions To Life Science, Healthcare, Pharmaceuticals, Clinical Research Labs, CROs, R&D Labs, Equipment Suppliers, IT-software Providers, And Automation Consultants.
- Arizona Offers Service For Computerized System Validation, IT-software Development, IT-GxP Administration Support, Compliance Training, Audit Support.
- Arizona provides IT-Software solutions that encourage organisations to go paperless and digital in order to achieve higher levels of accuracy and efficiency. Our GxP Software success factor is that we fully understand and implement the spirit and basics of the USFDA, MHRA, EU Annex 11, GMP, GAMP, and ISO.
- We are continuously and systematically developing our product in a way to define consumer goal and delivering satisfactory that moving forward to improve and simplify compliance for everyone.
- Our core competencies are providing comprehensive regulatory and compliance services in accordance with GAMP5, Risk Assessment (ICH Q9), and CFR Title 21 Part 11 and taking care of QRM & ALCOA++.
- Arizona Expertize to provide support for brownfield and greenfield project.
- Arizona Expertise has a proven track record of successfully completing compliance projects. We are delivering with continuous updates on technology and compliance fronts. Engineers make up a team led by technically expertize, skilled and experienced professionals.
- Our aim is to enhance and maximize the operational performance of our clients by helping to achieve their business objectives in a professional, timely, and cost-effective manner.

"Picture shown below worth a thousand words, but appreciation is priceless"



➤ CSV VALIDATION SERVICES

- Computerized system validation framework to achieve and maintain GxP compliance throughout the computerized system life cycle. This framework is based on system specific validation plans and reports and the application of appropriate operational controls.
- Validation plans and reports provide a disciplined and consistent approach to meeting regulatory requirements, leading to appropriate documentation at the right level. Such documents are valuable both in preparing for, and during, regulatory inspections.
- Validation of systems to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records. (Ref.: 21 CFR 11.10 (a)).
- A computerized system consists of the hardware, software, and network components, together with the controlled functions and associated documentation. (Ref.: ISPE GAMP5).



APPROACH FOR VALIDATION

- Risk-based approach.
- Based on the life cycle of the system.
- "V"-model for development and system test.

➤ Arizona Provides following length of full services in Validation :

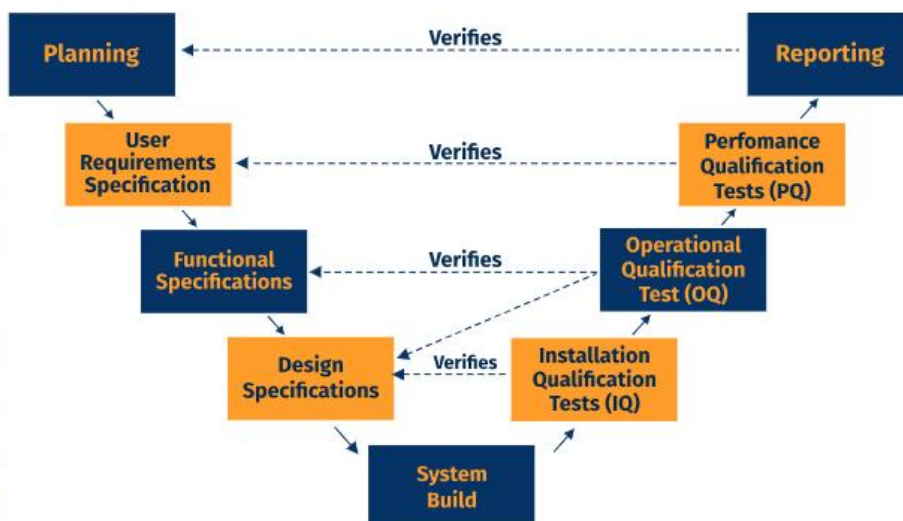
- Process Control System Validation (PLC/HMI/IPC/SCADA/DCS System Validation)
- Equipment Qualification (IQ, OQ, PQ)
- Laboratory Equipment Software Validation (HPLC, GC, FTIR, Spectrometer, UV, LCMS-MS and More)
- Building Management System (BMS) and Environment Management System (EMS) System Validation
- LIMS, EMPOWER, LabVIEW, Specialty Software Validation
- Aggregation, Serialization, Track and Trace, TracLINK, ReeTrak, L1 to L5 Integration Validation, Warehouse Management Software Validation.
- Analytical Software Validation (Chromeleon, SAS, WinOnlin & more)
- Enterprise Application Software Validation (SaaS, SAP, ERP, MES, LMS, TMS)
- Excel Sheet Development and Validation as per CFR Tittle 21 Part 11
- Cloud, Server, Network and IT infrastructure validation
- Customize Software Validation
- Desktop Validation, Meta data Validation
- CFR Tittle 21 Part 11 Assessment, GAP Assessment, GXP Assessment, Impact Assessment.
- CSV Audit and Audit Support, CSV Training.

➤ ARIZONA PROVIDE FOLLOWING CSV VALIDATION DELIVERABLES

We concentrate on implementing internationally accepted GAMP5 guidelines and designing in accordance with the CSV Validation protocol using a risk-based approach, in accordance with 21 CFR Part 11 and the life cycle management philosophy.

● The General V Model Documentation flow for Computer System Validation (CSV).

- 1. GxP Assessment and System Categorization
- 2. Validation Plan
- 3. User Requirement Specifications
- 4. Risk Assessment
- 5. Functional Design Specification
- 6. Installation Qualification
- 7. Operational Qualification
- 8. Performance Qualification
- 9. Validation Summary Report
- 10. Traceability Matrix
- 11. System Release Certificate
- 12. Periodic Review Report
- 13. Assessment of: GAP, GxP, Tittle 21 Part 11, Impact



Depending on the stage of the system's life cycle, the chosen V-model and its activities can be positioned to be more compatible with development activities and system testing.

> CQV

- Commissioning, qualification and validation, also known as CQV, is a complex, multi-step process. Commissioning ensures that facilities, systems and equipment are designed and installed as specified and function as intended. Qualification ensures equipment and systems function to produce products correctly. Validation ensures that the final product is built correctly.
- Arizona offers you full-service support to track and keep your project up to date and completed within the specified timeline, largely owing to our professional and experienced team.

> Data integrity

Data integrity refers to the completeness, consistency, and accuracy of data. where data are Attributable, Legible, Contemporaneous, Original, Accurate, Complete, Consistent, Enduring, and Available (ALCOA+)



- With increasingly growing use of computerized systems, complex pharmaceutical manufacturing processes, maintaining DI might become more challenging, and relying merely on legislation and guidance to maintain DI might be insufficient. Recent FDA Form-483 observations and warning letters indicate that DI is the main issue the pharmaceutical industry is currently dealing with. Failure to comply with DI requirements may result in a high number of un-validated results, which may cause post-marketing issues and frequent product recalls. To address the underlying causes of DI problems, a comprehensive approach is necessary.
- Arizona provides a well verse and highly trained personnel to driven the project and meet the compliance requirements with highly exceptional knowledge.

> EXCEL / SPREADSHEET DEVELOPMENT & VALIDATION

• 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, and authorizations are the key implications of rule 21 CFR Part 11.
- Spreadsheets are often used to perform GMP related calculations trend data, Plan Calibration and qualification work and manage laboratory assets
- Spreadsheet developed as per regulatory compliance should be eliminated possible risk from performing GxP work to increase business efficiency and reduce regulatory risk
- Spreadsheets are used to collate lists of instruments and perform a multitude of calculations in many regulated laboratories. But Spreadsheets also present an auditing and inspecting opportunity to find abundant instances of non-

➤ FUNCTIONALITY WE DEVELOPED WITHIN SPREADSHEET

- Developed User Management Facility in Spreadsheet
- Developed Audit Trail Facility with date & Time Stamp
- Developed spreadsheet with Hide /Unhide row & Column functionality
- Set Decimal with increase / Decrease functionality
- Developed spreadsheet with Hide / Unhide table functionality
- Developed spreadsheet with Showing Path with user name while printing.
- Developed spreadsheet with Facility to Set Password Security
- Developed spreadsheet with Facility to set Calculation as per unit change from dropdown
- Developed spreadsheet with Facility to link one data from one excel sheet to another excel sheet in a workbook
- Developing spreadsheet with many other functionalities as per client requirements
- We can develop spreadsheet fully comply as per 21 CFR Part 11 with above mention functionality but it's not limited



➤ REGULATORY & COMPLIANCE SUPPORT:

- **Help to achieve and review various activities related to Quality Management System**
Provide Pre Audit and Post Audit support for various Audit like USFDA, PIC/S, EU-GMP & WHO.
We can carried out FAT and SAT activity.
- **Review various documentation, Systems, Equipment's and Facilities as per client recommendation.**
- **Design Various GxP SOP to achieve compliances:**
 - Validation related SOP
 - Infrastructure/Server related SOP
 - QMS related SOP
 - Disaster Management & Business Continuity SOP
 - GxP related SOP
 - Data Backup & Restoration SOP
 - Training SOP
 - Audit trail review SOP
- **For GAMP 5 as a core with regulatory services as per USFDA, EUGMP, WHO or PICS which includes:**
 - Assessment of: GAP, Impact, GxP and Risk assessment
 - Audit trail review
 - IT infrastructure review
 - System & Utility review as well as Documentation review
 - Data storage, backup, restore, analysis and recommendation
 - Disaster Management solution
- **Highly expertise Team of CSV and DI**
- **Highly expertise team of QMS, IT-QMS, IT-GxP, IT-Administration**
- **Highly expertise team of Automation and MES system**
- **Highly expertise team of GMP Consulting**

➤ AUTOMATION & CONSULTING

ARIZONA AUTOMATION 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.

➤ We are one of the Leading Automation Consulting Firm & provide Solution in



- Turnkey Project Solution
- System Integration
- Automation Upgradation
- OEM Solution
- Retrofittings
- PLC/HMI/SCADA Programming

➤ CLEANROOM / HVAC VALIDATION

- HVAC system is acronym Heating Ventilation and Air Conditioning system.
- This system is used to control the Temperature, Humidity and Contamination of Airborne particle by regulating the movement of air.
- Arizona Automation & Technologies performed HVAC Validation as per ISO 14644-1,2,3, EU GMP/EC, WHO-TRS-937, WHO-TRS-961, Schedule M guidelines for all room classification.

➤ Arizona carried out following test for Cleanroom Validation

- | | |
|-------------------------------------|--|
| ➤ 1. Air Exchanges rate | ➤ 6. Air Particle Counter |
| ➤ 2. Room Pressure Testing | ➤ 7. Area recovery Test |
| ➤ 3. Air Velocity/CFM Measurements | ➤ 8. Containment Test |
| ➤ 4. Duct leakage Test | ➤ 9. Temperature & Relative Humidity Measurement |
| ➤ 5. HEPA filter integrity/DOP Test | |

➤ THERMAL VALIDATION & TEMPERATURE MAPPING

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.

➤ Temperature Mapping Study comprises four broad activities:



- Protocol development
- Trial execution
- Data analysis
- Reporting

➤ Arizona serves 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

> IT-SOFTWARE DEVELOPMENT

Arizona Automation & Technologies offers world class software solution to achieve compliance excellence. We achieve complete life cycle software development services that seamlessly adapt to your project objectives and business demands, we digitalize the process by keeping the industry best practices in mind. We make our software solution available on premises, through web and in cloud. Our products have a proven integration to LDAP, QMS, SAP and ERP Software

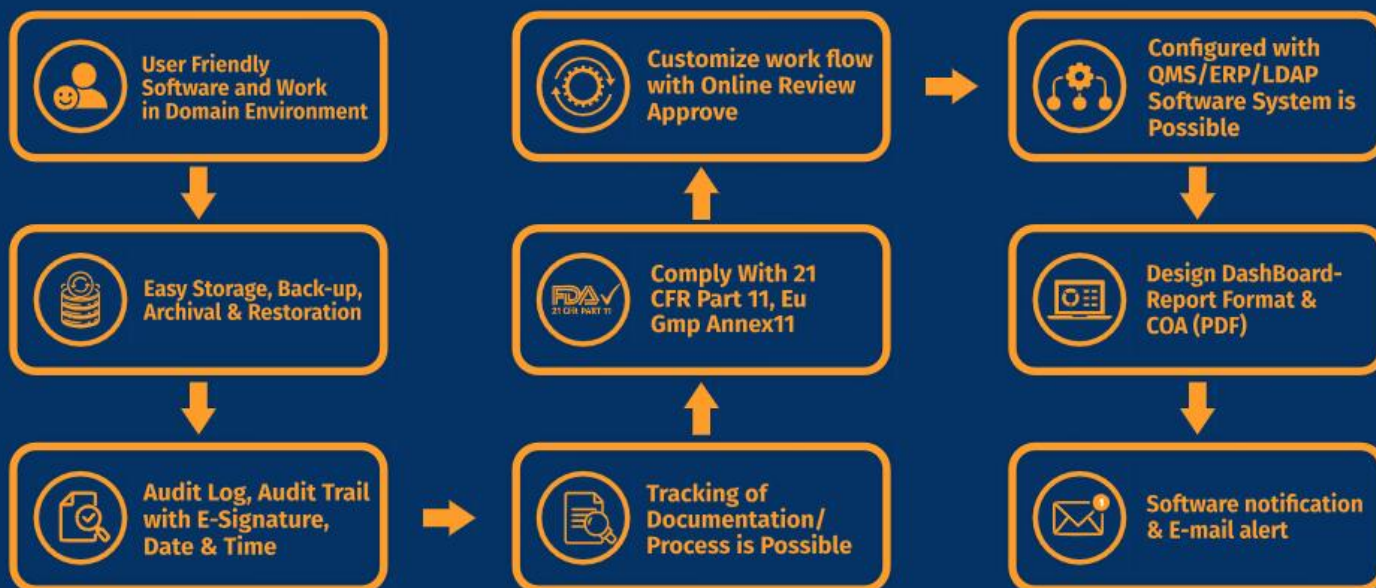
To make your business idea a reality, we provide a potent combination of in-depth technical competence, mature, low-risk processes, and demonstrated experience in a range of business domains. We give the best IT-Software solution and support to help your business grow by inventing and combining our technical competence with a combination of in-depth knowledge and experiences. We mold your concepts. We offer effective and reliable technology solutions built on a solid basis with the aid of frameworks, programming, and other tools.

Our products are designed to meet regulatory requirements. We help in achieving the compliance guidelines defined by the regulatory authorities. We can completely eliminate paper from the production process with our digital solutions.

PAPERLESS LABORATORY SOLUTIONS



> Leading Compliance Solution



WE FOLLOWS COMPLIANCE WITH ALL REGULATORY STANDARDS



➤ OUR SOFTWARE PRODUCTS

- Calibration Management/ Schedule Management Software.
- Laboratory Information Management System (LIMS)
- Quality Management System (e-QMS)
- Spreadsheet/ Excel Sheet Management Software
- User Management Records Software
- Stability Sample Management Software
- ShareDOC: Confidential documents sharing software
- Learning Management/Training Management System
- Electronic Batch Manufacturing Record and Electronic Batch Packing Records (E-BMR & E-BPR)
- Digital Validation Protocol Generation0 (E-Validation)
- Logbook Management (e-Logbook)
- Sample Management Software



➤ CALIBRATION MANAGEMENT/ SCHEDULE MANAGEMENT SOFTWARE.

- Arizona's "e-CMS" (Calibration Management Software) provides the complete software solution for calibration management
- The solution helps to organize, control and increase the efficiency of calibration programs through a simple and intuitive web interface.
- Calibration control software simplifies activities such as **planning, barcoding, scheduling, execution, labeling & Certification** of analysis and management of calibrations and measurements.
- "e-CMS" Calibration software help you complete a full calibration from entering the details of the instrument to printing out a calibration certificate. Reduce operating time by automating calibration procedures, reduce sources of error by automatically reading and storing values from the reference, and customize certificate templates to fit your needs. Try our calibration software today.



➤ LABORATORY INFORMATION MANAGEMENT SYSTEM (LIMS)

- Arizona's LIMS is ideal for highly regulated industries working to standards such as FDA 21 CFR Part 11, EU GMP Annex11, ISO 17025 and cGxP. The Pharmaceutical LIMS drives quality throughout the manufacturing flow by managing and tracking the samples of raw materials, intermediate and final product, ensuring they can be quickly related to the relevant product and batch. Arizona's LIMS helps you automate and control your sample testing, and record data results, ensuring your product meets your quality standards.

LIMS SOFTWARE



☒	INVENTORY	Inventory tracking without losses
☒	WORKFLOW	Streamline Workflow for online Review & Approve activities
☒	SAMPLE MANAGEMENT	Efficient sample management, tracking, edit or modify sample.
☒	REPORT	Automated data exchange, Automatic reporting and Certificates of Analysis.

- Arizona's LIMS helps to eliminate bottlenecks through the QC, R&D, Analytical, Micro Bio, Food, Environment Lab & Clinical Research laboratory, automate and streamline processes, and reduce human error. This results in fewer manufacturing delays and improved profitability for the business, while improved efficiency in the laboratory allows staff resources to add value rather than chase down discrepancies in data and lost sample information.



> ELECTRONIC DOCUMENTATION MANAGEMENT SOFTWARE (E-DMS)



- Arizona's Document Management System (EDMS) is an automated software program that helps you organize, secure, capture, digitize, tag, approve, and finish the task with your company's information. A document management system provides safe storage, water mark on documents, alert before expiry of revision time, version control of documents to the entire organization
- Types of documentation in organization : Instruction document such as sops, specifications, standards documents.
Record & Reports documents such as BMR, change control results, deviation report, training records, validation protocol etc.

> QUALITY MANAGEMENT SYSTEM (E-QMS)

- In any organization effective QMS will help to develop a culture of quality, support data integrity, reduce the time and cost to manage documents, identify and resolve problems in product development and introduction, manage supplier quality, and ensure a trained workforce. Arizona's e-QMS software can help pharmaceutical businesses quickly and easily become compliant by providing complete end-to-end quality visibility right from design to delivery.
- Our e-QMS Software is inline with International Conference on Harmonization (ICH) guidance like ICH Q10 Pharmaceutical Quality System, ICH Q9 Quality Risk Management,
- e-QMS Software helps organization to design, implementation, monitoring, and maintenance of an effective pharmaceutical quality system.



- The manufacturing of products must be maintained at high standards to ensure the strength of the active components, quality, and purity of the products. It facilitates compliance with ICH Q10 and ISO guidance for common quality principles such as total employee involvement, customer focus, and a process-oriented approach. By achieving excellence in these core quality principles, pharma companies can maintain quality control and embark on a journey of continuous improvement
- Software comprises with various modules: **Deviation Management, Change Control, CAPA, Vendor Qualification, OOT/OOS, complaint management, Incident Management and other.**



➤ SPREADSHEET/ EXCEL SHEET MANAGEMENT SOFTWARE

- Spreadsheets are often used to perform GMP-related calculations, trend data, plan calibration and qualification work, and manage laboratory assets. Arizona's Spreadsheet software (e-XLM) should eliminate possible risk from performing GxP work to increase business efficiency and reduce regulatory risk.



➤ USER MANAGEMENT RECORDS SOFTWARE:

- Monitoring users and their activities is an ideal method for obtaining a clear picture of what is happening on the network, and who is responsible. User monitoring is also an important component of compliance management, as most compliance regulations require specific controls around user privileges, access credential, roles, and behaviours.
- This requirement is enforced more so on systems that must comply with requirements, such as 21 CFR Part 11 and similar standards common in "FDA-regulated industries," such as pharmaceutical, food, and beverage.

➤ STABILITY SAMPLE MANAGEMENT SOFTWARE

- Stability testing of drug products is mandatory by 21 CFR Part 211.66 of the cGMP guideline.
- Also as per GMP guideline Stability program should demonstrate that the quality parameters of the drug substance and drug products remain acceptable throughout their labeled shelf life period. Inadequate stability studies that do not provide shelf life of the product may cause the facility to fail in FDA inspection and receive a warning letter.
- E-Stability provides you batch record, pull out, transfer to new storage location, total analysis information, Pull out deviation records.
- You can keep master as per specification and as per specific requirements or Market/ Country/ Customer.
- Also keep track of storage location / Batch wise.
- Additional sample management.
- Automatic calculation of result as per Specification.

➤ SHARED DOC: CONFIDENTIAL DOCUMENTS SHARING SOFTWARE



- ShareDOC, a confidential document-sharing program from Arizona, makes it simple to transmit and receive huge files securely with clients.
- By using ShareDOC software one can maintain Confidentiality of project/protocol/file.

- ShareDOC can protect document from download, save as, copy paste or print.
- Documents are in read only mode.
- Particular file/ protocol /documents remain accessible to user for certain period of time up to specific date.
- Only single copy documents can share with multiple user so no need to generate multiple documents copy.
- One can easily track the documents as per Project/ Department wise

> LEARNING /TRAINING MANAGEMENT SYSTEM

Learning process is continuous, its mandatory to record and documented all training conducted for the purpose of detail audit. Non-compliance not has only legal consequence but it also impacts production quality, customer service and results in loss due to incompetence.



Arizona's Advance Learning Management Solution tends to achieve both short term and long term business objectives since their employee engagement rate is significantly increased. A knowledgeable and competent work force trigger over all organization development.

● Life cycle of LMS is



> ELECTRONIC BATCH MANUFACTURING RECORD AND ELECTRONIC BATCH PACKING RECORDS (E-BMR & E-BPR)

- E-BMR Software is specially design to meet the Good Documentation and Manufacturing Practice. BMR should be prepared for each intermediates & API/ Formulations and its cover complete information about manufacturing and control of each batch.
- Its help all regulatory body to ensure product is manufactured correctly with all required data and through proper recipe method with compliance to 21 CFR Part11 & ALCOA.

● Process flow of E-BMR



➤ DIGITAL VALIDATION PROTOCOL GENERATION (E-VALIDATION)

- This E-Validation software help to generate paperless protocol of various analytical method and having online review and approve.

➤ LOGBOOK MANAGEMENT (e-LOGBOOK)

- Paper-based equipment use-logs and many logs are not completed appropriately and may create GMP compliance issues. From operational and compliance perspectives, maintaining detailed logbooks that clearly identify all equipment activities and recordings is essential. For immediate access to equipment data for analytics, visualization, and continuous improvement, a digital solution is essential.

● A robust and effective electronic equipment use-log must:

- Enable real-time data capture and equipment status management
- Have the end user at its core and support simple, guided entry for users of all capabilities
- Allow specific users to quickly view and analyze logbook data regardless of location or proximity
- Compliance with requirements for electronic records and signatures
- Enable data reporting and visualization to promote process improvement

➤ SAMPLE MANAGEMENT SOFTWARE

- A sample management setup must be able to cope with any size of sample throughput, multiple users and access-points, a diverse range of sample types, and offer comprehensive inventory, sample and process tracking.

> IT QMS SUPPORT

- Arizona Automation and Technologies offers QMS (Quality Management System) support in the IT industry (Information Technology). We have highly qualified engineers for QMS who have extensive experience in regulatory plants.

● Our expert can handle all compliance documents such as:

- | | |
|---|---|
| ➤ 1. Change Control | ➤ 5. Corrective Actions & Preventive Actions (CAPA) |
| ➤ 2. Deviation | ➤ 6. Validation Documents |
| ➤ 3. Risk/ Impact Assessment | ➤ 7. Planner (PM, Backup & Restoration) |
| ➤ 4. Standard Operating Procedures (SOPs) | ➤ 8. Inventory Management |



> IT-GxP ADMINISTRATION SUPPORT

- IT QMS, IT Administration, GxP activities, IT Infrastructure Configuration, Server Configuration & Validation, Network Configuration, Cloud System Validation
- IT Administration of the GxP System like Enterprise Application (ERP, SAP, LIMS, etc.), Lab Software, Process Control Systems.
- Backup, Periodic Restoration of GxP System, and Archival Management.
- PM activity of GxP Computerized System and Server.
- Inventory Management of GxP Systems.
- Prepared & Follow SOPs: User Management, Backup and Restoration, Password Policy, Asset Management, Privileges Management, Inventory, Security Policy.
- Qualification and Validation of IT-GxP Systems.
- Handling of IT-QMS activity: Change Control, CAPA, Deviation & Investigation, Effectiveness check related to IT-GxP.
- Provide Auditing related to all IT Administration, GxP & QMS activities.

Our Clients



Our Clients



Arizona Automation & Technologies

ISO 9001:2015 Certified

OUR VISION

To accelerate organization towards digitalization & leverage technology for business enhancement and fulfill compliance standards by committing innovation, excellence, transparency & business ethics.



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