GAMP SERVICES

Knowledge | Validation | Services

GMP & GAMP Validation, CQV, Audit & Consulting Services

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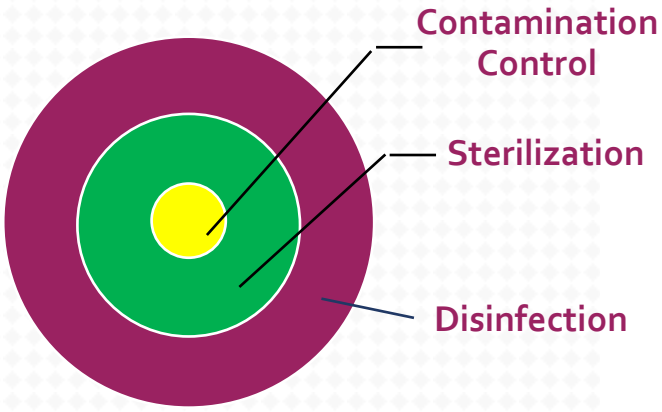
GAMP Services Pvt ltd is a leading GMP & GAMP Validation, C Q &V, GMP Audit, Sterility Assurance and Regulatory compliance services provider across Globe.

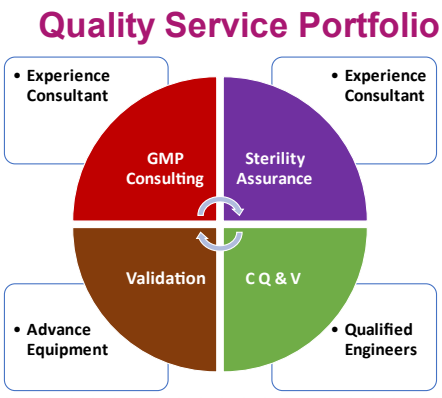
Mission & Vision

- To be the Quality services & solution partner for the entire spectrum of life science segment which includes pharmaceutical, hospitals medical devices and food industries.
- To follow the Quality management system (QMS), which includes SOP's, processes and data management, customer feedback, training, traceability records to ensure that we are holding ourselves to the highest level of quality.

Our Focus

- **GMP (Drug Quality) and GAMP (Data integrity)**
- **USFDA, EUGMP, UKMHRA or PICS approved pharmaceutical facility**
- **Focus on Total Sterility Assurance which includes Contamination Control, Sterilization or Disinfection**
- **Focus on CSV and DI projects, Audit and Regulatory Compliance Services**





- **We focus on Total project life cycle with Turnkey Validation Services and CQV Services for simple to complex life science projects**
- **Our consultants have expertise on GMP Consulting, Sterility Assurance Consulting and GMP audit for all type of pharma facilities.**
- **Team of experienced Engineers, Expert, Associates, SME and Advisors**
- **Core strength is ensuring data integrity**

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VALIDATION:

Basic Validation (with equipment and engineers)

FACILITY	•HVAC/CLEAN ROOM •CLEAN ROOM DEVICES LIKE LAF,PASSBOX ETC
UTILITY	•COMPRESSED AIR •STEAM •WATER
THERMAL	•FACILITY MAPPING •LABORATORY EQUIPMENT MAPPING

ADVANCE VALIDATION: Speciality in Thermal Validation, Smoke Study and Media fill with Protocol to Report and Review:

THERMAL	•KAYE VALIDOR AVS •AUTOCLAVE,LYOPHILIZER ,TUNNEL •MANUFACTURING TANK , CIP/SIP SKID
SMOKE STUDY	•WITH 4 CAMERA •REMOTE CONTROLLED FOGGER •LIVE STREAMING •HIGH END VEDIO PROCESSING WITH DATE AND TIME
SMOKE STUDY	•TURNKEY PROJECT -PROTOCOL TO REPORT •REVIEW
MEDIA FILL	•TURNKEY PROJECT -PROTOCOL TO REPORT •WITH MULTIPLE CAMERA •REVIEW

Multi Angle Smoke Study

Kaye AVS

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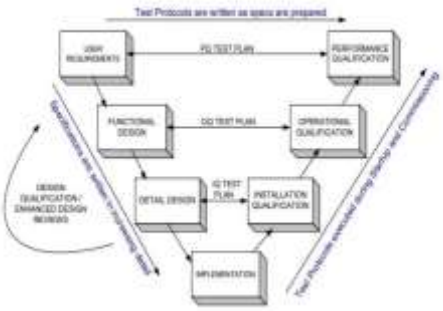
CQV (COMMISSIONING,QUALIFICATION AND VALIDATION)

We provide SME or take the lead on Equipment ,Facility and Utilities (EFU) related CQV services for any type of pharma facility.

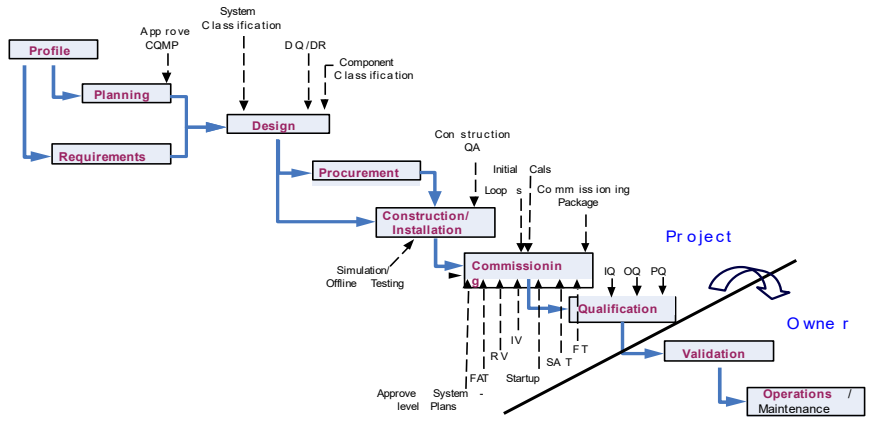
We can help you to correctly document the URS, DQ, DR, FS, RA, IQ, OQ, PQ, change management plan, Decommissioning plan as well as create the traceability matrix to meet the requirement of FDA.

We use a risk-based approach as well as impact assessment approach for CQV services.

C & Q Approach by ASTM E2500 & V Model



Overview of CQV Steps/Stages



*Refer: ISPE C&Q

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COMPUTERIZED SYSTEM VALIDATION (CSV)

Computer System Validation (CSV) is a regulatory requirement for all computerized systems used in regulated environments in the Pharmaceutical, Biotech, Nutraceutical, and Medical Device industries. CSV ensures that computerized systems are performing properly according to customer intended uses and regulatory requirements, such as:

- FDA 21 CFR Part 11
- FDA 21 CFR Part 210/211
- Eudralex and PIC/S Annex 11

Our Services Include:

- **Analysis and System Remediation**

o **Meets US FDA 21 CFR Part 11, EU Annex 11, PMDA ERES guidelines for 100% regulatory compliance**

- **Process Consulting**

o **CSV Process Harmonization and Optimization**
o **Regulatory Compliance**
o **Standard Operating Procedures (SOPs)**
o **Templates, Checklists and Training**

- **GxP Risk Assessment and Control Mitigation**

o **ICH GLP / GCP / GMP Risk Assessments**
o **Implementation of control requirements**

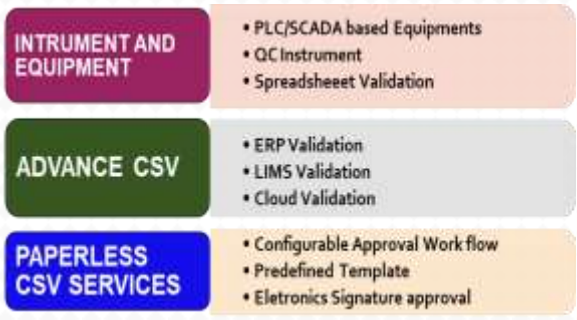
- **Validation Testing Services**

o **Unit Testing**
o **Integration Testing**
o **System Testing**
o **User Acceptance Testing**
o **Continuous Testing**

- **CSV Audits**

• **CSV Hands-on Services**

• **IT Infrastructure Management**



CSV PORTFOLIO

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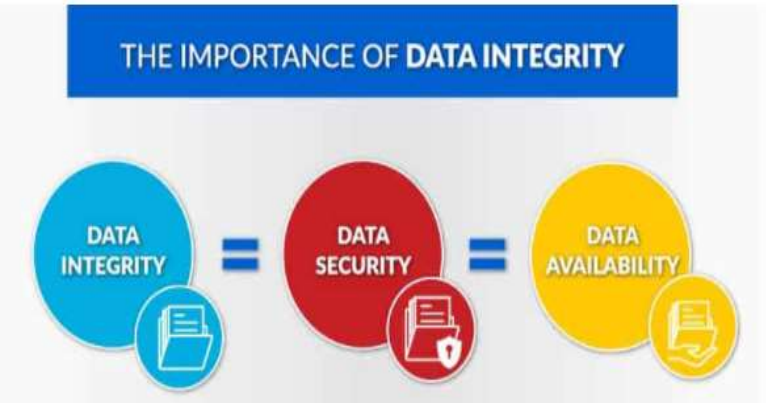
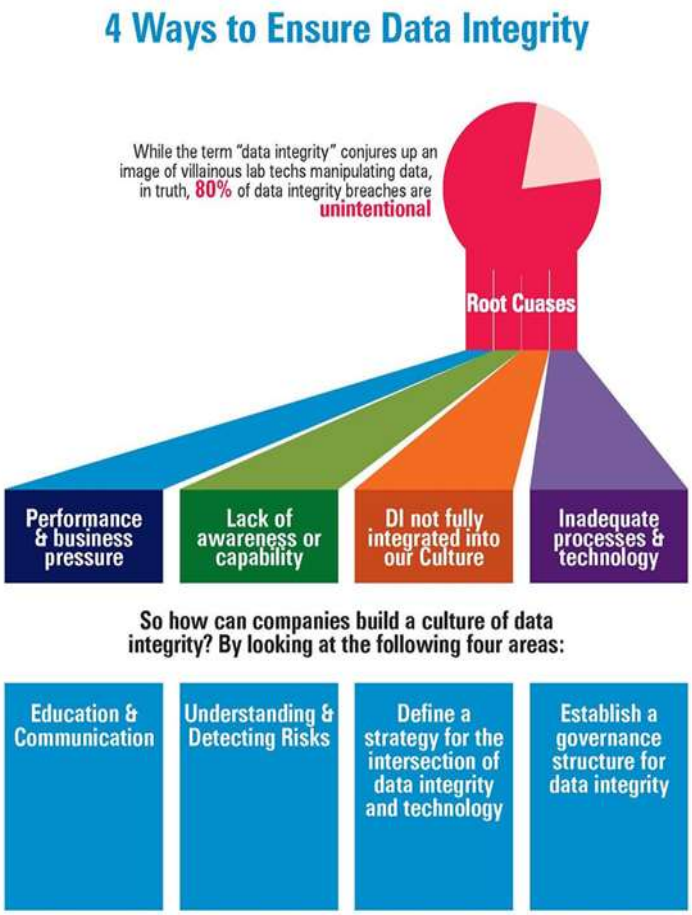
DATA INTEGRITY





Data Integrity Programs, Training, and Assessments

- **Data Integrity Training**
- **Data Integrity Assessments for both electronic and paper processes**
- **Development of data integrity programs, policies, and procedures**
- **Data process flows**
- **Data Integrity gap analysis of systems.**

Data Governance Portfolio:

AUDIT

- **Understand your DI Expoxure**
- **DI site Audit (Benchmarking and assessment)**
- **DI Program audit (Ongoing DI Program Vs best practice**

TRAINING

- **Ensuring competency of your team**
- **Basic and advance data integrity trainning**
- **Advance and efficient approach to perform paperless validation.**

TOOLKIT

- **Leverage and tailor our tools**
- **DI Policy, DI Strategic Plan & DI Project Definition**
- **DI Assessment Checklist & Procedure**
- **DI Risk Management Tools and reporting tool**

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STERILITY ASSURANCE & GMP CONSULTING

Sterility Assurance Services Includes:

Aseptic Assurance/Sterility Assurance
Contamination Control Strategy
Contamination Source Identification
EM Program viable / non-Viable
Risk Assessment for EM locations
Gowning Qualification
Audit Preparedness
Quality Management System
Media Fill
Smoke Study -Protocol To Review

SMOKE STUDY -PROTOCOL TO REVIEW

Contamination Control Strategy And EM Regulatory Compliance Review

GMP Consulting Services:

GMP compliance auditing ▫ Drug Product (DP) - Sterile and non-sterile ▫ Combination Products Medical Device ▫ Drug Substance (DS) and API ▫ Laboratory ▫ Cell-bank manufacturer ▫ Excipients ▫ Packaging and labelling ▫ Warehousing storage and distribution ▫ Printed packaging components ▫ Components and consumables ▫ Service providers
GMP Training

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SOP—Development, revision, and evolution
Inspection interview training
GAP analysis
Facility assessments

QMS PREPARATION & REVIEW

GMP GAP ASSESSMENT

Assessing Systems & Facility

- **GAMP's Good Manufacturing Practice (GMP) experts can work with you to ensure your organization and vendors (Third party audit) have a robust system in place to meet your manufacturing needs.**
- **We assess a wide range of potential contamination risk—most notably those in quality, production, packaging and labelling, materials, laboratories, and equipment and facilities.**
- **We conduct audits on your behalf, both internally and at your vendors' facilities to improve overall OMS preview.**
- **Preparing you for inspection**

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