QACAL

PROFESSIONAL SERVICES

Vision I Planning I Strategy I Execution

QAcal is a regulatory consulting firm providing quality and compliance services to pharmaceutical, biopharmaceutical, medical device, and other regulated companies. QAcal services encompass Validation, Quality, Regulatory Compliance, Training, and Capital Project Management. Our professionals work with our clients to deliver solutions that meet their strategic and business objectives.

Thing to Remember about GMP

GMP or cGMP refers to the FDA's "current Good Manufacturing Practice ". There are different GMPs for the various industries regulated by the FDA. i.e., Medical Device, Human Food, and Pharmaceuticals. The cGMP for medical devices is a set of quality system requirements very similar to the previous 1994 version of ISO 9000. The cGMP for Pharmaceuticals or Human Food set regulations which have the force of law and require that manufacturers, processors, and packagers take proactive steps to ensure that their products are safe and effective. Failure of firms to comply with GMP regulations is a federal offence and can result in recall, seizure, fines. You are required to implement processes and procedures that comply with the requirements listed in the applicable GMP's before you can release your product, and you can be audited by FDA inspectors at any time. TUV or UL will certify your organization to this standard. The cGMP integrates seamlessly with ISO 9000 and ISO 13485.

1. Validation Services

Validation is the cornerstone of Quality Assurance and our policy is to ensure that Quality Assurance is enhanced by our work.

Validation follows regulations and guidelines set forth by the US Food and Drug Administration (FDA) in the Federal Food, Drug and Cosmetic Act; Title 21 CFR Parts 210 and 211, Current Good Manufacturing Practices (cGMP) for finished pharmaceuticals and the Code of Federal Regulations (CFR), Part 820 for Medical Devices.

Validation is defined as the process of-
This is accomplished through the development of written protocols, definition of acceptance criteria, execution of the protocols, and documentation of the findings. The protocol represents an approved written plan to test, inspect, research and document results.

QACALs Validation Support Services

Offers a wide range of project-based services for your regulated company. We provide quality documents and services to support the GMP, GLP, GTP, and GCP regulatory guidelines. We will work with you to define the scope, deliverables and timeline which meet your requirements. We can provide a full team of qualified professionals or individual professionals based on your scope of work.

QACALs Validation Process

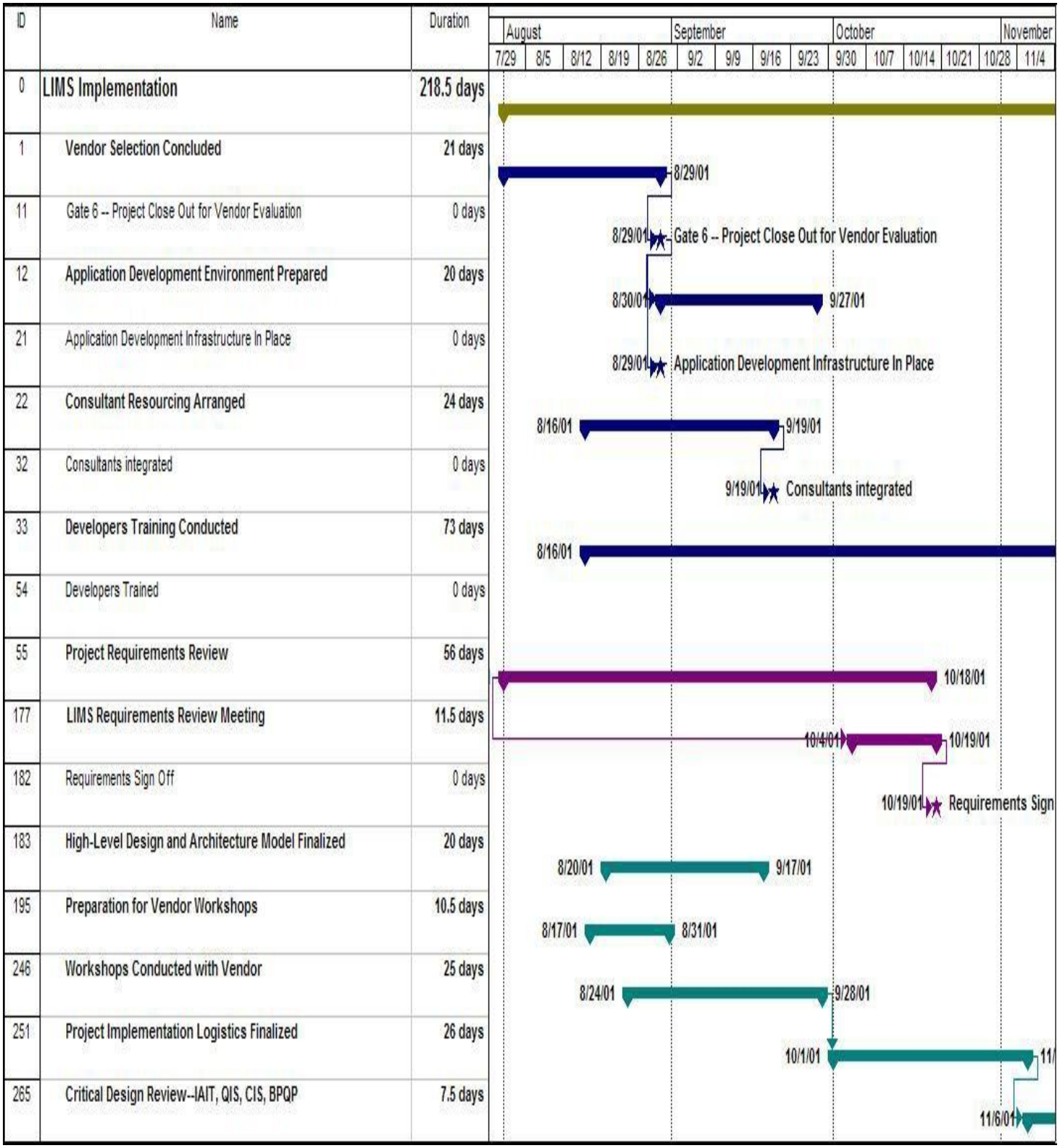
QAcal provides a proven validation process using a Systems Development Life Cycle (SDLC) model. This model supports the improvement of validation processes, and minimizes deviations and exceptions during protocol execution. The areas that the model addresses are:

- Validation Master Plan (VMP)
- Factory Acceptance Testing (FAT)
- Site Acceptance Testing (SAT)
- Commissioning
- User Requirements Specification (URS)
- Functional Requirements Specification (FRS)
- Detail Design Specification (DDS)
- Installation Qualification (IQ)
- Operation Qualification (OQ)
- Performance Qualification (PQ)
- Validation Summary Report (VSR)

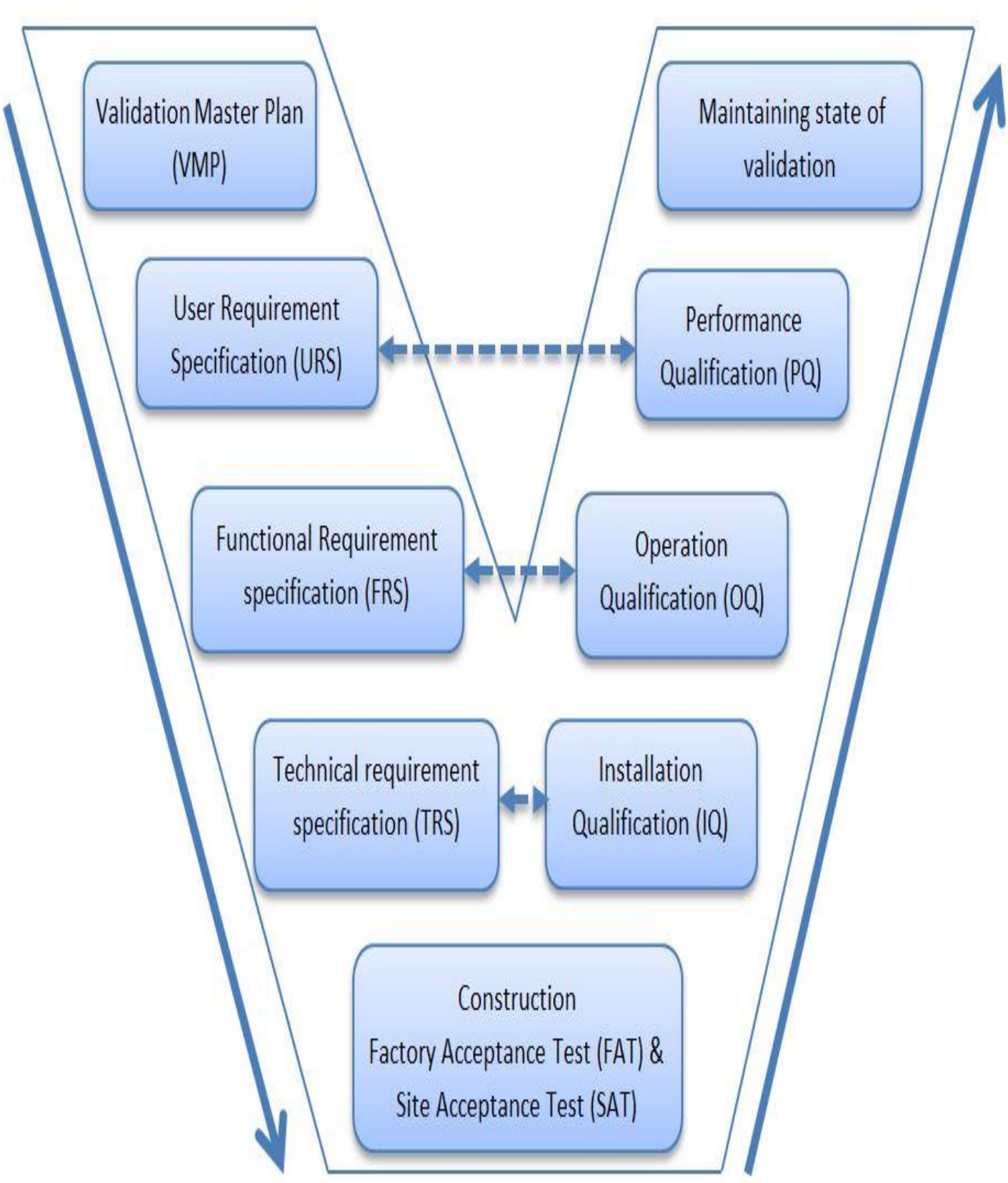
QACALs Project Management

QAcal will prepare a fully detailed project plan of events, from equipment delivery through to validation and certification and ensure that complete qualification packages, including all required information and test certificates, are handed over shortly after completion of validation.

Project Planning



Our Validation Approach



Let Our Validation Group Work for You

Validation Specifications

- Validation Master Plans
- Validation Plans
- Validation Reports

Technical Specifications

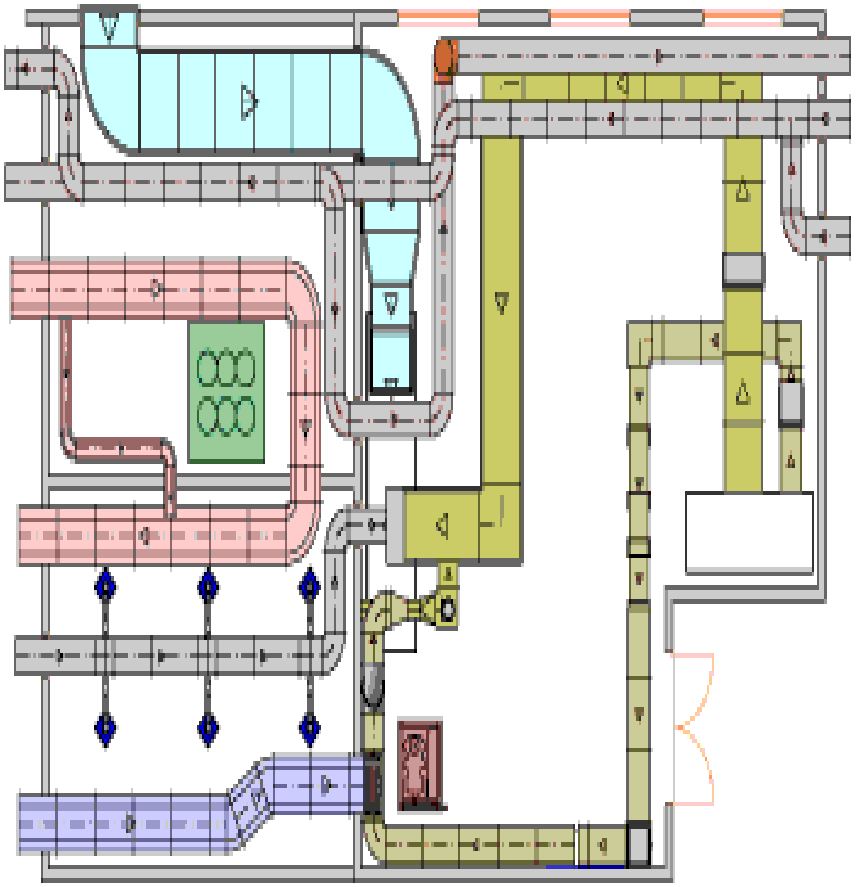
- User Requirements Specifications (URS)
- Functional Specifications (FS)
- Software Design Specifications (SDS)

Support Specifications & Testing

- Factory Acceptance Testing (FAT)
- Site Acceptance Testing (SAT)
- Engineering Turn Over Packages (ETOP)
- Design Qualification (DQ)
- Standard Operating Procedures (SOPs)

Test Planning

- Commissioning
- Installation Qualification (IQ)
- Operational Qualification (OQ)
- Performance Qualification (PQ)

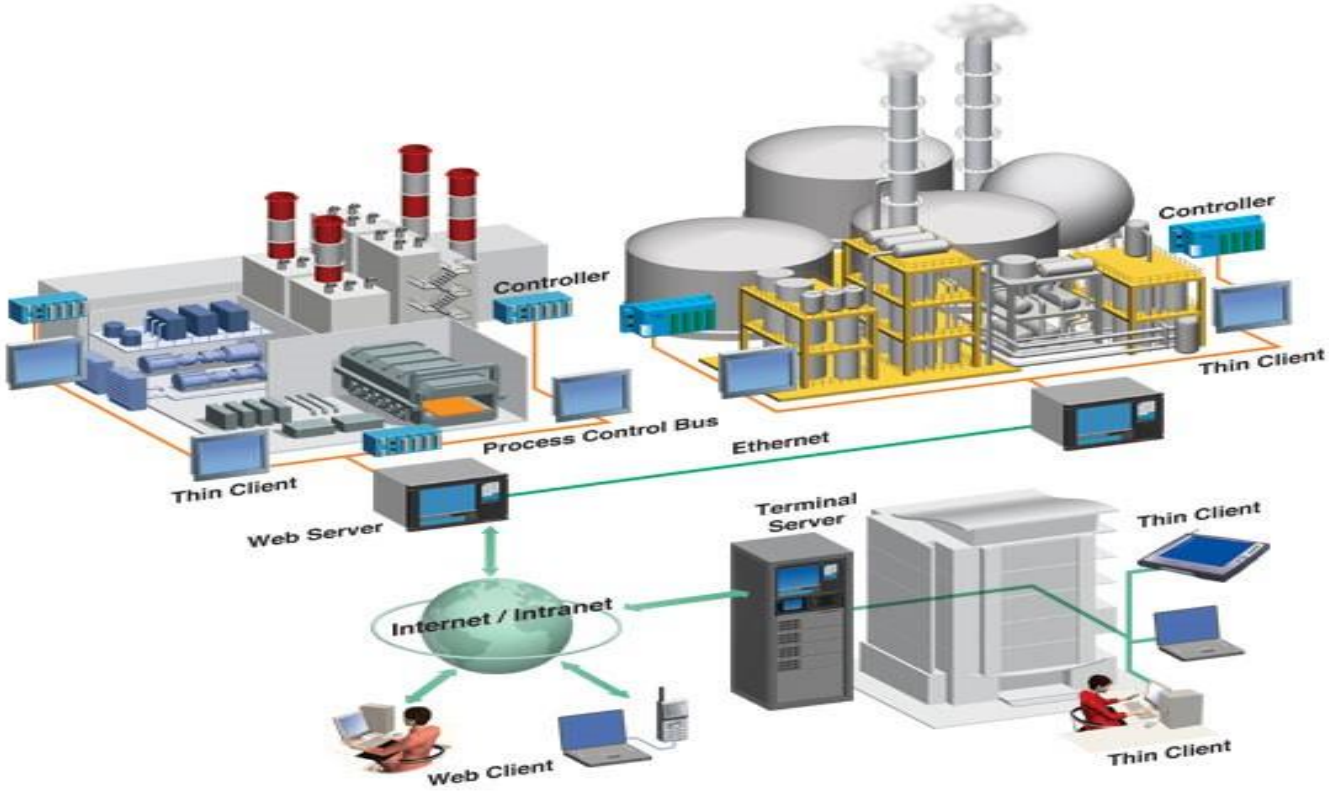


QAcal expertise encompasses the following areas:

- Equipment Validation
- Cleaning Validation
- Facility Qualification & Commissioning
- Computer System Validation
- Process / Product Validation
- Lab Instrumentation / QC Analytical Validation
- LIMS / Lab Software Validation
- Methods Validation
- Quality Assurance, Quality Reviews

Manufacturing/ Operations/ Enterprise Systems Validation

- Evaluation/ Qualification/ Validation of Computerized Systems, Instruments, and Networks
- Systems Engineering / Specification Development
- 21 CFR Part 11 Compliance (Assessment, Remediation, and Validation)
- Extensive Experience with the Development and Execution of Validation Plans, IQ, OQ and PQ Protocols, Test Plans and Scripts



Systems Validation includes but is not limited to:

- ERP/MRP-II Systems
- Document Control/ Management Systems
- Network & PC based Systems
- Facility/ Utility Systems
- Barcode Systems
- Warehouse Management Systems
- Building Automation Systems
- Computerized Maintenance Management Systems
- PLC/ DCS Systems
- SCADA/ MES/ EBRS
- Automated Process Equipment
- Water Systems (WFI/ USP/ DI/ RO)

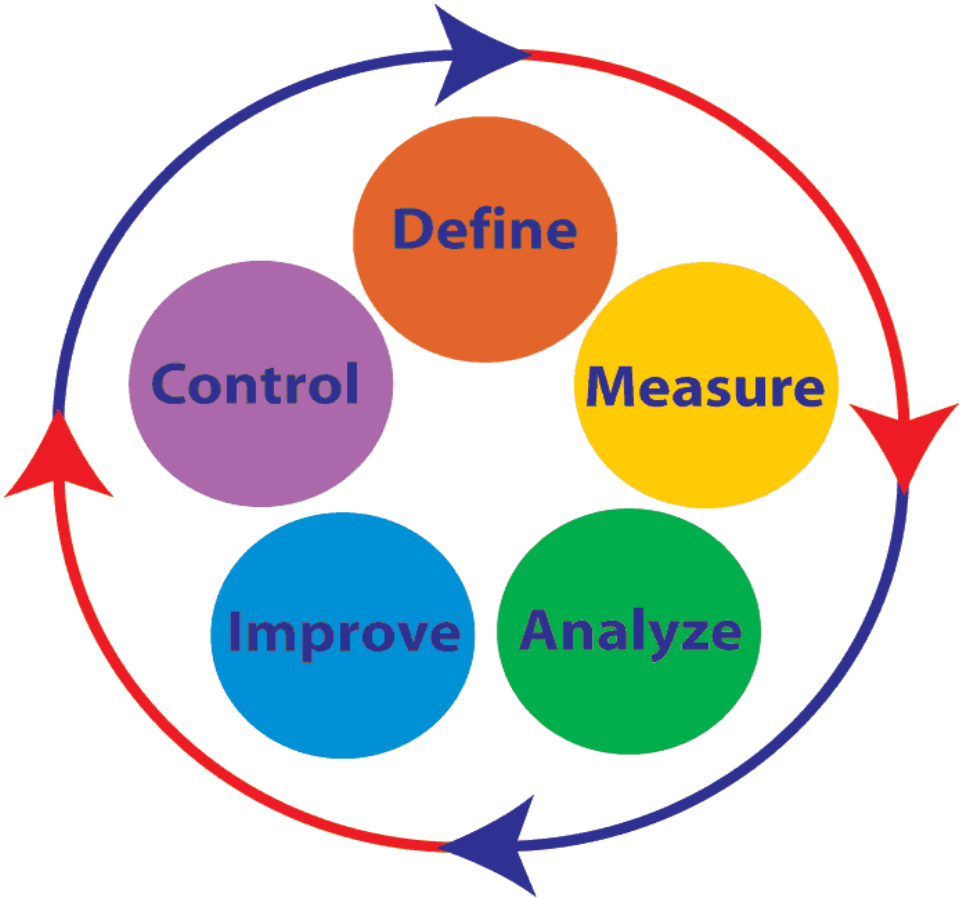
2. *Quality Systems & Quality Services*

Whether you're trying to bring a new drug or medical device to market, conduct FDA regulated production or distribution of finished products, are supplying materials and services to FDA regulated companies, or are buying supplies and services for your company, a sound quality system and an audit program are key cornerstones for the continued growth and compliance of your regulated company.

Let Our Quality Group Support You Today

QAcal can:

- Assist you in developing/enhancing a Quality System that is Phase Appropriate yet can grow with you.
- Develop, enhance or harmonize Policies, Procedures and SOPs
- Assess and provide a gap analysis and recommendations for compliance with US/ EU/ Other Standards
- Assist in developing or enhancing of Quality Assurance subsystems
- Provide qualified professionals to manage or assist with daily or periodic quality assurance activities, special projects (e.g., EDMS) or help with backlogs



QAcal quality professionals have hands-on experience which includes, but is not limited to:

- Quality System Design and Improvement
- Quality Manuals
- Vendor Management & Qualification
- Auditing
- Document Management Systems (paper, electronic)
- Management Responsibilities
- Change Control
- Deviations Management and Support
- Corrective and Preventive Action (CAPA)
- Nonconformance Management
- Annual Product Reviews (APR)
- Master Batch Record Reviews (MBR)
- Post Marketing Surveillance
- Product Complaints Handling (including writing MDRs and MDVs)
- Investigation Support
- Compliance Assessments
- Efficiency Assessments
- Quality Reviews of Validation
- Quality System Design and Improvement
- Nonconformance Management
- Deviations Management and Support
- Investigation Support (Batch Failure, OOS, etc.)
- Inspection Readiness
- QA Guidance for Contract Manufacturers and Laboratories
- QA Data Review
- QA Support for Tech Transfer
- Stability Programs and Data Review

Quality Systems Design/ Development/ Implementation

- Supplier Qualification/ Oversight
- Quality Agreements
- Product Complaints
- Change Control
- Deviations
- Document Systems (paper, electronic)
- Annual Product Reviews
- Investigations (Batch Failure, OOS)

Vendor Management

- Quality Agreements and Supplier Agreements
- Vendor Qualification Programs
- Vendor Management Programs
- Vendor Audits
- Man-in- Plant

Quality Risk Management Support

- Participate in risk assessment and risk mitigation of development projects
- Anticipate and prevent problems; identify alternatives and solutions
- Drive implementation of new company initiatives in terms of quality assurance and compliance with emerging national and international guidelines and regulations
- Ensure adherence to relevant protocols, SOPs, and ICH/GLP and GMP guidelines

SOP Development Services

- Corporate SOPs
- Quality System SOPs
- Training SOP's
- System administration SOPs
- Equipment SOPs
- IT SOPs
- Instrument SOPs
- Operation SOPs

Inspection Readiness Support

- Mock Audits
- Training of Inspection Response Teams
- SOPs and Support Processes

QACAL Auditing

Part of a robust Quality System is an Audit Program. Periodic internal and external audits ensure compliance and diminish overall risks connected with operating your company and working with vendors by identifying potential issues, implementing contingency plans and managing solutions before they become problems.

QAcal can:

- Set up or enhance your Internal and/or External Auditing Program
- Conduct Vendor/Supplier Qualification Audits
- Conduct On-going periodic Vendor/Supplier Audits
- Conduct Internal Audits/Assessments

QACAL Audit Services

QAcal's audit services include:

- Quality System Auditing
- Equipment and Facility Auditing
- IT Quality System Audits
- Software Quality Audits
- GMP Audits
- GCP Audits (CRO & Clinical Site Audits)
- Laboratory System and GLP Audits
- Contract Vendor & Supplier Audits
  - Contract Manufacturers
  - API/Excipient/Component Suppliers
  - Contract Testing Laboratories
  - Secondary Packaging

Our Audit Approach

- Identify Areas and/ or Systems to be audited and purpose of audit
- Determine the scope of the audit
- Request governing Standard Operating Procedures
- Identify the governing regulations/ compliance standards
- Prepare and disseminate audit checklist (based on above items)
- Meet with department or function to agree on audit expectations and schedule the audit
- Perform audit of relevant activities against established procedures, and regulations, and regulatory guidelines
- Debrief the auditees on findings and recommendations
- Prepare audit report draft and circulate for review
- Meet with principals to agree on final report guidelines
- Prepare final audit report incorporating appropriate and necessary revisions
- Issue final audit report

- Provides an External Viewpoint, familiar with industry practices
- Allows internal personnel to focus on other priorities and duties, without time out of their schedule for travel
- Provides specific expertise you may not have within your internal audit team

3. Regulatory Support Services

Why hire an experienced and knowledgeable regulatory compliance consultant from QACAL, Inc?

FDA compliance is not an easy target. Regulations should be viewed as a set of guidelines.

The potential cost of non-compliance can be staggering. Using our experienced regulatory consultants for a second set of eyes can add an added value for your in- house staff.

The solution is to minimize the total cost of compliance by developing the optimal compliance strategy. Creativity, hands-on operating experience, and a commitment to professional excellence are keys to addressing the regulatory risk depicted in figure 1:

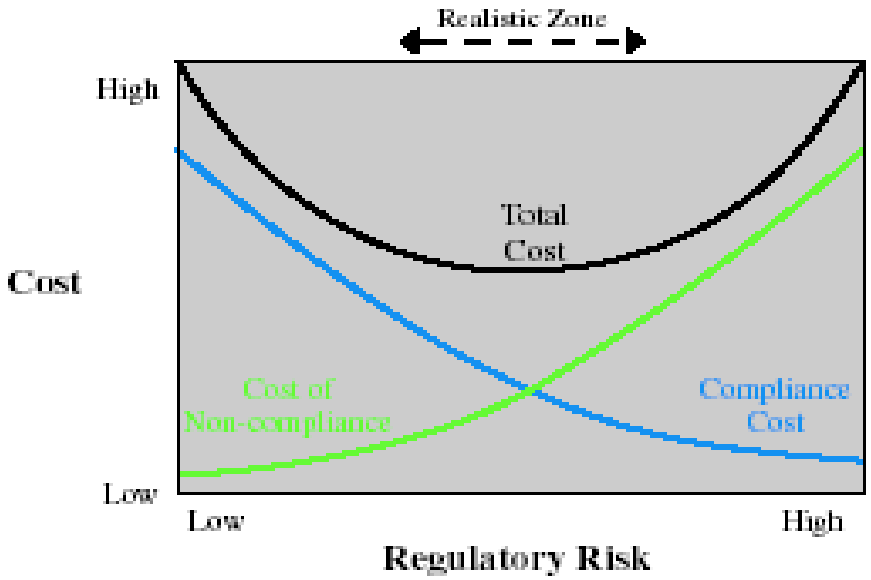


Figure 1 Source: FDA Compliance For The Life Sciences, Olin Thompson, August 2003.

Our regulatory support includes, but is not limited to:

- Pre-Approval Assistance, Mock PAI
- Warning Letter Reviews and Correction Planning
- Regulatory Guidance & Strategy
- Regulatory Guidance for CMO and CRO
- DDMAC

Can support a good regulatory program that inspects, audits, and oversees activities under current regulatory guidelines and processes. We will assist you in coordinating regulatory activities to meet the guidelines and requirements of the relevant regulatory bodies.

Regulatory Support Services

QAcal can help support a good regulatory program that inspects, audits, and oversees activities under current regulatory guidelines and processes.

We will assist you in coordinating your regulatory activities to meet the current governing guidelines.

Our Regulatory Support Services include:

- Support of Regulatory Submissions
- Strategic planning
- Due Diligence or Licensing Evaluation Projects
- Regulatory or Quality Strategic Evaluations (e.g., Assessment of strategic plans and recommendations)
- Support of FDA/EMEA meetings (I.e., pre-meeting preparations and meeting support)
- Review of INDs, NDAs, ANDAs, 505(b)(2)s, and supplements
- Assembly and Publication of Electronic Submissions
  - FDA and EMEA Submissions
  - Collection of Source documents in MS Word, Pdf, or Client-defined format
  - Assembly per eCTD or Client-defined Format
  - Hyperlinking
  - QC Verification
  - Final Publication Utilizing Electronic Publishing Tools
  - Submission to Regulatory Agencies
- Implementation and Validation of Electronic Publishing Solution
  - Development of Implementation and Validation Plans
  - IQ, OQ, PQ Protocol Development and Execution (Test Cases)
  - Authoring of Validation Report
  - Authoring of Operational SOPs
  - Training of System Users
- Regulatory support for clinical trials
- CMC and pre-clinical toxicology reviews
- Regulatory or Scientific Advisory Groups
- Regulatory Systems Design and Implementation (e.g., eCTD or Reg. Management systems)

4. Training Services

Whether you are a manufacturing firm, laboratory or a "virtual" company, appropriate GXP training must be developed and delivered in order for your firm to remain in compliance with FDA and other applicable regulations.
Regulatory agencies continue to cite firms for training deficiencies. Following are two examples of FDA 483 Observations highlighting such deficiencies:

"GMP Training is not conducted on a continuing basis and/or with sufficient frequency to assure employees remain familiar with cGMP requirements applicable to Them".
Employees are not given training in the particular operations they perform as part of their function, cGMPs, and/or written procedures required by cGMPs.

QAcal can help you remain in compliance with the following training services:

- Development of Corporate Training Systems - QAcal can assess your needs and assist in development and implementation of an effective and compliant corporate GXP training system. System(s) are designed to meet your specific needs and can be easily administered by your staff.
- Development and Delivery of Customized GXP Training Courses - Each training course can be tailored to fit your company's specific needs. Our knowledgeable trainers will work with you to create a curriculum that addresses the issues you and your employees face every day. Each course can be delivered on-site at your facility. In this way, your employees will benefit from these courses being taught in a familiar environment.

Custom Training: Your Perfect Fit

Each training course is designed to maximize the return on your investment by providing targeted, effective training solutions. We work diligently with you to design the training and to ensure the level of detail appropriate to your operations. At the same time, we ensure that you get quality instructor-student interaction with each course. This interaction allows the course instructor to answer more specific questions, in a confidential setting, and gives your employees the individual attention that makes our courses so effective.

Qualified Trainers: Industry-Leading Experts

QAcal Trainers are industry-leading subject matter experts. They speak from direct experience, and are therefore highly authoritative and credible. Their broad-based background allows them to develop and present highly relevant course content. Furthermore, QAcal's Trainers deliver courses in a professional, yet dynamic and interactive manner. You most certainly will not receive the "same old boring" reiteration of the regulations.

- QAcal provides customized training solutions, targeted specifically to your firm's needs.
- QAcal is fully focused on the development and timely delivery of the training solution(s), allowing your staff to continue work on their key priorities.
- QAcal trainers are knowledgeable industry-leading professionals who provide credible, authoritative, relevant, targeted training solutions based on experience and current industry practices.
- QAcal can provide training at your facility to reduce travel expenses and provide a confidential setting.

QAcal takes extra care to ensure we fully understand your training requirements before we propose a solution for you. We provide practical learning solutions, which work for you. Here is a sample listing of our training course topics.

Annual GMP/GLP/GCP Training
US & EU Regulations- Clinical and Commercial
Phase Appropriate Quality Systems
Roles & Responsibilities in a virtual Company
Management Responsibilities
Inspection Readiness Training/ Preparation of Inspection response Team

ICH GUIDELINES

- Q8- Pharmaceutical Development
- Q9- Quality Risk Management
- Q10- Pharmaceutical Quality System

FDA GUIDELINES

- Quality Systems Guidance
- Phase I GMPs Guidance
- OOS Investigation Guidance
- Aseptic Processing Guidance

QUALITY SYSTEM TOPICS

- Deviations/Investigations/CAPA
- Label Control Systems
- Change Control
- Auditing
- Quality Agreements
- Supplier Qualification
- Product Complaints
- Product Recalls
- Annual Product Reviews
- Batch Record Review
- Management Review
- Quality Manuals

OTHER TOPICS

- Validation
- Environmental Monitoring and QC
- SDLC (Software Development Life Cycle)
- Project Management
- Capital Project Management

5. Capital Project Management

With our Capital Project management experience QAcal can represent and guide our clients in the management and execution of Capital Projects that are critical to a company's success. Our mission is simple: to deliver successful projects with a high level of quality and efficiency within a regulatory environment. Our professional team has experience in projects ranging from small facility expansions to large Greenfield campus developments.

Provide all or any combination of the following in support of Capital Projects:

- Comprehensive project management
- Complete scheduling of project activities with ability to adapt to the evolving internal and external business environment
- Budget / cash flow / estimating
- Team identification, selection and development (external and internal)
- Specific project risk identification and management
- Communication management
- Contract management based on project specific primary and secondary contractor organization
- Project structure (contractual, team members, companies) and organization management
- Provide internal Executive Management project status reporting

Capital Project Management

At QAcal we truly become a part of your project team, we are your advocate and partner providing comprehensive services. We work closely with our client internal staff and all contracted service providers involved in the build process to ensure project success. The results are an integrated project team leading to effective communication, project planning, and project delivery. As required we supply clients with financial and scheduling updates providing complete visibility and control throughout the Capital Project process.

- Facilitate permits, licenses, local and state government engagements
- Design Reviews
- Engineering selection and management – P&IDs, specifications
- GC selection, contract negotiation and subcontractor selection
- Architect selection and management – drawings, specifications
- Equipment vendor selection and management – tax issues, payment schedule negotiation, change order review
- Internal stakeholder engagement and management
- Equipment and site inspections
- Project documentation management – submittals, RFIs, FATs, TOPs, VDRs
- Project start-up, commissioning and validation support

6. Staff Augmentation & Direct Hire Services

QAcal's Staffing Division offers qualified professionals for temporary or direct hire to support your internal needs. We can support a wide range of areas. Please call for details.

Do you need trained and capable staff members instead of a team of experts? Do you have gaps in project execution that can't be economically filled by a consultant? Are you too busy to recruit, qualify and manage temporary workers? Quality Compliance Partners, Inc. can help. We offer technical staffing solutions for short-term or long-term personnel assignments designed to meet your specific needs. Our associates work on site and re- port directly to your staff. Whether you need someone with substantial or minimal experience, QAcal has the resources to meet your project requirements.

Of course, you can interview and approve every individual we provide. All staff associates are thoroughly qualified by the professionals at QAcal

QAcal Staffing Services are perfect for companies that:

- Need qualified personnel to supplement your validation, quality, laboratory or engineering teams
- Have short term staffing needs to meet your project demands
- Are under a hiring freeze but still need qualified help

Let QAcal help fill the gaps in your quality, laboratory, engineering and validation projects.

Requesting a Proposal or Consultation

- Quality Compliance Proposals include:
  - Approach
  - Services
  - Required resources
  - Deliverables
  - Timelines
  - Cost

The Differences

At QAcal, our clients are our top priority.

Cost–Effective

At QAcal, we are committed to providing you with the most cost-effective, comprehensive compliance solutions available.

Value–added Service

We are dedicated to completely understanding your business goals and objectives and the industries in which your company competes. Drawing upon our extensive resources, our consultants are uniquely positioned to offer sound advice, bringing added value to our clients and their businesses.

Experience that Counts

QAcal and staff are dedicated to achieving the best possible solution for our clients. A keen understanding of how Regulatory Agencies operate at all levels, local, regional, state and federal, allows us to efficiently support our clients' issues.

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