

GVR SAI

R&D ENGINEERING LEADERS
Project & Program Management Experts
STRATEGY | SYSTEMS | TECHNOLOGY

GVR SAI Quality Assurance Statement

GVR SAI has expertise in areas of DoD, FDA, ISO, ICH, GxP, and CLIA Regulation. We have also extensive expertise in all aspects of data management, and resource management, Program, Project, Engineering and laboratory research – From Materials Specification to Device Design, Clinical Diagnostics, Sequencing, Micro arraying, High Throughput Screening, Cell Assay Automation, Methods Development and Environmental GLP and FDA compliance, to Systems Evaluation, Acquisition, Configuration, Validation for several areas of research.

We conduct workflow throughput analysis, new product and evaluation of scientific technology & Optical sample analysis, real-time flow measuring, pressure vessel & inert fluid flow path R&D of mirror finish (0-RMS) new “Inert Material”, Chemiluminescence tag technology Design & microprocessor controlled medical devices, nuclear power plant water safety systems, DOD, NAVSEA, Air Force on board test instrumentation.

We have experience in the conducting of Pre- Phase 0 and Phase I-IV clinical trials, for Immunogenicity, Virology, Emerging Pathogens, Pathology laboratories with emphasis in coordination of effort between subject, communities, clinic, hospital, laboratories and to distribution through complex, qualified, remote and satellite infrastructures for final analysis, cohort time points, iterative test result to end points statistical analysis.

GVR SAI philosophy and processes of CQI (Continuous Quality Initiative) provide a means by which a R&D regulated service can reach the highest level of operational distinction. In achieving these goals, we recommend a through definition, documentation and test qualification for equipment, validating procedures for test methods, unless otherwise, responsibility is client’s dedicated access and under client’s infrastructure management and approved use.

GVR SAI policy does not allow for perceived or estimated assumptions, unless otherwise built into statistical models designed to request or to be followed. Given this policy we are not responsible for any lack of information, response, or omission of important information leading to misunderstanding within contract vehicle, inclusive of business documents.

In the event of critical information change request we will not act on request unless proper guidelines and request for deviation is submitted by the appropriate and approved source. We will escalate and report issues thru appropriate channels to stake holders.

Out of Scope and Deferred Requirements

GVR SAI policy requires a documentation specification for change control, process control and OOS (Out Of Specification) procedure to be followed for all business transactions involving a pre-approved process.

Document SOP and Workflow will be developed to task order and available on request following contract award.

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Contractual and OQ (Operation Qualification), PQ (Procedure/Process Qualification) , for qualifying equipment and software validation procedures, methods, and reports will be generated and enforced for use unless otherwise furnished by Client Organization for dedicated access and under client(s) infrastructure management and approved use.

1. PROCESS DESCRIPTION

GVR SAI - Approach to Additional Cost Savings

GVR SAI for the purpose of fulfilling SEAPORT-e Task Order(s) under solicitation number N00178-10-R-4000 proposes and commits to the following:

- Screen, select and hire, qualified contractors delivering product, services and contracting personnel capable of understanding mission and delivering best long term value added to the program;
- Leverage labor category skills sets across various functional areas to meet TO (Task Order) requirements while maintaining cost effective savings and key qualified personnel for each and related functional areas;
- A TO approach to cost savings will be considered during the initial task order evaluation and audit. Findings and suggestions will be communicated to Seaport Personnel, PMO (Program Management Office) responsible for specific functional area TO for assessment and inclusion;
- Develop strategy to evaluate systems in use, define systems effectiveness, and enhance deficiencies, workflows and personnel training;
- Introduce state of the art risk assessment diagnostic tools, and methods, improve and implement scientific and defense systems interface, to enable real time data capture and analysis, initiate software development as well as new technology;
- Define process streamlining optimization, auditing for quality assurance programs review and update to capture new technology ease of validation;
- Providing business supply chain management expertise and initiate cost effective logistics models, services, and monitoring systems that will benefit SEAPORT-e;
- Given infrastructures complexities and security requirements develop initiatives to facilitate research secure communication and obtain Intellectual Property Secure LCM (Life Cycle Management) assurance;
- Develop effective methods for software & methods “Validation” and Hardware Systems components “Quality Control”;
- Provide engineering expert advance methods development and R&D for new materials, device research and R&D efforts.

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APPROACH TO QUALITY ASSURANCE



FIGURE -1 QUALITY & COMPLIANCE PROCESS

QUALITY ELEMENTS

GVR SAI will conduct a **Stage- I** – Audit Study an Assessment of Site, Test, and Define Test tools approach, Participants requirements, and test to results, analysis and diagnostics.

GVR SAI during **Stage-II-** wishes to improve the processes involved in creating customer satisfaction by implementing proven standardized quality system concepts or enhancing ones already established.

“Quality Improvement: Integrating Five Key Quality System Components is one of a series of NCCLS documents focused specifically on healthcare clinical service quality system management”. Accordingly, the quality system matrix of a healthcare service at one level should fit with the quality system matrix of the service at the next level—one organization level’s quality system merging with the other organizational level’s quality system.

There needs to be a fit, one service level’s quality system dovetailing with the next. Each quality system will consist of the same standard components—or quality system essentials—of policies, processes, and procedures.

The core array of policies, processes, and procedures of a quality system forms a grouping of 12 quality system essentials (QSEs). These 12 QSEs are the most fundamental managerial activities that are universally important for supporting any healthcare service operational path of workflow. The QSEs form the infrastructural framework necessary for the delivery of any type of product or service—they incorporate all managerial resources by which any service performs its operational work. The 12 QSEs are:

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QUALITY SYSTEMS COMPONENTS

- Documents & Records
- Equipment
- Information Management
- Process Improvement
- Organization
- Purchasing & Inventory
- Occurrence Management
- Service & Satisfaction
- Personnel
- Process Control
- Assessment
- Facilities & Safety

QUALITY ACTION MONITORING

GVR SAI will map all the QSE's (Quality Systems Essentials) aspects necessary to integrate quality throughout the business model and processes for a ready to deploy, transfer, replicate, and retire or expand, and upgrade system.

Following the referenced TABLE 1 - Quality Systems Essential Matrix, Quality Systems Management Guidelines correlate and can be cross reference to ISO 15189 (International Organization for Standardization) documents: *Medical laboratories: Particular requirements for quality and competence*.

TABLE 1 – The 12 Quality Systems Essential MATRIX

QUALITY SYSTEMS ESSENTIALS MATRIX											
DOCUMENTS & RECORDS	ORGANIZATION	PERSONNEL	EQUIPMENT	PURCHASING & INVENTORY	PROCESS CONTROL	INFORMATION MANAGEMENT	OCCURRENCE MANAGEMENT	ASSESSMENT	PROCESS IMPROVEMENT	SERVICES & SATISFACTION	FACILITIES & SAFETY
	X	X						X	X		

(Adapted from NCCLS Document HS1 A Quality Management System for Health Care)

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The four QSEs and their five CQI components function sequentially, as follows:

- QSE: Organization: **Quality Planning component; Stage -I-**
- QSE: Personnel: Quality Teamwork component; **Stage -II-**
- QSE: Assessment: Quality Monitoring component; **Stage -III-**
- QSE: Process Improvement: Quality Improvement component; and
 - QSE: Organization: Quality Review component; **Stage -III-**

GVR SAI will implement guidance from regulatory agencies governing Business Units, Commands into Task Order. We will develop a plan and approach to compliance and risk assessment & analysis that includes test, monitoring and reporting over the Quality Essential Matrix components accordingly, following ISO, IEEE, DoD, FDA or any other agency requirements and mandate.