



QUALITY MANAGEMENT SYSTEM MANUAL

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QUALITY POLICY STATEMENT

Global Strategic Solutions, LLC, a sole-member LLC, is committed to consistently providing products and services that meet or exceed customer requirements and applicable statutory and regulatory requirements. GSS will achieve this through:

1. Establishing and pursuing measurable quality objectives aligned with our strategic direction
2. Fostering a culture of continuous improvement across all processes and functions
3. Applying risk-based thinking to prevent defects, nonconformities, and customer dissatisfaction
4. Engaging all personnel in the understanding and application of quality management principles
5. Maintaining a Quality Management System that satisfies the requirements of ISO 9001:2015

This policy is communicated to all personnel, reviewed annually, and available to interested parties upon request. It is posted on the Global Strategic Solutions, LLC website: <https://globalstrategicsolutions.com/>

David R Rutledge, Pharm.D., FCCP, FAHA

Chief Executive Officer & Founder

Signed: *David R Rutledge*

Date: August 9, 2026 09-Aug-2026

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1 — SCOPE

This Quality Management System Manual defines the scope, structure, and operation of the Quality Management System of Global Strategic Solutions established in conformance with the applicable requirements of ISO 9001:2015.

1.1 Scope of the QMS

Global Strategic Solutions, LLC (GSS), a sole-member LLC, has determined the scope of its Quality Management System (QMS) to include the provision of global regulatory consulting, quality management system advisory services, regulatory and quality management system training, internal auditing services, and regulatory strategy support for medical technology, medical device, and life sciences organizations.

The GSS QMS applies to the design, development, planning, and delivery of applicable consulting and professional training services. All requirements of ISO 9001:2015 apply to the organization.

Scope: Applies to the provision of global regulatory consulting, quality system advisory services, regulatory, quality, and clinical training, internal auditing services, and regulatory strategy support for medical technology, medical device, and life sciences organizations.

Location: 1631 Mercy Street, Mountain View, CA 94041

ISO 9001:2015 Certification Scope: Medical Technology, Medical Device, and Life Sciences Organizations

ISO 9001:2015 Service Description: The table below provides examples of GSS's potential outputs in terms of products or services.



Global Strategic Solutions Outputs: Potential Products or Services

GSS Output	Product or Service
GAP Assessment Report	Product
Training Slide Deck	Product
CAPA Readiness Checklist	Product
Audit Checklist	Product
Regulatory Strategy Report	Product
Customized Training Course	Service + Product
Live Training Delivery	Service
Regulatory Consulting	Service
Internal Audit Engagement	Service

1.2 Permitted Exclusions

Global Strategic Solutions, LLC has determined that all ISO 9001:2015 clauses are within its scope and context.

Clause	Clause Title	Justification for Exclusion
N/A	N/A	N/A

2 — CONTEXT OF THE ORGANIZATION

4.1 Understanding the Organization and Its Context (ISO 9001:2015 Cl. 4.1)

Global Strategic Solutions, LLC has identified internal and external issues relevant to its purpose and strategic direction that affect its ability to achieve the intended results of its QMS. This analysis is reviewed annually as part of the Management Review process (QMS-PRO-09).

Issue Type	Issue Description	Relevance to GSS QMS	Review Frequency
External – Regulatory	Frequent changes to US FDA, EU, ISO, and international regulatory and quality requirements	Requires current regulatory knowledge and timely revision of consulting and training outputs	Ongoing: Formally at Management Review
External – Market	Increased demand for specialized regulatory, QMS, audit, and professional training services	Influences GSS service offerings, competence priorities, and quality objectives	Annual
External – Customer	Customers require accurate, practical, timely, and defensible regulatory and quality advice	Directly affects service planning, contract review, deliverable review, and customer satisfaction	Ongoing
External – Technology	Rapid adoption of Artificial Intelligence (AI), digital tools,	Creates opportunities for efficiency but introduces risks	Annual and Upon Significant Change

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	virtual training, and cloud-based collaboration	involving accuracy, confidentiality, and output verification	
External – Economic	Changes in client budgets, consulting demand, and life sciences investment	May affect project volume, resource availability, pricing, and business continuity	Annual
External – Climate Change	Climate-related events may affect travel, virtual delivery, infrastructure, client operations, or continuity of service	Requires determination of relevance and consideration of applicable interested-party requirements	Annual
Internal – Organizational Structure	GSS operates as a sole-member LLC with key activities performed by the CEO and Founder	Creates key-person dependency and requires effective knowledge, record, and continuity controls	Annual
Internal – Competence	GSS services depend heavily on current regulatory, clinical, auditing, and quality management expertise	Requires maintenance of competence and continuing professional development	Annual
Internal – Process	Consulting and training services are frequently customized to specific client needs	Requires effective requirements review, design and development, review, and control of changes	Ongoing: Formally at Management Review
Internal – Technology	GSS relies on Microsoft 365, SharePoint/OneDrive, virtual meeting platforms, and other digital tools	System availability, cybersecurity, confidentiality, and document control can affect QMS effectiveness	Annual
Internal – Knowledge	Significant organizational knowledge is based on the professional expertise and experience of the CEO and Founder	Requires preservation of organizational knowledge and documented methods to support continuity	Annual

Relevant internal and external issues are evaluated for associated risks and opportunities in accordance with the GSS Risk and Opportunity Management process. Significant changes are considered during the Management Review and may affect QMS processes, quality objectives, resources, or strategic priorities. This creates a clear GSS internal audit trail:

4.1 Context → 6.1 Risk and Opportunity → 6.2 Objectives → 9.3 Management Review

3 — CLIMATE CHANGE CONSIDERATIONS (ISO 9001:2015/AMD 1:2024)

In February 2024, ISO published Amendment 1:2024 (Climate Action Changes) to ISO 9001:2015. This amendment became effective immediately upon publication with no transition period. It adds a mandatory requirement to Clause 4.1 and an explanatory note to Clause 4.2. Global Strategic Solutions, LLC complies with this amendment as follows.

Clause 4.1 — Climate Change as an External Issue

In accordance with ISO 9001:2015/Amd 1:2024, Global Strategic Solutions, LLC has determined whether climate change is a relevant issue to its Quality Management System. This determination is documented in the Climate Change Relevance Assessment (QMS-FRM-01) and reviewed as part of the annual context analysis under QMS-PRO-01. Climate change is explicitly considered as an external issue in the



organization's context analysis, alongside the political, economic, social, technological, legal, and environmental factors already assessed through the PESTLE framework.

The assessment considers, where relevant to Global Strategic Solutions, LLC's operations: physical climate risks (extreme weather events affecting facilities, supply chain disruption, resource and raw material scarcity); transition risks (changing environmental regulations, carbon pricing, customer and market expectations for sustainability); and climate-related opportunities (enhanced reputation, access to environmentally conscious markets, operational resilience). Where Global Strategic Solutions, LLC concludes, after a reasoned assessment, that climate change is not a relevant issue to a specific process or to the QMS as a whole, that conclusion is documented with supporting rationale – the standard requires evidence that the assessment was made, not that action is taken on an irrelevant risk.

In summary, GSS determines whether climate change is a relevant issue affecting its ability to achieve the QMS's intended results. Potential impacts include business continuity, travel disruption, technology infrastructure, customer requirements, and changes in regulatory or market expectations. The relevance of climate change is reviewed as part of the organization's context analysis and Management Review.

4.2 Understanding the Needs and Expectations of Interested Parties (ISO 9001:2015 Cl. 4.2)

Global Strategic Solutions, LLC has identified the interested parties relevant to its Quality Management System and the requirements of those interested parties relevant to the QMS. GSS monitors and reviews information concerning these interested parties and their relevant requirements. Changes in relevant interested-party requirements are considered during Management Review and, where applicable, are evaluated through the Risk and Opportunity Management process.

Interested Party	Key Requirements / Expectations	How Addressed in GSS QMS
Consulting Clients	Accurate, practical, timely, confidential, and defensible regulatory and quality services; fulfillment of contractual requirements	Customer requirements and contract review; project planning; deliverable review; customer feedback
Training Clients and Learners	Accurate, current, engaging, and applicable training content; effective course delivery	Training design and development controls; content review; competence; learner and client feedback
Contracting and Training Organizations, e.g., notified body	Reliable delivery, qualified instructors/consultants, contractual compliance, timely communication, and protection of client relationships	Contract review; competence records; communication controls; service performance monitoring
Regulatory Authorities	Accurate interpretation and application of applicable statutory and regulatory requirements	Regulatory intelligence; competence maintenance; document and deliverable review
Standards and Accreditation Community	Appropriate application of applicable standards and current technical requirements	Standards monitoring; continuing professional development; controlled QMS updates
Certification Body	Objective evidence of QMS implementation, conformity, effectiveness, and continual improvement	Documented information; internal audit; management review; corrective action
External Providers and Subject-Matter Experts	Clear requirements, defined responsibilities, appropriate communication, and timely payment	External provider selection and control; contractual requirements; performance monitoring
GSS Owner and Top Management	Sustainable business performance, protection of reputation, effective risk management, customer satisfaction, and achievement of strategic objectives	Quality objectives; risk and opportunity management; KPI monitoring; management review
Technology and Cloud	Appropriate use of services, licensing	Technology controls; access

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Service Providers	compliance, account security, and adherence to service terms	management; document control; business continuity planning	
Professional and Industry Organizations	Ethical conduct, professional competence, and compliance with applicable membership or professional expectations	Professional development; competence records; ethical business practices	

Clause 4.2 — Interested Parties and Climate Change

In accordance with the note added to Clause 4.2 by Amendment 1:2024, Global Strategic Solutions, LLC recognizes that relevant interested parties can have requirements related to climate change. When determining the needs and expectations of interested parties (documented in the Interested Party Register, QMS-FRM-01), Global Strategic Solutions, LLC considers whether each relevant party — including customers, regulators, GSS Owner and Top Management, the local community, and suppliers — has climate-related requirements or expectations that could affect the QMS. Examples include customers requiring evidence of sustainable practices, regulators imposing emissions or environmental reporting obligations, and customers or contracting organizations establishing climate-related or sustainability expectations. Where such requirements are identified as relevant, they are recorded in the Interested Party Register and addressed within the QMS.

Note: The addition to Clause 4.2 is a NOTE within the standard. Notes guide understanding a requirement and are not themselves auditable requirements. However, the underlying Clause 4.2 requirement — to determine the requirements of relevant interested parties — remains fully auditable, and climate-related requirements are considered within that determination where relevant.

Clause 4.3 — Determining the Scope of the QMS (ISO 9001:2015 Cl. 4.3)

Global Strategic Solutions, LLC has determined the boundaries and applicability of its Quality Management System. The scope of the QMS is documented in Clause 1.1 of this manual.

In determining the scope of the QMS, GSS considers:

- i. The external and internal issues identified in accordance with Clause 4.1;
- ii. The relevant requirements of interested parties identified in accordance with Clause 4.2;
- iii. The products and services provided by GSS;
- iv. The nature of GSS consulting, training, auditing, and regulatory support activities; and
- v. The organizational, operational, and geographic boundaries applicable to the QMS.

GSS has determined that all requirements of ISO 9001:2015 are applicable within the defined scope of the Quality Management System. No ISO 9001:2015 requirements have been determined to be not applicable. The QMS scope is maintained as documented information and is available to relevant interested parties. The continuing suitability of the scope is reviewed during Management Review and when significant changes occur to GSS services, organizational context, business activities, or applicable requirements. Changes to the QMS scope are evaluated and controlled through the GSS Change Management process and communicated to the certification body when applicable.

This creates a clear GSS internal audit trail:

4.1 Context + 4.2 Interested Parties → 4.3 Scope → 6.3 Change Management →
9.3 Management Review

4.4 — QMS and Its Processes (ISO 9001:2015 Cl. 4.4)

Global Strategic Solutions, LLC has established, implemented, maintains, and continually improves a Quality Management System, including the processes needed and their interactions, in accordance with the requirements of ISO 9001:2015.



GSS applies a process-based approach to the planning, design, development, delivery, monitoring, and improvement of its consulting, training, auditing, and regulatory support services.

For applicable QMS processes, GSS determines:

- i. Required inputs and expected outputs;
- ii. The sequence and interaction of processes;
- iii. Criteria, methods, monitoring, measurements, and performance indicators needed to ensure effective operation and control;
- iv. Resources required and their availability;
- v. Responsibilities and authorities;
- vi. Risks and opportunities requiring action;
- vii. Methods for evaluating process performance and implementing necessary changes; and
- viii. Opportunities for improvement of the processes and the QMS.

The interaction of key GSS QMS processes is summarized in the following Process Interaction Matrix.

Process	Key Inputs	Key Outputs	Monitoring / Measure	Reference Document
Context, Strategy & QMS Planning	Internal/external issues; interested-party requirements; risks and opportunities	QMS scope; quality objectives; risk and opportunity actions	Objective achievement; risk action status	QMS-PRO-01, QMS-PRO-02
Customer Inquiry & Requirements Review	Customer inquiry; RFP; proposed scope; customer requirements	Accepted requirements; proposal; contract or engagement scope	Requirements review completion; customer acceptance	QMS-PRO-05
Service Design & Development	Customer requirements; regulatory requirements; standards; technical knowledge	Training materials; reports; checklists; audit tools; consulting deliverables	Review completion; identified revisions; verification/validation status	QMS-SOP-04
Project & Service Planning	Approved scope; deliverables; schedule; customer requirements	Project or training plan; milestones; resource requirements	Milestone status; schedule performance	QMS-SOP-01
Consulting, Training & Audit Service Delivery	Approved plans; controlled materials; competent resources	Consulting services; training delivery; audit activities; regulatory support	On-time delivery (OTD); service performance; customer feedback	QMS-SOP-01
Deliverable Review & Release	Draft report, slide deck, checklist, audit report, or other deliverable	Reviewed and authorized GSS output	Review completion; corrections identified before release	QMS-SOP-02
External Provider Control	Service requirements; competence needs; external provider requirements	Approved and monitored external services	Provider performance; conformity with requirements	QMS-PRO-06
Customer Feedback & Issue Management	Customer feedback; complaints; service concerns	Corrections; responses; nonconformity or corrective action, when applicable	Customer satisfaction; issue resolution; recurrence	QMS-PRO-07
Performance Evaluation &	KPIs; customer feedback; audit	Improvement actions; corrective actions;	KPI trends; action closure; QMS	QMS-PRO-08; QMS-PRO-09

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Improvement	results; nonconformities; risk status	management decisions	effectiveness	

GSS QMS processes operate as an integrated system. Customer and interested-party requirements provide inputs to planning and service realization processes. Service outputs and customer feedback inform performance evaluation, risk management, internal audit, and Management Review. Decisions and improvement actions resulting from performance evaluation are used to improve GSS processes and services.

The general sequence and interaction of GSS processes is:

Context & Interested Parties → QMS Planning → Customer Requirements → Service Design and Planning → Service Delivery → Deliverable Review and Release → Customer Feedback → Performance Evaluation → Management Review → Continual Improvement

Risk-based thinking, competence, documented information, external provider control, and organizational knowledge support applicable processes throughout the QMS.

GSS maintains documented information necessary to support the operation of its processes and retains documented information necessary to provide confidence that processes are carried out as planned.

The GSS value stream:

Someone needs regulatory or quality help → GSS understands the need → designs the solution → plans the engagement → delivers the work → reviews the output → gets feedback → learns and improves.

CLAUSE 5 — LEADERSHIP

5.1 Leadership and Commitment (ISO 9001:2015 Cl. 5.1)

David R Rutledge, CEO & Founder of Global Strategic Solutions, LLC, demonstrates leadership and commitment to the QMS by:

- i. Taking accountability for the effectiveness of the QMS
- ii. Ensuring quality policy and quality objectives are established and compatible with the context and strategic direction
- iii. Ensuring integration of QMS requirements into business processes
- iv. Promoting the use of the process approach and risk-based thinking
- v. Ensuring the necessary resources for the QMS are made available
- vi. Communicating the importance of effective quality management and conformance to QMS requirements
- vii. Ensuring the QMS achieves its intended results through active participation in management reviews
- viii. Engaging, directing, and supporting persons to contribute to the QMS
- ix. Promoting improvement and supporting other relevant roles



5.1.2 Customer Focus (ISO 9001:2015 Cl. 5.1.2)

David R Rutledge, Top Management, ensures that:

- i. Customer requirements and applicable statutory and regulatory requirements are determined, understood, and consistently met
- ii. Risks and opportunities that can affect conformity of products and services are identified and addressed
- iii. Focus on consistently enhancing customer satisfaction is maintained across all functions

5.2 Quality Policy (ISO 9001:2015 Cl. 5.2)

The Quality Policy is documented at the beginning of this manual. David R Rutledge ensures the Quality Policy:

- i. Is appropriate to the purpose and context of the organization and supports its strategic direction
- ii. Provides a framework for setting quality objectives
- iii. Includes a commitment to satisfy applicable requirements
- iv. Includes a commitment to continual improvement of the QMS

The Quality Policy is maintained as documented information (this manual), communicated, understood, and applied within the organization, and available to relevant interested parties.

5.3 Organizational Roles, Responsibilities, and Authorities (ISO 9001:2015 Cl. 5.3)

Global Strategic Solutions, LLC operates as a sole-member limited liability company. The CEO and Founder serves as Top Management and retains overall accountability for the effectiveness of the Quality Management System.

GSS assigns responsibilities and authorities based on QMS processes and activities rather than maintaining artificial departmental management positions. Responsibilities may be performed by the CEO and Founder or, where appropriate, by qualified external providers, subject-matter experts, or contracted personnel operating under GSS control.

Top Management ensures that responsibilities and authorities for relevant QMS activities are assigned, communicated, and understood. The following summarises key QMS responsibilities:

Role	Assigned To	Key Responsibilities
Top Management	CEO & Founder	Accountability for QMS effectiveness; strategic direction; Quality Policy; quality objectives; resources; Management Review
QMS Administration & Document Control	CEO & Founder	Maintain QMS documented information; document approval and change control; Master Document Register
Customer Requirements & Engagement Planning	CEO & Founder	Review customer requirements; define scope; confirm commitments; plan consulting, training, and audit engagements
Service Design & Development	CEO & Founder and/or Qualified Subject-Matter Expert	Develop and review training materials, consulting deliverables, audit tools, regulatory strategies, and other GSS outputs
Service Delivery & Deliverable Release	CEO & Founder and/or Qualified Personnel	Deliver services; verify completion of planned activities; review and authorize deliverables before release
External Provider Control	CEO & Founder	Select, evaluate, approve, and monitor external providers and subject-matter experts
QMS Performance &	CEO & Founder	Monitor KPIs, customer feedback, risks and opportunities, nonconformities, corrective actions, and improvement

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Improvement		activities
Internal Audit	Qualified Independent Internal Auditor	Conduct objective internal audits in accordance with the GSS Internal Audit Procedure and report results to Top Management

Due to GSS's size and organizational structure, a single individual may assume multiple QMS responsibilities. GSS manages potential conflicts of interest through defined review controls, documented evidence, and the use of qualified independent personnel where objectivity or impartiality is required.

Internal auditors shall be selected and audits conducted to ensure objectivity and impartiality of the audit process. GSS will use a qualified independent internal auditor for activities where self-audit would compromise audit objectivity.

Top Management remains accountable for ensuring that:

- i. The QMS conforms to the requirements of ISO 9001:2015;
- ii. QMS processes deliver their intended outputs;
- iii. QMS performance and opportunities for improvement are reported and reviewed;
- iv. Customer focus is promoted throughout GSS activities; and
- v. The integrity of the QMS is maintained when changes are planned and implemented.

CLAUSE 6 — PLANNING

6.1 Actions to Address Risks and Opportunities (ISO 9001:2015 Cl. 6.1)

When planning the QMS, Global Strategic Solutions, LLC considers internal and external issues (Cl. 4.1) and interested party requirements (Cl. 4.2) to identify risks and opportunities to be addressed. The organization applies risk-based thinking throughout the PDCA cycle.

Risks and opportunities are identified, analyzed, evaluated, and treated in accordance with QMS-PRO-02 (Risk & Opportunity Management Procedure) and recorded in QMS-RRP-01 (Risk & Opportunity Register).

Risk treatment actions are: integrated into QMS processes; assigned to process owners; monitored for effectiveness; reviewed at each Management Review.

6.2 Quality Objectives and Planning to Achieve Them (ISO 9001:2015 Cl. 6.2)

Global Strategic Solutions, LLC establishes measurable quality objectives at relevant functions, levels, and processes of the Quality Management System. Quality objectives are aligned with the GSS Quality Policy, strategic direction, organizational context, customer requirements, and identified risks and opportunities. Quality objectives are monitored using defined performance indicators and reviewed at planned intervals and during Management Review. GSS determines what will be done, the resources required, responsibility for achieving each objective, the planned completion or review timeframe, and how results will be evaluated.

Quality objectives and associated performance results are maintained in QMS-KPI-01, Quality Objectives and KPI Tracker.

Quality Objective	KPI / Measure	Proposed Target	Frequency
Enhance customer satisfaction	Average customer/client satisfaction score (1–10 scale)	≥ 9.0/10	Quarterly
Deliver services as committed	Engagements delivered by agreed	≥ 95%	Quarterly



	date or approved revised date		
Ensure quality of GSS deliverables	Deliverables requiring substantive correction after customer release	≤ 5%	Quarterly
Maintain current professional and regulatory competence	Planned professional development and regulatory intelligence activities completed	100%	Semiannual
Respond effectively to customer concerns	Customer concerns acknowledged within 2 business days	≥ 95%	Quarterly
Maintain QMS effectiveness	Planned internal audit and Management Review activities completed	100%	Annual
Drive continual improvement	Documented QMS or service improvement actions implemented	≥ 3/year	Annual

Performance against quality objectives is evaluated using available objective evidence. Where a quality objective is not achieved, Top Management evaluates the cause, associated risks and opportunities, and the need for correction, corrective action, resource changes, or revision of the objective.

Quality objectives may be added, revised, or retired when changes occur in GSS strategic direction, services, customer requirements, applicable requirements, organizational context, or identified risks and opportunities.

This creates the following GSS audit trail:

4.1 Context + 4.2 Interested Parties → 6.1 Risks and Opportunities → 6.2 Quality Objectives → 9.1 Performance Evaluation → 9.3 Management Review → 10.3 Continual Improvement

6.3 Planning of Changes (ISO 9001:2015 Cl. 6.3)

When Global Strategic Solutions, LLC determines the need for a change to the QMS, the change is carried out in a planned manner in accordance with QMS-SOP-06 (Change Management SOP). All changes consider: the purpose of the change and its potential consequences; the integrity of the QMS; the availability of resources; the allocation or reallocation of responsibilities and authorities.

CLAUSE 7 — SUPPORT

7.1 Resources (ISO 9001:2015 Cl. 7.1)

Global Strategic Solutions, LLC determines and provides the resources necessary for establishing, implementing, maintaining, and continually improving the Quality Management System, as well as for the effective delivery of consulting, training, auditing, and regulatory support services.

In determining resource needs, GSS considers existing internal capabilities and constraints and determines when qualified external providers, subject-matter experts, technology resources, or other support are necessary.

7.1.2 People (ISO 9001:2015 Cl. 7.1.2)

GSS determines and provides the personnel necessary for the effective implementation of the QMS and for the operation and control of its processes. Due to GSS's sole-member structure, activities may be performed by the CEO and Founder or by qualified external providers, subject-matter experts, or contracted personnel operating under GSS's control.



7.1.3 Infrastructure (ISO 9001:2015 Cl. 7.1.3)

GSS determines, provides, and maintains the infrastructure necessary for the operation of its processes and for the conformity of its products and services. Applicable infrastructure includes computer hardware, internet and telecommunications services, Microsoft 365 and SharePoint/OneDrive, virtual meeting and training platforms, regulatory and standards information resources, and other digital tools used to develop, control, review, and deliver GSS outputs.

Infrastructure availability and associated risks are considered through the Risk and Opportunity Management and business continuity processes.

7.1.4 Environment for the Operation of Processes (ISO 9001:2015 Cl. 7.1.4)

GSS determines and manages the environment necessary for the operation of its processes and achievement of conforming products and services. GSS activities are primarily professional, knowledge-based, and digitally enabled.

Relevant factors may include an appropriate professional work environment, confidentiality, freedom from avoidable distractions, reliable access to technology, professional and ethical conduct, and conditions that support effective virtual or in-person consulting, auditing, and training activities.

7.1.5 Monitoring and Measuring Resources (ISO 9001:2015 Cl. 7.1.5)

GSS determines the monitoring and measuring resources needed to provide valid and reliable results when monitoring or measurement is used to verify conformity of products or services.

GSS does not currently use physical measuring equipment that requires calibration or metrological traceability to verify the conformity of its consulting, training, auditing, or regulatory support services.

GSS uses appropriate monitoring and evaluation methods, including customer feedback, KPI data, deliverable review records, training evaluations, audit results, and other documented evidence, to evaluate service and QMS performance. Applicable monitoring and measuring resources may include regulatory intelligence tools, controlled checklists, templates, rubrics, survey instruments, and other resources used to evaluate conformity of GSS products, services, or QMS processes. Such resources are maintained and periodically evaluated for continuing suitability and fitness for their intended purpose.

If GSS introduces monitoring or measuring equipment requiring calibration, verification, or metrological traceability, appropriate controls will be established before use.

7.1.6 Organizational Knowledge (ISO 9001:2015 Cl. 7.1.6)

Global Strategic Solutions, LLC determines the organizational knowledge necessary for the operation of its processes and for achieving conformity of its products and services.

GSS organizational knowledge includes regulatory and quality management expertise, clinical and medical device knowledge, auditing methods, training methods, customer and project experience, lessons learned, and knowledge of applicable statutory, regulatory, and standards requirements.

Organizational knowledge is maintained and made available, as appropriate, through controlled QMS documented information, regulatory intelligence activities, professional development, project and training records, reusable tools and templates, lessons learned, and retained reference materials.

GSS considers current knowledge and determines how to acquire or access additional knowledge when addressing changing needs, emerging regulatory requirements, new standards, technologies, or customer requirements.



7.2 Competence (ISO 9001:2015 Cl. 7.2)

GSS determines the necessary competence of persons performing work under its control that affects QMS performance and the conformity of products and services.

Competence is based on appropriate education, training, professional qualifications, skills, and experience. Where external providers, subject-matter experts, or contracted personnel perform work affecting GSS outputs, GSS evaluates their competence before assignment.

GSS takes action, where applicable, to acquire necessary competence and evaluates the effectiveness of those actions. Appropriate documented information is retained as evidence of competence.

7.3 Awareness (ISO 9001:2015 Cl. 7.3)

Persons performing work under GSS control are made aware, as applicable, of the GSS Quality Policy, relevant quality objectives, their contribution to QMS effectiveness and improved performance, and the implications of not conforming to QMS requirements.

Awareness may be established through direct communication, engagement planning, review of applicable QMS requirements, contractual communication, or other methods appropriate to the person's role and assigned activities.

7.4 Communication (ISO 9001:2015 Cl. 7.4)

Global Strategic Solutions, LLC determines the internal and external communications relevant to the Quality Management System, including what will be communicated, when communication will occur, with whom communication will occur, how communication will be conducted, and responsibility for communication.

QMS communications may include customer requirements and engagement changes, Quality Policy and quality objectives, QMS performance and improvement activities, internal and external audit results, Management Review decisions, regulatory and standards changes, external provider requirements, and customer feedback or concerns.

Communication methods may include email, telephone, virtual or in-person meetings, controlled documented information, project records, audit reports, training materials, and other methods appropriate to the nature and significance of the communication.

The CEO and Founder retains overall responsibility for ensuring relevant QMS communications are timely, accurate, and appropriately documented.

Communication	What	When	With Whom	Communication Methods
Quality Policy	Policy statement and objectives	Induction + annual refresh	Relevant Personnel and Interested Parties when requested	Induction, email
Management Review Outcomes	Decisions, actions, and improvement initiatives	After each Management Review, usually within 30 working days	Relevant Functions	Meeting minutes, email
Internal Audit Results	Findings, Nonconformities (NCs), and corrective actions	Within 10 working days of audit	Auditees and Top Management	Audit report, CAPA log
Customer Communication	Requirements, changes, complaints, satisfaction	As required	Customers	Email, telephone, meetings
Regulatory / Compliance	Changes in applicable	Within 30 working	Relevant	Briefing,

 GLOBAL STRATEGIC SOLUTIONS		Global Strategic Solutions, LLC QMS-MAN-01 Rev 1.0 August 9, 2026		
Updates	law or standards	days or sooner based on effective date, significance, or impact	Personnel	procedure update

7.5 Documented Information (ISO 9001:2015 Cl. 7.5)

The QMS includes documented information required by ISO 9001:2015 and deemed necessary for the QMS's effectiveness. Document creation, review, approval, version control, distribution, retention, and disposal are governed by QMS-PRO-03 (Document & Records Control Procedure).

The complete list of QMS documented information is maintained in QMS-MDR-01 (Master Document Register & Document Tree).

CLAUSE 8 — OPERATION

8.1 Operational Planning and Control (ISO 9001:2015 Cl. 8.1)

Global Strategic Solutions, LLC plans, implements, and controls the processes necessary to meet requirements for its consulting, training, auditing, and regulatory support products and services.

Operational planning is proportionate to the nature, complexity, risk, and customer requirements of the engagement. GSS determines applicable customer, statutory, regulatory, standards, contractual, and technical requirements; establishes criteria for processes and deliverables; determines necessary resources and competence; implements appropriate review and control activities; and retains documented information necessary to provide confidence that activities have been performed as planned.

Planned changes are controlled, and unintended changes are reviewed to determine potential consequences and necessary actions.

Externally provided activities affecting GSS products or services are controlled in accordance with applicable QMS requirements.

8.2 Requirements for Products and Services (ISO 9001:2015 Cl. 8.2)

GSS communicates with customers regarding service information, inquiries, proposals, engagement requirements, changes, customer feedback, concerns, and complaints.

Before accepting an engagement, GSS determines applicable customer requirements, intended deliverables, schedules, statutory and regulatory requirements, applicable standards or technical criteria, confidentiality requirements, and other requirements necessary for successful delivery.

GSS reviews requirements before committing to provide products or services to ensure that requirements are defined, differences are resolved, and GSS has the capability and resources necessary to fulfill the engagement.

Changes to customer or engagement requirements are reviewed, documented as appropriate, and communicated to relevant persons.

8.3 Design and Development (ISO 9001:2015 Cl. 8.3)

GSS plans and controls the design and development of applicable consulting, training, auditing, and regulatory support products and services.

Design and development activities may apply to customized training courses, slide decks, regulatory strategy reports, gap assessment reports, audit tools, checklists, assessment methods, and other customer-specific deliverables.



GSS determines appropriate design and development stages and controls based on the nature, duration, complexity, intended use, and risk associated with the output.

Design and development inputs may include customer requirements, contractual requirements, statutory and regulatory requirements, applicable standards, guidance documents, technical and clinical information, prior experience, lessons learned, and other relevant knowledge.

Design and development outputs are reviewed to ensure they meet applicable input requirements and are suitable for their intended use.

Review, verification, and validation activities are performed as appropriate to the nature and risk of the product or service. Changes are identified, reviewed, and controlled to prevent adverse effects on conformity.

8.4 Control of Externally Provided Processes, Products and Services (ISO 9001:2015 Cl. 8.4)

GSS ensures that externally provided processes, products, and services that affect QMS performance or the conformity of GSS outputs conform to applicable requirements.

External providers may include subject-matter experts, contracted consultants, technology and cloud service providers, professional service providers, training support resources, and other organizations or individuals whose outputs may affect GSS products or services.

GSS determines the type and extent of control applied to external providers based on the potential impact of the processes, products, or services they provide.

External providers are selected and evaluated based on applicable criteria such as competence, experience, qualifications, technical capability, reliability, confidentiality, service performance, and ability to meet specified requirements.

GSS communicates applicable requirements to external providers and monitors performance as appropriate.

8.5 Production and Service Provision (ISO 9001:2015 Cl. 8.5)

GSS performs consulting, training, auditing, and regulatory support activities under controlled conditions appropriate to the nature of the engagement.

Controlled conditions may include:

- i. Availability of documented information defining customer requirements, engagement scope, intended deliverables, and applicable acceptance criteria;
- ii. Use of suitable infrastructure, technology, controlled information, and reference resources;
- iii. Assignment of competent persons;
- iv. Implementation of appropriate review, monitoring, verification, or validation activities;
- v. Prevention of human error through review, checklists, templates, peer or subject-matter review, and other appropriate controls;
- vi. Appropriate control of customer property and confidential information;
- vii. Identification and control of engagement records and deliverables; and
- viii. Appropriate post-delivery activities, including customer support, correction of identified errors, clarification of deliverables, and response to customer feedback or concerns.

GSS preserves products and documented outputs during internal processing and delivery to the extent necessary to ensure conformity with requirements.

Customer or external-provider property under GSS control is identified, protected, and safeguarded as appropriate. Loss, damage, unauthorized disclosure, or other conditions affecting customer or external-provider property are communicated to the applicable party and documented as appropriate.



Changes affecting service provision are reviewed and controlled to ensure continuing conformity with requirements.

8.6 Release of Products and Services (ISO 9001:2015 Cl. 8.6)

GSS ensures that planned review and acceptance activities are satisfactorily completed before products or deliverables are released to the customer.

Applicable deliverables, including reports, slide decks, regulatory strategies, audit reports, checklists, and other customer-facing outputs, are reviewed against defined requirements and acceptance criteria before release.

Documented information is retained, as appropriate, to provide evidence of conformity with acceptance criteria and identification of the person authorizing release.

Where formal documented release is not appropriate to the nature of the service, completion and delivery records provide evidence of service release.

8.7 Control of Nonconforming Outputs (ISO 9001:2015 Cl. 8.7)

GSS identifies and controls products, deliverables, or services that do not conform to applicable requirements to prevent unintended use, release, or continued reliance.

Nonconforming outputs may include inaccurate or outdated regulatory content, incorrect customer deliverables, failure to meet agreed requirements, use of an incorrect document version, training content errors, audit report errors, or other failures to meet specified requirements.

Depending on the nature and significance of the nonconformity, GSS may take action through correction, withdrawal or replacement of the affected output, customer notification, suspension of delivery, acceptance under authorized concession where appropriate, or corrective action.

Corrected outputs are re-reviewed or otherwise verified for conformity as appropriate.

GSS retains documented information describing the nonconformity, actions taken, concessions obtained (where applicable), and the authority for disposition.

CLAUSE 9 — PERFORMANCE EVALUATION

9.1 Monitoring, Measurement, Analysis and Evaluation (ISO 9001:2015 Cl. 9.1)

Global Strategic Solutions, LLC determines the QMS processes, products, services, and performance measures that require monitoring, measurement, analysis, and evaluation.

GSS determines appropriate methods, timing, responsibilities, and documented information necessary to evaluate QMS performance and effectiveness.

Monitoring and measurement may include quality objective performance, customer satisfaction and feedback, on-time delivery, project and service performance, deliverable review results, nonconforming outputs, corrective actions, internal audit results, external provider performance, risk and opportunity actions, and other relevant indicators.

Results are analyzed and evaluated at planned intervals and are considered during Management Review.

9.1.2 Customer Satisfaction

GSS monitors customers' perceptions of the degree to which their needs and expectations have been fulfilled.



Customer satisfaction information may be obtained through direct customer feedback, post-training or post-engagement evaluations, surveys, complaints or concerns, repeat engagements, referrals, customer communications, and other appropriate sources.

Customer satisfaction information is analyzed for trends, recurring concerns, and opportunities for improvement, and this analysis is considered during the Management Review.

9.1.3 Analysis and Evaluation

GSS analyzes and evaluates appropriate data and information arising from monitoring and measurement activities.

Analysis and evaluation are used to assess:

- i. Conformity of GSS products and services;
- ii. Degree of customer satisfaction;
- iii. Performance and effectiveness of the QMS;
- iv. Effectiveness of planning and actions taken to address risks and opportunities;
- v. Performance of external providers;
- vi. Achievement of quality objectives;
- vii. Effectiveness of corrective actions; and
- viii. Need for improvements to GSS products, services, processes, or the QMS.

Methods of analysis are proportionate to the nature and amount of available data. They may include trend analysis, comparisons against established targets, reviews of recurring issues, qualitative evaluations, and other appropriate analytical methods.

9.2 Internal Audit (ISO 9001:2015 Cl. 9.2)

Global Strategic Solutions, LLC conducts internal audits at planned intervals to provide information on whether the Quality Management System:

- i. Conforms to GSS's own QMS requirements and the applicable requirements of ISO 9001:2015; and
- ii. Is effectively implemented and maintained.

GSS establishes, implements, and maintains an internal audit program that considers the importance of QMS processes, changes affecting the organization, identified risks and opportunities, and the results of previous audits.

The audit program defines audit frequency, methods, responsibilities, planning requirements, reporting, audit criteria, and audit scope.

Auditors are selected, and audits are conducted to ensure the audit process is objective and impartial. Because GSS operates as a sole-member LLC, independent qualified external auditors may be used to audit activities for which self-audit could compromise objectivity or impartiality.

Audit results are reported to Top Management. Appropriate correction and corrective action are initiated without undue delay when nonconformities are identified. Follow-up activities include verifying actions taken and evaluating the effectiveness of corrective actions, as applicable.

GSS retains documented information as evidence of implementation of the audit program and audit results.

Internal audit activities are conducted in accordance with QMS-PRO-08 (Internal Audit Procedure). Audit tools, including QMS-CKL-01 (Internal Audit Checklist), may be used to support audit planning and conduct.



9.3 Management Review (ISO 9001:2015 Cl. 9.3)

Top Management reviews the QMS at planned intervals to ensure its continuing suitability, adequacy, effectiveness, and alignment with strategic direction. Management Reviews are conducted in accordance with 9.3.1, QMS-PRO-09 (Management Review Procedure) and include all mandatory inputs defined in Clause 9.3.2 and produce outputs as required by Clause 9.3.3.

Mandatory Review Input (Cl. 9.3.2)	GSS Data Source
Status of actions from previous management reviews	Management Review minutes and action tracker
Changes in external and internal issues relevant to the QMS	Context analysis; PESTLE review; Risk and Opportunity Register
Information on QMS performance and effectiveness	KPI and Quality Objective results
Customer satisfaction and feedback from relevant interested parties	Customer feedback; training evaluations; complaints or concerns; repeat engagements
Extent to which quality objectives have been met	QMS-KPI-01
Process performance and conformity of products and services	Process performance data; project and service results; deliverable review records
Nonconformities and corrective actions	Nonconformity and corrective action records; trend analysis
Monitoring and measurement results	KPI trends; service performance results; customer satisfaction results
Audit results	Internal audit reports; external and certification audit results
Performance of external providers	External provider evaluations and performance records
Adequacy of resources	Resource, competence, technology, infrastructure, and workload assessment
Effectiveness of actions taken to address risks and opportunities	Risk and Opportunity Register and action status
Opportunities for improvement	Improvement actions; audit observations; customer feedback; lessons learned

9.3.3 Management Review Outputs (ISO 9001:2015 Cl. 9.3.3)

Management Review outputs include decisions and actions related to:

- i. Opportunities for improvement;
- ii. Any need for changes to the Quality Management System; and
- iii. Resource needs.

GSS may also identify actions related to quality objectives, risks and opportunities, customer satisfaction, process performance, external provider performance, organizational knowledge, competence, technology, and strategic priorities.

Management Review decisions and actions are assigned, tracked, and reviewed for completion. GSS retains documented information as evidence of Management Review results.



CLAUSE 10 — IMPROVEMENT

10.1 General (ISO 9001:2015 Cl. 10.1)

Global Strategic Solutions, LLC determines and selects opportunities for improvement and implements actions to meet customer requirements and enhance customer satisfaction. Improvement activities include correcting, preventing, or reducing undesired effects, as well as improving the performance and effectiveness of the QMS.

10.2 Nonconformity and Corrective Action (ISO 9001:2015 Cl. 10.2)

When a nonconformity occurs, including those arising from complaints, Global Strategic Solutions, LLC reacts to the nonconformity and, as applicable, takes action to control and correct it and addresses resulting consequences.

GSS evaluates the need for action to eliminate the cause of the nonconformity to prevent recurrence or occurrence elsewhere. Appropriate corrective actions are implemented, and their effectiveness is reviewed. Risks and opportunities and the Quality Management System are updated or changed when necessary.

Corrective actions are appropriate to the effects of the nonconformities encountered. The corrective action process is managed in accordance with QMS-PRO-07, and documented information is retained as evidence of the nature of nonconformities, actions taken, and corrective action results.

10.3 Continual Improvement (ISO 9001:2015 Cl. 10.3)

Global Strategic Solutions, LLC continually improves the suitability, adequacy, and effectiveness of the Quality Management System.

GSS considers the results of analysis and evaluation, as well as the outputs of Management Review, to identify needs and opportunities for continual improvement.

Improvement initiatives may arise from customer feedback, audit results, quality objective performance, process performance, risks and opportunities, lessons learned, changes in technology, regulatory or standards developments, and Management Review.

Improvement initiatives are evaluated, prioritized, implemented, and monitored using methods proportionate to their significance and potential impact. Corrective action is initiated when the nature of a nonconformity warrants action to eliminate its cause and prevent recurrence.

QMS DOCUMENT CROSS-REFERENCE SUMMARY

The following table cross-references ISO 9001:2015 clauses to the key supporting documents in this kit:

ISO 9001:2015 Clause	Clause Title	Primary Supporting Documents
4.1 – 4.3	Organizational Context & Scope	QMS-PRO-01, QMS-MAN-01 Cl.4, QMS-FRM-01
4.4	QMS & its Processes	QMS-MAN-01 Cl. 4.4, QMS-MDR-01
5.1 – 5.3	Leadership, Policy, Responsibilities	QMS-MAN-01 Cl.5, QMS-MAN-02
6.1	Risks & Opportunities	QMS-PRO-02, QMS-RRP-01
6.2	Quality Objectives	QMS-KPI-01
6.3	Planning of Changes	QMS-SOP-06
7.1	Resources	QMS-MAN-01 Cl.7, + Applicable Records
7.1.5	Monitoring & Measuring Resources	QMS-SOP-05, Monitoring & Measuring Resource Register, applicable controlled



		checklists/templates/rubrics
7.2 – 7.3	Competence & Awareness	QMS-PRO-04, + Competency / Training Records
7.4	Communication	QMS-MAN-01 Cl.7.4
7.5	Documented Information	QMS-PRO-03, QMS-MDR-01
8.1 – 8.2	Operational Planning & Customer Requirements	QMS-PRO-05, QMS-SOP-01
8.3	Design & Development	QMS-SOP-04
8.4	External Provider Control	QMS-PRO-06, + External-Provider Records
8.5	Production & Service Provision	QMS-SOP-01 + Project/Service Records
8.6	Release of Products/Services	QMS-SOP-02 + Deliverable/Release Evidence
8.7	Nonconforming Outputs	QMS-PRO-08 + Applicable Records
9.1	Monitoring, Measurement & Evaluation	QMS-KPI-01, Customer Feedback/Survey Records, Applicable Performance Records
9.2	Internal Audit	QMS-PRO-07, QMS-CKL-01, Audit Records
9.3	Management Review	QMS-PRO-09, QMS-FRM-03
10.1	Improvement – General	QMS-PRO-08, QMS-MAN-01 Cl 10
10.2	Nonconformity & Corrective Action	QMS-PRO-08 + Corrective Action Records
10.3	Continual Improvement	QMS-PRO-08, QMS-MAN-01 Cl.10, QMS-PRO-09

David R Rutledge

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