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LEADERSHIP, CULTURE AND STRATEGIC DIRECTION MANUAL

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This policy is communicated to all personnel through onboarding training (e.g., employees, contractors, consultants) and reviewed at least annually at Management Review meetings, periodically whenever revised, and available to interested parties upon request. It is also publicly 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*

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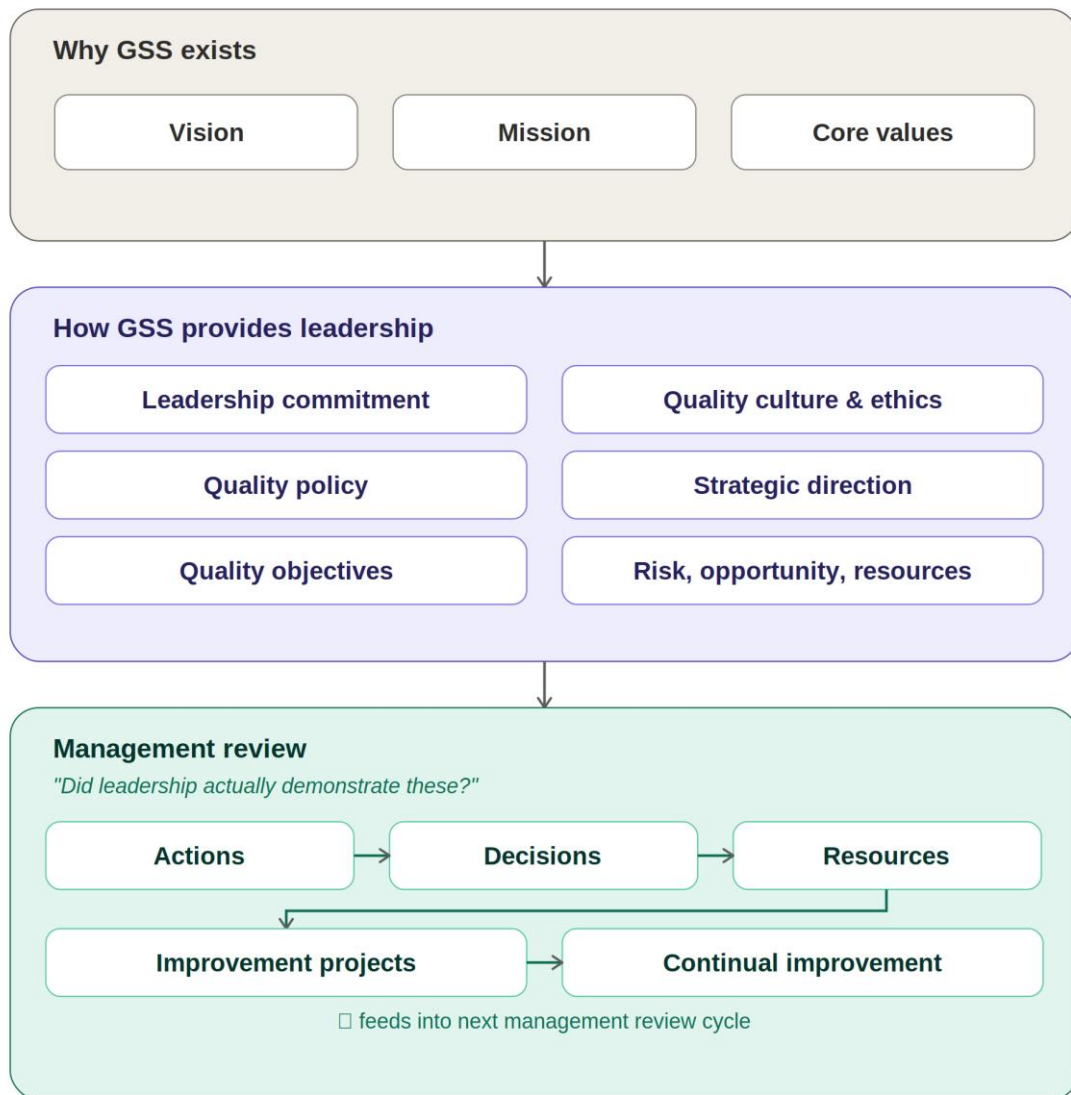
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Figure 1. GSS Leadership Framework and Audit Trail



Leadership is demonstrated through actions, evaluated through Management Review, and strengthened through continual improvement.

ORGANIZATION PURPOSE - Why GSS Exists (North Star)

Vision | Mission | Core Values |

HOW GSS PROVIDES LEADERSHIP (Clause 5)

Leadership Commitment Statement | Quality Culture & Ethics | Quality Policy | Strategic Direction | Quality Objectives | Risks ➡ Opportunities ➡ Resources |

MANAGEMENT REVIEW (Evidence)

"Did leadership actually demonstrate these?" Actions ➡ Decisions ➡ Resources ➡
Improvement Projects ➡ Continual Improvement



DOCUMENT NAVIGATION [PRO-03 Document Control]

Where can objective evidence be found for each leadership element in table?

Leadership Topic	Primary Document	Objective Evidence
Vision	MAN-02	PRO-09 Annual Management Review
Mission	MAN-02	Strategic Planning
Core Values	MAN-02	Management Review, Leadership Decisions
Leadership Commitment	MAN-02	PRO-09 Management Review, Resource Allocation
Quality Culture	MAN-02	Training, PRO-04 Competence, Management Review, PRO-07 Internal Audits
Ethical Behavior	MAN-02	Management Review, Customer Feedback
Quality Manual and Policy	QMS-MAN-01	Employee Awareness, Management Review
Strategic Direction	MAN-02	Business Planning, KPIs
Quality Objectives	KPI Tracker	KPI Results
Risks & Opportunity	PRO-02	Risk Register, Opportunities Register
Organizational Context	PRO-01	Content Register

Leadership ≠ intentions. Leadership = evidence.

1. PURPOSE

The purpose of this manual is to define the leadership philosophy, strategic direction, organizational culture, and governance principles that guide Global Strategic Solutions, LLC (GSS).

This manual establishes the framework through which Top Management communicates the organization's Vision, Mission, Core Values, Leadership Commitments, Quality Culture, Ethical Behavior expectations, and Strategic Direction. Collectively, these elements establish the foundation upon which the GSS Quality Management System (QMS) is developed, implemented, maintained, and continually improved.

Unlike operational procedures that describe **how** individual QMS processes operate, this manual explains **why** the GSS Quality Management System exists, **what** principles guide leadership decision-making, and **how** leadership expectations are translated into measurable actions throughout the organization.

This manual supports the GSS Quality Policy by ensuring leadership decisions remain aligned with the organization's strategic direction, customer focus, continual improvement objectives, and commitment to delivering technically sound, ethical, and practical consulting, auditing, and training services.

Leadership effectiveness is evaluated through the GSS Management Review process, where Top Management periodically assesses whether the principles described in this manual continue to be demonstrated throughout the organization and remain appropriate for the evolving needs of GSS, its customers, and other relevant interested parties.



2. SCOPE

This manual applies to all leadership activities performed within the Global Strategic Solutions, LLC Quality Management System.

It establishes the leadership principles that govern organizational decision-making, quality culture, ethical behavior, strategic planning, resource allocation, customer focus, continual improvement, and management oversight.

The principles contained within this manual apply to Top Management, employees, contractors, consultants, subject-matter experts, and other individuals whose activities may influence the effectiveness of the GSS Quality Management System or the quality of products and services delivered to GSS customers. Although GSS is a small organization, the leadership principles described in this manual are intended to be scalable as the organization grows and expands its products, services, personnel, and global partnerships.

3. LEADERSHIP FRAMEWORK

The GSS Leadership Framework illustrates how organizational purpose is translated into leadership actions, strategic planning, and continual improvement. The framework begins with the organization's Vision, Mission, and Core Values, which establish why GSS exists and the principles that guide leadership decisions. These foundational elements influence Leadership Commitment, Quality Culture and Ethics, the Quality Policy, Strategic Direction, Quality Objectives, and the management of risks, opportunities, and resources. Leadership evaluates the effectiveness of this framework through the Management Review process, where decisions, actions, resource needs, and continual improvement opportunities are reviewed and monitored.

4. GSS VISION

Global Strategic Solutions, LLC envisions a world where organizations consistently deliver safe, effective, and high-quality products because quality, scientific integrity, and continual improvement are embedded within their culture - not merely documented within their Quality Management Systems.

GSS strives to be recognized as a trusted global partner that transforms complex regulatory and quality challenges into practical, sustainable business solutions while helping organizations improve compliance, accelerate innovation, and ultimately protect patients.

5. GSS MISSION

Global Strategic Solutions, LLC exists to help medical technology, medical device, diagnostics, biotechnology, pharmaceutical, and life sciences organizations strengthen their Quality Management Systems through practical consulting, professional education, internal auditing, and regulatory strategy services.

We combine scientific expertise, international regulatory experience, and practical implementation strategies to help organizations develop compliant, effective, and sustainable management systems that



improve organizational performance and ultimately support the delivery of safe and effective products to patients around the world.

The following Core Values are intended to guide leadership decisions, customer interactions, project execution, and continual improvement throughout GSS.

6. GSS CORE VALUES

The Core Values of Global Strategic Solutions, LLC (GSS) define the principles that guide our leadership, influence our decisions, shape our organizational culture, and establish expectations for everyone representing GSS.

These values serve as the foundation for how we conduct business, interact with clients and business partners, support one another, and continually improve the effectiveness of our Quality Management System. They are intended to be demonstrated through daily actions rather than expressed solely through written statements.

Leadership periodically evaluates these values during Management Review to confirm they remain relevant to the strategic direction of GSS and continue to be reflected throughout the organization.

6.1 Patient Focus

Although GSS does not manufacture medical devices or provide direct patient care, we recognize that our consulting, auditing, and training services influence the Quality Management Systems used to develop, manufacture, and support products intended for patients around the world.

Accordingly, every recommendation, training program, audit, and consulting engagement is intended to contribute - directly or indirectly - to safer, more effective healthcare products and services.

Leadership Commitment

"We help organizations build quality systems that we would trust to support products used by our own families."

-David R Rutledge, Pharm.D., FCCP, FAHA, CEO & Founder

6.2 Integrity

Integrity forms the foundation of every GSS business relationship.

We communicate honestly, provide objective recommendations supported by evidence, acknowledge limitations when they exist, and conduct our business with professionalism, impartiality, and transparency.

Commercial interests shall never compromise scientific judgment or ethical decision-making.

We communicate difficult truths professionally, even when they are unpopular or commercially inconvenient.

6.3 Technical Excellence

GSS is committed to delivering technically accurate, practical, and scientifically sound solutions.

We continually develop our knowledge of international regulations, standards, and industry best practices so that our clients receive advice that is both compliant and practical to implement.

We believe technical excellence requires continual learning.

We distinguish between regulatory requirements, industry best practices, and professional opinion so our clients can make informed decisions.



6.4 Client Partnership

We measure success not by the reports we deliver, but by the capability our clients develop.

Our objective is to strengthen our clients' capabilities by sharing knowledge, developing competence, and helping organizations establish sustainable management systems that continue to improve long after each engagement has concluded.

6.5 Continuous Learning and Innovation

Learning is an ongoing responsibility for every member of GSS.

We encourage curiosity, professional development, thoughtful questioning, innovation, and the responsible application of emerging technologies to continually improve our services and the effectiveness of our Quality Management System.

6.6 Respect

We foster an environment of professionalism, mutual respect, collaboration, and open communication.

We value diverse business perspectives and encourage respectful discussions that improve decision-making, strengthen relationships, and support continual improvement.

6.7 Accountability

Each individual representing GSS is accountable for the quality of their work, fulfillment of commitments, and contribution to the continual improvement of the organization.

Leadership demonstrates accountability by providing clear direction, allocating appropriate resources, reviewing organizational performance, and taking timely action when improvement opportunities are identified.

6.8 Practical Solutions

Compliance should enable organizational success rather than create unnecessary complexity.

GSS is committed to developing practical, scalable, and sustainable solutions that satisfy regulatory requirements while supporting our clients' operational objectives.

6.9 Knowledge Transfer

Knowledge is most valuable when it can be understood, applied, and sustained.

GSS is committed to transferring practical knowledge - not merely delivering information - so that our clients become more capable, more confident, and less dependent on external support over time.

We measure our success by the capability we help others develop.

6.10 Living Our Values

The GSS Core Values are intended to guide daily leadership decisions, customer interactions, business practices, and continual improvement activities. These values are reinforced through Top Management leadership, employee awareness, competency development, Management Review, customer feedback, internal audits, corrective actions, and continual improvement initiatives.

Leadership periodically evaluates whether these values continue to support the strategic direction of GSS and whether they are consistently demonstrated throughout the organization.



7. GSS LEADERSHIP COMMITMENT STATEMENT

7.1 Leadership Commitment

Top Management recognizes that an effective Quality Management System is not achieved solely through documented procedures, but through visible leadership, consistent decision-making, active participation, and a culture that promotes quality, integrity, continual learning, and continual improvement.

At Global Strategic Solutions, LLC, leadership begins with personal accountability. Top Management accepts responsibility for establishing the organization's strategic direction, maintaining the effectiveness of the Quality Management System, providing necessary resources, promoting customer focus, fostering ethical behavior, and ensuring that quality objectives remain aligned with the long-term mission and vision of GSS.

Leadership is expected to be demonstrated through actions that build trust, encourage open communication, support evidence-based decision-making, and create an environment where continual improvement becomes part of everyday business operations.

Leadership commitments are periodically evaluated during Management Review to ensure they continue to support the strategic direction of the organization and remain effective.

7.2 Our Leadership Commitments

Leadership Pillar 1 – Lead by Example

Top Management demonstrates the behaviors expected throughout the organization by following established QMS processes, maintaining documented information, participating in Management Reviews, supporting internal audits, and encouraging continual improvement. Leadership is expected to model the standards it asks others to follow.

Leadership Pillar 2 – Keep the Customer at the Center

Before recommending solutions, GSS seeks to understand each client's objectives, constraints, and expectations. Leadership promotes practical, risk-based decisions that strengthen customer capability while supporting compliance and long-term success.

Leadership Pillar 3 – Make Decisions Based on Evidence

Leadership decisions are guided by objective evidence, applicable regulations and standards, risk assessment, customer feedback, performance data, and professional judgment rather than assumptions or convenience.

Leadership Pillar 4 – Invest in People and Knowledge

Leadership recognizes that knowledge is GSS's greatest asset. We invest in competency development, mentoring, knowledge transfer, and continual learning to ensure expertise is retained, expanded, and shared.

Leadership Pillar 5 – Drive Continual Improvement

Leadership actively seeks opportunities to improve the Quality Management System, services, and organizational effectiveness. Improvement opportunities identified through audits, customer feedback, Management Reviews, lessons learned, or innovation are evaluated and acted upon where appropriate.

7.3 Leadership in Daily Practice

Leadership at Global Strategic Solutions, LLC is demonstrated through consistent daily actions rather than isolated events or periodic meetings. Top Management recognizes that leadership is reflected in the



decisions made, the behaviors demonstrated, the questions asked, and the example set throughout the organization.

Leadership is expected to be visible, accessible, and actively engaged in guiding the organization toward achieving its Vision, Mission, Core Values, strategic direction, quality objectives, and continual improvement commitments.

At GSS, leadership is demonstrated by routinely:

Understanding Customer Needs

Listening carefully to customers before proposing solutions to ensure services are practical, technically sound, appropriately scoped, and aligned with customer expectations.

Setting Clear Direction

Establishing priorities, communicating expectations, and ensuring that projects remain aligned with the GSS Vision, Mission, strategic direction, and Quality Policy.

Making Evidence-Based Decisions

Using objective evidence, applicable regulations, international standards, customer feedback, risk assessments, lessons learned, and professional judgment when making business and quality decisions.

Developing People

Encouraging continual learning, mentoring, professional development, constructive feedback, and knowledge sharing so that competence continues to grow throughout the organization.

Managing Risk

Considering risks and opportunities before making significant business decisions and encouraging proactive actions that strengthen organizational resilience and customer confidence.

Maintaining Technical Excellence

Remaining current with evolving regulations, international standards, guidance documents, industry best practices, and emerging technologies so GSS recommendations remain accurate, practical, and relevant.

Supporting Ethical Decision-Making

Creating an environment where individuals are encouraged to raise concerns, ask questions, challenge assumptions respectfully, and communicate openly without fear of retaliation.

Monitoring Organizational Performance

Regularly reviewing customer feedback, Quality Objectives, Key Performance Indicators, internal audit results, Management Review outputs, corrective actions, and improvement initiatives to evaluate organizational performance and identify opportunities for improvement.

Leading by Example

Following the same documented processes, quality expectations, and ethical standards expected of everyone working under the GSS Quality Management System.

Leadership credibility is established by consistently demonstrating the behaviors expected throughout the organization.

Leadership Is Measured by Actions

Observable outcomes rather than intentions ultimately evaluate leadership at GSS.

Examples of objective evidence include:

- i. Customer satisfaction and repeat business
- ii. Achievement of Quality Objectives
- iii. Effective Management Reviews



- iv. Timely completion of improvement actions
- v. Internal audit results
- vi. Professional development activities
- vii. Effective management of risks and opportunities
- viii. Continual improvement of the Quality Management System
- ix. Positive feedback from customers, business partners, and other relevant interested parties

These activities provide objective evidence that leadership commitments are actively demonstrated and contribute to the effectiveness of the GSS Quality Management System.

“Leadership at GSS is not defined by authority—it is demonstrated by consistently helping people succeed, making sound decisions based on evidence, and continually improving the systems that ultimately support safe and effective products for patients.” – David R Rutledge, Pharm.D., FCCP, FHAH, CEO & Founder

7.4 How Leadership is Evaluated

The effectiveness of Top Management is not determined solely by organizational performance or financial results. Leadership at GSS is evaluated by the extent to which leadership behaviors, decisions, and actions consistently support the organization’s Vision, Mission, Core Values, Leadership Commitments, Quality Policy, and strategic direction.

Top Management periodically evaluates leadership effectiveness during Management Review using objective evidence generated by the Quality Management System.

Examples of objective evidence include:

- i. Achievement of Quality Objectives.
- ii. Customer feedback and customer retention.
- iii. Internal audit results.
- iv. Management Review outputs.
- v. Progress toward strategic objectives.
- vi. Resource planning and competency development.
- vii. Risk and opportunity management.
- viii. Continual improvement initiatives.
- ix. Corrective Action effectiveness.
- x. Professional development and knowledge transfer.
- xi. Evidence of ethical decision-making.
- xii. Feedback from employees, contractors, and business partners, when applicable.

Leadership evaluation focuses not only on organizational performance, but also on whether leadership behaviors continue to foster a culture of quality, integrity, continual learning, customer focus, and continual improvement.

The results of these evaluations provide important input into the continual improvement of leadership practices, organizational culture, and the Quality Management System.



Table Shows Leadership performance is assessed, in part, using objective evidence, such as:

Leadership Activity	Objective Evidence
Strategic Direction	Vision, Mission, Business Planning
Customer Focus	Customer Feedback, Repeat Engagements
Resource Management	Competency Matrix, Resource Planning
Risk-Based Thinking	Risk & Opportunity Register
Quality Performance	KPI Dashboard
Continual Improvement	CAPAs, Improvement Projects
Leadership Participation	Management Review Minutes
Organizational Learning	Training Records, Lessons Learned
QMS Effectiveness	Internal Audit Results

Because leadership directly influences organizational culture, the following section describes the quality culture and ethical behaviors that GSS seeks to promote throughout the organization.

8. GSS QUALITY CULTURE, ETHICAL BEHAVIOR, AND BEHAVIORAL EXPECTATIONS

8.1 Purpose

Global Strategic Solutions, LLC recognizes that an effective Quality Management System is sustained not only by documented processes and technical competence, but also by the behaviors, attitudes, and ethical principles demonstrated throughout the organization.

Top Management is committed to fostering a culture in which quality, integrity, accountability, continual learning, customer focus, and continual improvement become part of everyday decision-making.

The purpose of this section is to define the organizational culture GSS seeks to promote, establish expectations for ethical behavior, and describe the professional behaviors expected of everyone representing GSS.

8.2 Our Quality Culture

Quality at GSS extends beyond compliance with applicable standards and regulatory requirements. It reflects the collective commitment of leadership, employees, contractors, consultants, and business partners to consistently deliver services that are technically sound, practical, ethical, and focused on customer success.

The GSS Quality Culture is characterized by individuals who:

- i. Take personal ownership of the quality of their work;
- ii. Seek continual improvement rather than minimum compliance;
- iii. Base decisions on objective evidence and sound professional judgment;
- iv. Promote collaboration and respectful communication;
- v. Encourage innovation while appropriately managing risk;



- vi. Share knowledge to strengthen organizational capability; and
- vii. View quality as everyone's responsibility.

Leadership recognizes that organizational culture is developed over time through consistent actions, decisions, and behaviors rather than through policies alone.

8.3 Ethical Behavior

Integrity and ethical conduct are fundamental to maintaining the trust of our customers, business partners, regulatory authorities, and other interested parties.

Individuals representing GSS are expected to:

- i. Conduct business honestly, professionally, and transparently.
- ii. Comply with applicable legal, regulatory, contractual, and professional obligations;
- iii. Maintain confidentiality of customer and proprietary information;
- iv. Identify and appropriately manage actual, potential, or perceived conflicts of interest;
- v. Distinguish clearly between objective requirements, industry best practices, and professional opinion;
- vi. Communicate uncertainties openly rather than making unsupported conclusions; and
- vii. Treat customers, colleagues, auditors, regulators, and business partners with professionalism and respect.

Leadership promotes an environment in which ethical concerns may be raised without fear of retaliation and where doing the right thing is valued above short-term convenience.

8.4 Behavioral Expectations

The behaviors expected at GSS support both our Core Values and our Quality Management System.

Individuals representing GSS are expected to:

- i. Prepare thoroughly before engagements;
- ii. Listen actively before offering recommendations;
- iii. Respect differing technical opinions and encourage constructive discussion;
- iv. Support recommendations with objective evidence;
- v. Accept responsibility for commitments and follow through on agreed actions;
- vi. Communicate openly, professionally, and respectfully;
- vii. Learn from both successes and mistakes;
- viii. Seek opportunities to improve customer value and organizational performance; and
- ix. Represent GSS with professionalism in every interaction.

These behaviors apply regardless of job title or organizational role.

8.5 Speaking Up and Open Communication

GSS encourages an environment where individuals feel comfortable asking questions, reporting concerns, respectfully challenging assumptions, and proposing new ideas.

Constructive disagreement, when supported by evidence and conducted professionally, is recognized as an important contributor to better decision-making and continual improvement.

Leadership values open communication and recognizes that diverse perspectives strengthen both technical decisions and organizational learning.



8.6 Becoming a Learning Organization

Continual learning is an essential element of the GSS culture.

Leadership encourages ongoing professional development, mentoring, knowledge sharing, and reflection on completed projects to capture lessons learned and improve future performance.

Mistakes are evaluated objectively to understand contributing factors, strengthen processes, and reduce the likelihood of recurrence. The emphasis is on learning and improvement rather than assigning blame.

8.7 Leadership Responsibilities for Culture

Top Management supports the GSS Quality Culture by:

- i. Demonstrating the behaviors expected throughout the organization;
- ii. Providing adequate resources;
- iii. Recognizing quality achievements and continual improvement;
- iv. Encouraging innovation while maintaining appropriate oversight;
- v. Promoting ethical decision-making;
- vi. Supporting professional development and competency growth;
- vii. Maintaining open communication;
- viii. Reinforcing customer focus;
- ix. Evaluating organizational culture during Management Review; and
- x. Taking appropriate action when improvements are identified.

8.8 Evaluating Our Quality Culture

Top Management periodically evaluates the effectiveness of the GSS Quality Culture through objective evidence generated by the Quality Management System.

Examples of objective evidence shown in Table below include:

Evaluation Area	Examples of Objective Evidence
Customer Focus	Customer Feedback, Repeat Engagements, Referrals
Leadership	Management Review Discussions, Leadership Actions
Competency	Training Records, Competency Assessments
Communication	Internal Audit Observations, Lessons Learned
Continual Improvement	CAPAs, Improvement Projects, Preventive Actions
Ethical Behavior	Conflict-of-Interest Disclosures, Customer Feedback, Leadership Discussions
Organizational Learning	Knowledge-Sharing Sessions, Post-Project Reviews
QMS Effectiveness	Internal Audit Results, KPI Performance, Management Review Outputs

The results of these evaluations provide input into Management Review and support the continual improvement of leadership practices, organizational culture, and the effectiveness of the GSS Quality Management System.

9. THE GSS DECISION FILTER

Before making an important decision, we ask:

- i. Is it ethical?
- ii. Does objective evidence support it?



- iii. Does it support our Vision, Mission, and Core Values?
- iv. Is it in the best interest of our customer?
- v. Would we be comfortable explaining this decision to an auditor, a regulator, or our peers?

If the answer to any question is “no,” we stop and reassess.

David R Rutledge

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