**QUALITY MANAGEMENT SYSTEM MANUAL**

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**Invest in Your Success, LLC**

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**Certificate No: 1234567**

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**Q01 Document Control**

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**Q02 Document Amendments**

All copies of this Quality Management Systems Manual (QMSM) must be kept under strict control to prevent the system from becoming unreliable. The following controls will ensure that the system remains current and valid.

1. All copies of the manual will be clearly numbered and the Holder recorded.
2. Each page in the manual will carry its own number.
3. The Document Controller will be responsible for all revisions and additions being recorded.
4. Changes can be suggested by any Employee but must receive signed approval before being entered into the QMSM.
5. All changes must be recorded on the Amendments Table below and appropriate pages in each QMSM changed. Significant changes will be shaded to make them easy to identify. (Where existing text is reworded or reorganized in the document, these changes will not be shaded.)

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| **Amendments Table** |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Doc. No.** | **Page No.** | **Issue** | **Date** | **Description of change** | **Authorization** |
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**Q03 Invest in Your Success’s Organization Chart**



**Q04 Quality Management System**

**4. Context of the organization**

**4.1 Understanding the Organization and its Context**

We have determined the relevant external and internal issues that affect our ability to achieve the intended outcomes of our management system. We have considered the full business environment, the key drivers and trends having impact on the objectives of the organization and the relationship and values of external stakeholders. Details of the context of our organization are given below:

Document 1201

**4.2 Understanding the Needs and Expectations of Interested Parties**

We have identified the interested parties and their requirements with the emphasis being on quality. We have included a process to determine any legal requirements relating to activities, and services that are relevant to the scope of our management system.

Document 1202

**4.3 Determining the Scope of the Quality Management System**

We have determined the boundaries and applicability of our management system and have taken into account the issues identified in Clause 4.1 and 4.2 (above) as well as those that relate to our services when establishing the scope.

See document – M01 Scope of QMS

**4.4 Quality Management System and its processes (QMS)**

We have established and implemented, and will look to maintain and continually improve our quality management system, including the processes and their interactions needed to meet the requirements of the international standard.

In order to deliver the requirements, we have identified:

* the processes needed for the implementation, operation and maintenance of the management system along with opportunities for its improvement and their application throughout the organization;
* the inputs required and outputs expected from these processes;
* the sequence and interaction of these processes;
* criteria and methods needed to ensure that both the operation and control of these processes are effective;
* the availability of resources and information necessary to support the operation and monitoring of these processes;
* the risks and opportunities within the management system and how to plan to address them;
* the monitoring, measuring and analyzing of these processes, and implement actions necessary to achieve planned results and continual improvement.

Appropriate documented information is maintained to support these processes and is retained as records to demonstrate that all processes are working as planned.

QMS Process Diagram



















































**5. Leadership**

**5.1 Leadership and Commitment**

5.1.1 General

Our Top management have demonstrated leadership and commitment with respect to our QMS by taking accountability of the effectiveness of the QMS; by establishing a quality policy and quality objectives that are compatible with the direction of the organization; by ensuring that both policy and objectives are communicated, understood and applied within the organization; by ensuring integration of QMS requirements into the organization’s business processes and by promoting awareness of a process approach and risk based thinking.

In addition, our Top Management have provided the necessary resources for the QMS; communicated the importance of effective quality management and of conforming to QMS requirements; ensuring that the QMS achieves intended results; engaging with, directing and supporting persons to contribute to the effectiveness of the QMS; promote improvement and support other members of the management team to demonstrate their leadership as it applies to their area of responsibility.

5.1.2 Customer Focus

As an organization, we strive to meet our clients’ expectations; our management has demonstrated their leadership and commitment by ensuring that clients’ requirements and applicable regulatory and statutory requirements are met; that risks and opportunities that could affect our products and services have been addressed and that our focus is on consistently providing client satisfaction.

**5.2 Policy**

Our Top Management has developed a quality policy that is in line with the requirements of the standard. The Policy is available as documented information, is communicated throughout the organization and is also available to interested parties, as appropriate.

See Document – M02 Quality Policy

**5.3 Organizational Roles, Responsibilities and Authorities**

Our Top management will ensure that the responsibilities and authorities for relevant roles are assigned and communicated throughout the organization. The organization has identified, documented and communicated the roles, responsibilities and authorities of those involved in the management system and their interrelationships within the organization.

See Document – R01 Job description

**6. Planning**

**6.1 Actions to Address Risks and Opportunities**

We have considered the issues detailed in clause 4.1 and 4.2of this document and have determined the risks and opportunities that need to be addressed to assure the QMS can achieve its intended outcomes; that we prevent or reduce undesired effects and achieve continual improvement.

We have put a plan in place to address these risks and opportunities and also a plan to integrate and implement these actions in the QMS and evaluate their effectiveness. We have produced a risk assessment register to show what has been achieved.

See document – M03 Risk Assessment Procedure

R02 Risk Assessment Register

**6.2 Quality Objectives and Planning to achieve them**

We have established quality objectives at various levels throughout the organization in line with the requirements of ISO 9001:2015 Clauses 6.2.1 and 6.2.2; a document has been produced detailing these objectives and the procedure around establishing them.

See document – M04 Quality Objectives Procedure Document

R03 Quality Objectives

**6.3 Planning of Changes**

If we make changes to our QMS they would be carried out in a planned and systematic manner. We will consider the purpose of any change, its potential consequences, the integrity of the QMS, the availability of resources and the allocation or reallocation of responsibilities and authorities.

See document – R14 Document Change Request

**7. Support**

**7.1 Resources**

7.1.1 General

We have determined and provided the resources needed for the establishment, implementation, maintenance and continual improvement of our QMS. We have considered the capabilities of our existing resources and what we need to obtain from external providers.

7.1.2 People

Those resources include people who have the necessary skills and competencies to effectively operate our QMS and to meet and exceed our clients’ expectations. Also see Clause 7.2.

7.1.3 Infrastructure

We have provided the infrastructure determined necessary for the provision of our processes and conformity of our products and services.

7.1.4 Environment for the Operation of Processes

We have provided the environment determined necessary for the provision of our processes and conformity of our products and services.

7.1.5 Monitoring and Measuring Resources

We have looked at the requirements of this clause in the standard and have determined that they are not applicable to the scope of our management system.

We have determined that we need to use measuring and monitoring resources for evidence of conformity for our products and services and have created specific documented information detailing how we have approached this requirement.

See document – M05 Measuring and Monitoring Resources

R04 Calibration Register

7.1.6 Organizational Knowledge

We have determined the knowledge necessary to operate our processes when achieving conformity of our products and services. We have systems in place to address any changes to our needs and possible trends that come up from time to time. The knowledge is in the form of documented information and is available to those who require it.

**7.2 Competence**

We have determined the competence of people doing work under our control that affects performance to ensure that these people are competent on the basis of appropriate education, training or experience and where applicable, take actions to acquire the necessary competence and evaluate the effectiveness of the actions taken.

See document – R05 Competency Record

R06 Training Record

**7.3 Awareness**

We have ensured that people doing work under our control are aware of our policies; our quality objectives relevant to them; their contribution to the effectiveness of the system and the implications of not conforming to the QMS requirements.

See document – R06 Training Record

**7.4 Communication**

We have determined the need for internal and external communications relevant to the system including on what, when, with whom, how and who would communicate.

**7.5 Documented Information**

We have written policies and procedures as appropriate to meet the requirements of our QMS and the ISO9001:2015 standard. Details of how we produce and control our documented information are given in M06.

See document – M06 Document Control & Records

**8. Operation**

**8.1 Operational Planning and Control**

We have planned, implemented and controlled processes needed to meet requirements for the provision of our products and services, and to implement the actions determined in clause **6.1** of this document by determining the requirements of our products and services; establishing criteria for those processes and for the acceptance of our products and services. We have also determined the resources needed to achieve conformity of our products and services and by implementing control of the processes in accordance with the detailed criteria.

We keep documented information to the extent necessary to have confidence that the processes have been carried out as planned and that demonstrate the conformity of our products and services.

We shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects as necessary. We shall ensure that outsourced processes are also controlled.

See document – R07 Conformity Documentation

**8.2 Requirements for Products and Services**

8.2.1 Customer Communication

We communicate with clients where necessary in relation to information related to our products and services, enquiries, contracts or order handling including changes, customer property, obtaining their feedback, including complaints and specific contingency actions where appropriate.

8.2.2 Determination of Requirements Related to Products and Services

When determining the requirements for our products and services offered to potential clients, we have ensured that applicable regulatory and statutory requirements have been defined, that we have the ability to meet those requirements and that we can substantiate any claim made for our products and services.

8.2.3 Review of Requirements Related to Products and Services

We review our Clients’ requirements, including those for delivery and post-delivery activities and any statutory and regulatory requirements applicable to the product and service being provided. We also review those requirements not stated by the client, when known, plus any contract or order requirements that are different from the original request.

We conduct this review prior to our commitment to supply our products and services; we always provide a documented confirmation of the order, even if the client has not; details of all orders are recorded on document R08.

Where requirements change, we ensure that all relevant documentation is amended and that personnel are made aware prior to delivery.

See document – R08 Results of Review of Products and Services

8.2.4 Changes to requirements for products and services

We will ensure that when changes are made to our products and services relevant persons are made aware and relevant documentation is amended to reflect those changes made.

**8.3 Design and Development of Products and Services**

We have looked at the requirements of this clause in the standard and have determined that they are not applicable to the scope of our management system.

We have determined that we need to use design and development resources for evidence of conformity for our products and services and have created specific documented information detailing how we have approached this requirement.

See document – M07 Design and Development Procedure

R09 Confirmation of D & D Requirements

R10 Design and Development Process Output

R11 Design and Development Changes

**8.4 Control of Externally Provided Processes, Products and Services**

We have produced a procedure (M08) which outlines our supplier onboarding process and audit schedule for approved vendors.

See document – M08 Supplier onboarding and audit monitoring

R12 External Providers' Evaluation Results

**8.5 Production and Service Provision**

8.5.1 Control of Production and Service Provision

We have implemented controlled conditions for the production and service provision, including delivery and post-delivery activities in line with the requirements of Clause 8.5.1 of the ISO9001: 2015 quality management system standard.

8.5.2 Identification and Traceability

Where necessary we have introduced a system to uniquely identify our products and services for the purposes of traceability. We identify the status of our processed outputs with respect to monitoring and measurement requirements throughout the provision of our products and services. We retain documented information appropriate to maintaining identification and traceability.

8.5.3 Property belonging to Customers or External Providers

We exercise due care and attention when dealing with property belonging to external providers (including clients). We report any defect, damage or loss to the external provider as soon as it has been identified by our personnel.

8.5.4 Preservation

We ensure the preservation of our products and services to the extent necessary to maintain their conformity throughout the production process.

8.5.5 Post-delivery Activities

We ensure that where applicable we meet the requirements for post-delivery activities associated with our products and services to the extent that we have considered the risks associated with the products and services, the nature of use and lifetime of the products and services, customer feedback and statutory and regulatory requirements.

8.5.6 Control of Changes

We review and control changes necessary for the production and service provision to ensure continued conformity of our products and services. We keep documented records of any such changes using form R14.

See document – M09 Production and Service Provision

R14 Document Change Request

R13 Traceability Record

**8.6 Release of Products and Services**

We have implemented arrangements at appropriate stages of production or service provision to verify that product and service requirements have been met; evidence of such acceptance criteria are recorded on the product and service record (see form R15).

Products and services will not be released to our clients until the verification arrangements have been met; the exception is when authorized by XXXXX or by the client themselves. Appropriate records of who authorized the release are recorded on the product and service record (see form R15).

See document - R15 Acceptance Documentation *to be created by the Client*

**8.7 Control of Nonconforming Outputs**

We have produced a procedure (M10) which details how our organization would deal with the control of nonconforming process outputs, products and services.

See document – M10 Non-conformance & Corrective Action

**9. Evaluation**

**9.1 Monitoring, measurement, analysis and evaluation**

9.1.1 General

We have determined what needs to be monitored and measured; the methods for monitoring, measurement, analysis and evaluation, as applicable, to ensure valid results; when the monitoring and measuring shall be performed and when the results from monitoring and measurement shall be analyzed and evaluated.

We retain documented information on the results of such monitoring and measurement to enable us to evaluate the effectiveness of our QMS.

See document – M11 Monitoring and Measurement Results

9.1.2 Customer Satisfaction

We have determined the methods for obtaining information regarding our clients’ perception of our organization in terms of meeting or exceeding their requirements in the provision of our products and services. The information gathered is reviewed as part of the Management Review process.

See document – M11 Monitoring and Measurement Results

9.1.3 Analysis and Evaluation

We analyze and evaluate data gathered as part of our monitoring and measuring activities and the results are used as part of our Management Review process.

See document – M11 Monitoring and Measurement Results

**9.2 Internal Audit**

We conduct internal audits at planned intervals to provide information on whether our QMS conforms to our requirements, to the requirements of ISO9001:2015 Quality Management System standard and is effectively implemented and maintained; it also takes into consideration the importance of the processes concerned. We have implemented a procedure (M12) that covers in detail the process surrounding the internal audit process.

See document – M12 Internal Audit

R16 Internal Audit Programme

R17 Internal Audit Report

**9.3 Management Review**

Our Top management reviews the organization’s QMS at planned intervals, at least once every 12 months, to ensure its continuing suitability, adequacy and effectiveness. Each review will take into consideration the status of actions from any previous meetings and any changes in internal or external issues relevant to our QMS and performance information, including trends and indicators as detailed in ISO 9001: 2015 Clause 9.3.1 and 9.3.2.

Information relating to each of these meetings is recorded using document R18 Management Review Agenda and Minutes

See document – M13 Management Review

R18 Management Review Agenda and Minutes

**10 Improvements**

**10.1 General**

We have determined and shall select such opportunities as necessary for improving our clients’ requirements and satisfaction. This will include improving our products and services; correcting, preventing or reducing undesired effects improving the performance and effectiveness of our QMS.

**10.2** **Nonconformity and Corrective Action**

When non-conformity occurs, we shall react to the nonconformity and take action to control and correct it and then deal with the consequences. We will evaluate the need for action to eliminate the causes of the nonconformity, in order that it does not recur or occur elsewhere in the organization. We will implement the actions required and review the effectiveness of any corrective action taken, update risks and opportunities determined during planning (if necessary) and make changes to the QMS, where necessary.

We record all nonconformities, actions taken and the results of any corrective action using the appropriate documentation.

See documents – M10 Non-conformance and Corrective Action

R19 Non-conformance Report Form

R20 Corrective Action Report Form

**10.3 Continual Improvement**

We shall continually improve the suitability, adequacy and effectiveness of our QMS. We consider the results of analysis and evaluation and the outputs from management review to determine if there are needs or opportunities that could be addressed as part of our continual improvement.

**Q05 Document Register**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Reference** | **Title** | **Issue No.** | **Date** | **Authority** |
| M01 | Scope of QMS | 1 |  |  |
| M02 | Quality Policy | 1 |  |  |
| M03 | Risk Assessment Procedure | 1 |  |  |
| M04 | Planning to Achieve Quality Objectives | 1 |  |  |
| M05 | Monitoring & Measuring Resources | 1 |  |  |
| M06 | Document Control & Records | 1 |  |  |
| M07 | Design & Development | 1 |  |  |
| M08 | Control of Externally Provided P & S | 1 |  |  |
| M09 | Production & Service Provision | 1 |  |  |
| M10 | Non-conformance & Corrective Action | 1 |  |  |
| M11 | Monitoring & Measurement Results | 1 |  |  |
| M12 | Internal Audit | 1 |  |  |
| M13 | Management Review | 1 |  |  |
|  |  |  |  |  |
| R01 | Job Description | 1 |  |  |
| R02 | Risk Assessment Register | 1 |  |  |
| R03 | Quality Objectives | 1 |  |  |
| R04 | Calibration Register | 1 |  |  |
| R05 | Competency Statement | 1 |  |  |
| R06 | Training Record | 1 |  |  |
| **Reference** | **Title** | **Issue No.** | **Date** | **Authority** |
| R07 | Conformity Documentation | 1 |  |  |
| R08 | Results of Review of Products & Services | 1 |  |  |
| R09 | Confirmation of D & D Requirements | 1 |  |  |
| R10 | D & D Process Outputs | 1 |  |  |
| R11 | D & D Changes | 1 |  |  |
| R12 | External Providers' Evaluation Results | 1 |  |  |
| R13 | Traceability Record | 1 |  |  |
| R14 | Document Change Request | 1 |  |  |
| R15 | Acceptance Documentation | 1 |  |  |
| R16 | Internal Audit Program | 1 |  |  |
| R17 | Internal Audit Report | 1 |  |  |
| R18 | Management Review Agenda & Minutes | 1 |  |  |
| R19 | Non-conformance Report Form | 1 |  |  |
| R20 | Corrective Action Report Form | 1 |  |  |
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