ISO 9001:2015

Quality Management Systems Documentation

Quality Manual / Documented Information

Document No. QM-001

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Introduction

Rely Contract Manufacturing a.k.a Rely developed and implemented a Quality Management System in order to document the company's best business practices, better satisfy the requirements and expectations of its customers and improve the overall management of the company.

To fully understand the organization and its context, Rely determined the external and internal issues that are relevant and that affect its ability to achieve the intended results of the quality management system.

The Quality Management System of Rely meets the requirements of the international standard ISO 9001:2015. It incorporates the process approach where consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes.

This process approach provides for the management of the quality system and its processes through the application of a "Plan-Do-Check-Act" methodology and a focus on "Risk-Based-Thinking" leading to the prevention of undesirable outcomes.

The manual is divided into sections that correlate to the Quality Management System sections of ISO 9001:2015. The manual describes the Quality Management System, delineates authorities, inter relationships and responsibilities of the personnel responsible for performing within the system. The manual also provides the documented information with procedures or references for all activities comprising the Quality Management System that ensures the compliance to the necessary requirements of the standard.

This manual is used internally to guide the company's employees through the various requirements of the ISO standard that must be met and maintained in order to ensure customer satisfaction, continuous improvement and provide the necessary instructions that create an empowered work force.

This manual is used externally to introduce our Quality Management System to our customers and other external organizations or interested parties. The manual is used to familiarize them with the controls that have been implemented and to assure them that the integrity of the Quality Management System is maintained and focused on customer satisfaction and continuous improvement.

The manual is approved by a top management representative.

President: Kim Korth Date: 01/02/2024

Section 01 Scope or the Quality Management System

General

To determine and establish the scope of the QMS, Rely determined the boundaries and applicability of the QMS and considered the external and internal issues, the requirements of relevant interested parties, and the products and services of the company.
The scope is available and maintained as documented information stating the products and services covered by the QMS.
Rely applies all the requirements of ISO 9001:2015 when they are applicable within the determined scope of the QMS.

As developed with procedure P-400 for Organizational context, The scope of the Quality Management System includes the major product and service categories associated with the primary functions of contract manufacturing for our client's products at the Menomonee Falls location and the distribution of products to our clients or their end customers.

Conformity to ISO 9001:2015 may only be claimed if the requirements determined as not being applicable do not affect the organization's ability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction.
In the event that any requirement is not applicable at Rely, justification for any instance where a requirement cannot be applied is documented.
Rely has determined that the following requirement(s) is/are not applicable to the operations at this site: P-830 Design and Development, P-840-5.5.1

Section 02 References

a. Normative reference – ISO 9000:2015 Quality Management Systems – Fundamentals and vocabulary.
.
b. Definitions Applicable definitions are included in documented procedures and instructions at par 3.0 to enhance the understanding of the process.

Section 03 Document information

a. Distribution control list

Quality Manual latest revision: Number: _1_

Date of Issue: _____01/02/2024__ Issued by: _____Jim Lowe_____

The status of the quality manual and/or description of changes are provided in the revision status page of this manual.

Controlled copies are issued to:

Copy No. 1 President

Chief Operating Officer

Copy No 2 Chief Financial Officer

Copy No. 3 Quality Manager

Copy No. 4 Operations Manager

The master copy is held by the Quality Manager / Management representative.

This manual is issued and controlled by the Quality Manager / Document Control Coordinator.

All matters or inquiries relating to its contents or usage are to be referred to that individual.

It is the responsibility of all holders of the above controlled copies to:

- Ensure that this manual is read by and available to the personnel under their control.
- Ensure that superseded pages are returned to the Quality Manager / Document Control Coordinator.

Uncontrolled copies of this manual will be identified with the word "uncontrolled" in bold letters across this page

b. Manual revision status

Rev. #	Description of changes	Initials	Date
1	Initial issue of Manual QM-001-A	JC	12/22/2023
2	Approval Release	JL	12/27/2023

- Authority to issue --------- Quality Team Leader / Management representative
- Authority to revise and approve -- Individual responsible for the procedures and the instructions documents contained in the manual.

The table below is used to provide the revision status for procedures and instructions:

Rev.	Date	Section	Paragraph	Summary of change	Authorized by

The signature in the "Authorized by" area in the revision table provided at the bottom of the procedures and instructions indicates the review and the approval for the latest revision to the procedures and instructions.

Revisions are identified by indicating the affected section and paragraph in the revision table.

All pages in the manual bearing dates prior to and including the date of the revision remain valid.

c. Quality Policy – Attachment A-520-001

QUALITY POLICY

Rely Contract Manufacturing Quality Policy is committed to manufacturing and assembling the highest quality products to our existing and growing customer base in an accurate and timely manner. We are committed to ISO 9001 policies and procedures and a culture of continuous improvement. We are dedicated to meet all of the requirements of ISO and we will meet or exceed customer expectations.

QUALITY OBJECTIVES

1. **Defects**: Send out fewer than 5% of products with a defect.
2. **Efficiency**: Efficiency target is to maintain service levels above 100%
3. **Safety**: Have zero recordable safety incidents in the workplace or zero product recalls.
4. **Delivery**: Achieve 90% of on-time deliveries.
5. **Customer service**: Maintain a customer satisfaction rate of at least 90%.

STRATEGIC DIRECTION

VISION

To be the highest quality contract manufacturer in every market we serve. We are committed to meet or exceed customer expectations and to have the highest commitment to quality through the strength of our greatest asset: our people. We are dedicated to maintaining a world class facility that showcases our clients products and demonstrates modern contract manufacturing practices.

MISSION

To become the most highly rated contract manufacturer in Wisconsin. We will do this through maintaining extremely high quality standards, highly skilled and motivated associates and 100% on time delivery

GOALS

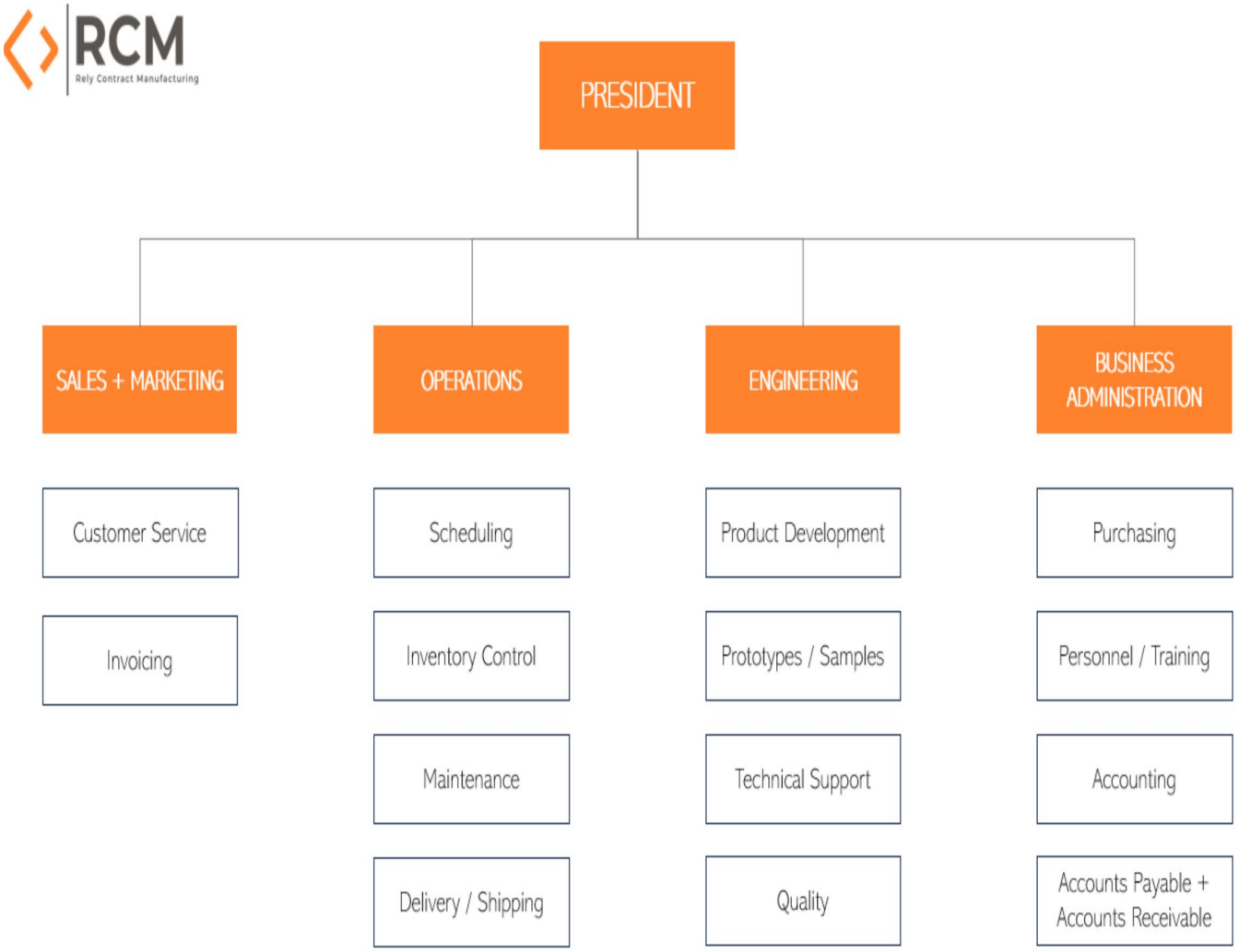
I. ISO 9001 certification
II. An operational system that drives decision-making as low in the organization as possible

Top Management Approvals:

Title: CEO	Name	Kim Korth,	Date 12/27/2023
Title: COO	Name	Katie Malnight,	Date 12/27/2023
Title: Production Manager	Name	Kimmi Roehrborn,	Date 12/27/2023
Title: Business Admin/ CS Mgr.	Name	Tracy Breitzmann,	Date 12/27/2023
Title: VP of Engineering	Name	Jim Lowe,	Date 12/27/2023
Title: VP of Strategy and Scalability	Name	Erin Greenwald,	Date 12/27/2023
Title: CFO	Name	Josh Nissen,	Date 12/27/2023

d. Organization chart – Attachment A-530-001

ORGANIZATION CHART for *Rely Contract Manufacturing*



e. Company Background - Products and Services

Your industry

We are experts at products for a variety of industries including injection molding, plastic, medical equipment, electrical and metal fabrication. We are particularly adept at Transitioning from manual to automated assembly as well as the assembly of electrical harnesses. Another specialty of ours would be out excellent kitting capabilities and the quality inspection services of product that we offer driven by an outstandingly training and constantly excelling team of quality trained associates. Rely Contract Manufacturing Website www.Relycm.com .

Your organization

Rely wants to take the problem jobs and non-core programs off clients shopfloors to allow them to focus on what they are really good at. We have created a sophisticated, state-of-the-art contract manufacturing and packaging facility that can handle a high mix of different types of business and volumes. Driven by robust KPI's and varying degrees of automation, we have created a more stable and highly efficient work environment. We have intentionally focused on becoming experts in areas where most manufacturers are weakest.

f. The Process Flow Diagram – FD-810-001

The process flow chart with steps from the raw materials to invoicing for the product supplied is included in the following page.

The **FD-810-001** Process Flow Diagram represents each step in the manufacturing process and includes other relevant factors associated with the steps.

Process Flow	Relevant Factors	
1 Sources of Materials	Raw materials, products and other components are purchased and received	Approved suppliers, Incoming inspections
2 Hauling, Transportation	Personnel - Manpower Equipment -Trucks	
3 - Existing Operations and Production	Manpower – Laborers Machines – Automation	Quality control – Operator self-inspect
3. a - New Production	(x) New Machines Manpower – Laborers	Training – machines, maintenance Operator self-inspect,
4. Products, services for delivery	Products, Sub-assemblies, Components. Servicing	Sales and Marketing
5. Deliveries to customers	Manpower - Drivers Equipment –Trucks Permits	**6. Income - Invoice for products/services delivered**

Section 04 **Document information** – Form F-750-001

This list of Documented Information covers the ISO standard clauses 4 through 10 and provides the responsibility, approval date, and revision status for the documents.

- The QM designation indicates a Quality Management System Manual.
- The P designation indicates Procedures.
- The WI designation indicates Work Instructions.
- The number following the document numbers listed in the Document column below identifies the clause of the standard that the document is associated with.
- Additional documented information relevant to procedures and instructions is outlined in the spreadsheets of Master Documentation Lists, form F-750-003.

Doc. #	Description	Responsibility	Approve date	Revise date	Revise date
Quality Management System					
QM-001	QMS Manual – Document Information	Quality Manager	1/02/2024		
Clause 4 – Context of the Organization					
P-400	Organizational context	President	1/02/2024		
Clause 5 – Leadership					
P-500	Leadership	President	1/02/2024		
Clause 6 – Planning					
P-600	Planning for the QMS	Quality Manager	1/02/2024		
Clause 7 – Support					
P-710	Resource management	Operations manager	1/02/2024		
P-715	Control of monitoring and measuring equipment	Quality manager	1/02/2024		
P-720	Competence and awareness	Production Supervisor	1/02/2024		
P-740	Communication	Quality Manager	1/02/2024		
P-750	Control of documented information	Document Control Coordinator	1/02/2024		
WI-750-001	Document numbering	Document	1/02/2024		

	system	Control Coordinator			
Clause 8 - Operation					
P-810	Operational planning and control	Operations Manager	1/02/2024		
P-820	Customer related process	Sales, Marketing manager	1/02/2024		
P-840-A	Control of external providers	Materials manager	1/02/2024		
P-840-B	External Supplier Approval	Quality Manager	2/20/2024		
P-851	Control of production and service provision	Operations Manager	1/02/2024		
P-852	Identification and traceability	Operations Manager	1/02/2024		
P-854	Preservation	Operations Manager	1/02/2024		
P-870	Control of nonconforming outputs.	Quality manager	1/02/2024		
Clause 9 – Performance Evaluation					
P-910	Monitoring, measurement, analysis and evaluation	Quality Manager	1/02/2024		
P-912	Customer Satisfaction	Sales, marketing manager	1/02/2024		
P-920	Internal audits	Quality Manager	1/02/2024		
P-930	Management review	President	1/02/2024		
Clause 10 - Improvement					
P-1010	Improvement	Quality Manager	1/02/2024		
P-1020	Nonconformity and corrective action	Quality Manager	1/02/2024		

Sections 05 through Section 10 are intentionally designated as spares.

Section 11 Records Documentation Matrix – Form F-750-002

This section of the Manual contains the Records Documentation Matrix.

- The last column indicates where in the QMS the documents are used.
- A sample of the latest attachment, form, registers and flow diagram is included.
- Additional documented information relevant to attachments, forms, registers and flow diagrams is outlined in the Records table, form F-750-004.

Doc #	Description of document	1st Rev. Date	Last Rev. Date	Used with Manual, Procedure, Instruction
	Attachments			
A-520-001	Quality Policy	P. 8	Manual	QM-001 / P-500 / P-740
A-530-001	Organization Chart	P. 9	Manual	QM-001 / P-500 / P-600 P-740
A-600-001	PDCA guidelines			P-600 / P-740
	Forms			
F-440-001	QMS-Process identification worksheet	12/23	12/23	P-400 / P-600 / P-810 P-851
F-610-001	Risk and opportunity worksheet	01/24	01/24	P-600 / P-1010
F-620-001	Quality objectives planning record	12/23	12/23	P-600
F-710-001	Equipment problem report	12/23	12/23	P-710 / P-715
F-710-002	Resource maintenance record			P-710
F-715-001	Equipment calibration list	12/23	12/23	P-715
F-720-001	Training action plan			P-720
F-720-002	Group training record	12/23	12/23	P-720
F-720-003	Employee training summary	12/23	12/23	P-720
F-720-004	Job description	12/23	12/23	P-720
F-740-001	Comment, suggestion report	12/23	12/23	P-740
F-750-001	List of documented information	P. 12-13	Manual	QM-001 / P-750
F-750-002	Records documentation matrix	This form.	Manual	QM-001 / P-750 P-1010 / WI-750-001

F-750-003	Master documentation lists	12/23	12/23	P-750 / P-740
F-750-004	Quality records table			P-750
F-750-005	Document change request	12/23	12/23	P-750
F-750-006	Document revision checklist	12/23	12/23	P-750
F-750-007	Software inventory spreadsheet	12/23	12/23	P-750
F-810-002	Project planning worksheet	01/24	01/24	P-600 / P-810 P-851 P-910
F-820-001A	Customer Scorecard	01/24	01/24	P-820
F-820-001B	Supplier Scorecard	01/24	01/24	
F-820-002	Production order	12/23	12/23	P-820
~~F-830-001~~	~~Design plan~~			~~P-830~~
~~F-830-002~~	~~Design review record~~			~~P-830~~
~~F-830-003~~	~~Design change form~~			~~P-830~~
F-840-001	Supplier Approval Form	02/24	02/24	P-840
F-840-002	Approved Supplier List	02/24	02/24	P-840
F-840-003	Supplier corrective action request – SCAR	12/23	12/23	P-840 / P-870
F-840-004	Purchase requisition	12/23	12/23	P-840
F-840-005	Purchase order	12/23	12/23	P-840
F-840-006	Business agreement – contract			P-840
F-851-001	Process routing sheet - summary	12/23	12/23	P-851
F-851-002	Process routing sheet - detail	12/23	12/23	P-851
~~F-851-003~~	~~Process validation worksheet~~			~~P-851 / P-852~~
F-851-004	Packing slip / Invoice	12/23	12/23	P-851 / P-854
~~F-851-005~~	~~Service projects log~~			P-851
F-851-006	External property control log			P-851

~~F-851-007~~	~~Project inspection / report~~			P-851
F-852-001	Identification tag	12/23	12/23	P-715 / P-851 / P-852 P-870
~~F-852-002~~	~~Traceability serial number log~~			P-852
~~F-852-003~~	~~Traceability label~~			P-852 / P-854
F-854-001	Storage inspection report			P-854
F-870-001	NCR- Nonconforming report	12/23	12/23	P-870
F-910-001	Production-Monitoring, measuring and analysis	12/23	12/23	P-810 / P-830 / P-840 P-851 / P-852 / P-910 P-1010
F-910-002	QMS-Monitoring, measuring and analysis	12/23	12/23	P-810 / P-910 / P-1010
F-910-003	Production Log	12/23	12/23	P-910
F-910-004	Inspection report	12/23	12/23	P-851 / P-852 / P-910
F-912-001	Customer survey and analysis	2/24	2/24	P-912
F-920-001	Procedure by work area	12/23	12/23	P-920
F-920-002	Internal audit checklist	12/23	12/23	P-920
F-920-003	Audit plan	12/23	12/23	P-920
F-920-004	Audit report	12/23	12/23	P-920
P-930-001	Management review agenda	12/23	12/23	P-930
P-930-002	Management review output report	12/23	12/23	P-930
F-1010-001	Data analysis worksheet	12/23	12/23	P-1010
F-1020-001	Corrective action request-CAR	12/23	12/23	P-870 / P-920 / P-1020
	Flow diagrams			
FD-440-001	Process interaction			P-400
FD-510-001	Business process map			P-500
FD-810-001	Process flow diagram	P. 11	Manual	QM-001 / P-810
FD-850-001	Operations-Production, service			P-851
