STANDARD OPERATING PROCEDURE
(OPERATIONAL PLANNING AND CONTROL)

Organizations Name:	Precision Swiss Products, Inc.	**SOP-8.1-001 Operational Planning and Control Process** Rev: 4
Responsible Person:	Process Engineer	Effective Date: 04/05/22
Related Quality Process:	SOP-8.1.1-001 Risk Management Process	
Related Standards:	AS9100/ISO9001 sections 8.1, 8.2, 8.2.1, 8.2.2, 8.2.3, 8.2.4 and 8.5.6 ISO13485 sections 7.2, 7.2.1, 7.2.2, and 7.5.10	

1.0 PROCESS:

1.0 Process Inputs:

PSP's overall strategic business plan as well as all customer required documents, and those requirements that are not stated by the customer but necessary for the specific or intended use.

2.0 Purpose:

To ensure Precision Swiss Products, Inc. (PSP) has a procedure for reviewing all customer contracts, specifications, drawings, and associated relevant documents in order to provide conforming product, on time to customer and ensure their satisfaction. Through the marketing activities, PSP ensures we continually target a customer base that provides long term future potential.

3.0 Responsibilities

1. Customer Service Representatives (CSR): responsible for the management of this process, ensuring all customer required documents (drawings, solid models, contracts) are received and accurate per the purchase order, all documentation is saved in the correct location and linked to the ERP System where applicable, entering orders into the ERP System and ensuring that is accurate, when necessary assisting the Process Engineer in retrieving any additional information required from the customer for contract review, and shall be the main point of contact for all customer related issues, questions, etc.
2. Process Engineer: responsible for all aspects of this process, ensuring all drawings, specifications, work instructions, and other customer documents have been reviewed for accuracy and the important information transferred into the risk management form as well as the ERP System. Responsible for completing/adjusting the routing for all for purchase orders and communicating if there are any issues. Acting as a backup and assisting with the CSR functions when necessary.
3. Quality Assurance Manager (QAM): responsible for ensuring and following up on all open issues as it pertains to the quality department, reading over quality contracts when help is needed, assisting with all pFMEA's, controlled processes, and working with the customer regarding requests for changes to a controlled process.

4.0 Marketing:

Marketing activities are strategically targeting a customer base that aligns with set expectations as follows:

- Potential of production run parts
- Potential of 1 million dollars a year of business

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- Aerospace, Medical, or Semi-conductor
- Customers that are looking for ISO9001/ISO13485/AS9100 certified suppliers
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Precision Swiss Product, Inc. (PSP) desired customer blend is decided during top management meetings but shall not stray from Medical, Aerospace, and Semi-conductor targeted customers. The desired ratio between new work and repeat orders is 70% repeat and 30% new. If a customer is a good fit, and PSP receives a purchase order, then the customer will be put on the approved customer list.

Every exception to the expectation must be authorized verbally by the CEO or an authorized person.

5.0 Pre-quoting:

Estimating activities are initiated when a request for quote (RFQ) is received.
Requirement reviews and initial risk assessment occurs at this step. PSP does not complete a formal documented risk management form during the quoting stage due to the ratio of quotes requested vs. quotes won. It is not feasible for PSP to complete this on every part quoted.
Quotations/no bid are issued to customers after review.

6.0 New Customer Acceptance:

The credit package is sent out by the CSR's and followed up on by finance

Note 1: This process of reviewing the contract, planning of operations, and customer communication prior to a purchase order being entered into the ERP System is considered PSP's "Gate 1 Process".

7.0 Customer Communication:

Main customer feedback/communication points during Gate 1:

- Notification within 1 business day of receipt of purchase order (soft acknowledgement)
- Official purchase order acknowledgement

The CSR's are the number one gate for communication to customers and mostly occurs through email and phone. They are responsible for sending all enquiries to the team to start the quoting process, forwarding all purchase order contracts that are received from a customer to the appropriate person, and initiate the contract review and risk management process, reference SOP-8.1.1-001 Risk Management. The associated documents regarding product information and requirements from a purchase order contract are received and saved by the CSR and/or requested (if the customer did not send the information).

If there are any changes or amendments to a contract, the CSR's will communicate if we can or cannot accept their changes. Any possible contingencies due to capacity, operational risks, tooling, personnel, etc. are all discussed with scheduling and management and are communicated to the customer when management deems it necessary based off the potential for a nonconformance or late delivery.
If PSP requests or is required to use any customer or external provider property, then PSP shall establish with the customer or external provider and the Gate 1 Team, the requirements for handling, identification, verification, safeguard and storage of their property. PSP ensures that all customer or external provider property is treated with the utmost care.

8.0 Contract Review/Gate 1:

Gate 1 timeframe to process an order:

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- New parts/new revisions: 7 business days
    - This is when PSP receives a new purchase order that has a part PSP has never previously manufactured, or we have previously manufactured this part at a lower revision
- Repeat parts: 5 business days
    - This is when PSP receives a new purchase order that has a part PSP has previously manufactured and there are no revision changes.
- Repeat need review: 3-5 business days (depending on the nonconformances prior or if we have to move machines/work centers and need to consider this like a new part review)
    - This is when PSP receives a new purchase order that has a part PSP has previously manufactured, there are no revision changes, however we have had previous nonconformance's associated with this part, and/or we have not manufactured the part in over three years.
- Assemblies: 10 business days (depending on the complexity and number of components)
- Change orders/up rev's: 5 business days, 10 business days for assemblies (depending on the complexity and number of components)
    - This is when PSP receives a change (qty, price, dimensional, etc.) to an already existing purchase order.

The CSR's are responsible for retrieving all pertinent information from the customer as requested by the Process Engineer, and/or DOO and is reviewed by the Gate 1 Team (Process Engineer, DOO, CSR's, Quality, DOM). Please see Contract Review Checklist (DOC-8.1-002) as a reference for what information the CSR's request/obtain from the customer when applicable.
The contract review results in a determination and assurance of the following:

- PSP has the ability to meet the requirements for the products and services that are specified by the customer including the requirements for delivery and post-delivery activities (where applicable), requirements not specified by the customer but necessary for the specified/intended use (when known), PSP's own requirements, regulatory and statutory requirements, and any changes to a requirement that was previously expressed.
    - Regulatory requirements are identified by reviewing customers quality agreements, purchase orders and terms and conditions. CSR's and PE's are responsible to compare the latest customer revisions/updates against the Customer Requirements Matrix and alerting the Quality Assurance department if there are new revisions of these documents. Quality is responsible to review and ensure PSP is meeting all flowed down regulatory requirements. If PSP does not have a customer Quality Agreement on file that is within the last 5 years, CSR's are to request a new one. Not all customers provide a quality agreement, in which case a note shall be placed on the Customer Requirements Matrix stating such.
- If there are no customer requirements for a purchase order or part, PSP communicates and confirms with the customer that they do not require anything in particular.
- Any training requirements or gaps that need to be filled to ensure performance and safe use, are identified and training assigned during the kick off meeting.
- The processes required for manufacturing (manufacturing, any outside process, in house passivation, cleaning, etc.) are defined and documented which results in the full product realization routing sequence.
- If we have process requirements that we cannot fulfill in house, PSP ensures that the vendor can do the work requested. PSP places controls (critical information/flow down information) throughout the routing sequence notes to ensure it meets customer product requirements. Also, considered "special processes".

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- Any transfer of work (from PSP to a vendor, vendor to another vendor, or vendor to PSP) is controlled, and all risks are identified and managed through the written information in the vendor routing step. Example: shipping/packaging instructions to and from vendor.
- The acceptance criteria that shall be used and at what point in the product realization sequence (selecting statistical process control points (SPC) for key characteristics, verifications, pFMEA's, etc.).
- We have the resources to inspect the processes that we are doing.
- What resources are required to achieve conformity to the product requirements and to meeting on-time delivery goals.
- That we have control over processes to ensure conformity to requirements (ex: inspection points). PSP places inspection routing steps and engineering holds in the routing sequence to prevent the delivery of nonconforming products and services to the customer (incoming inspection, in-process inspection, final inspection).
- All documented information that is necessary is maintained and retained to ensure we have confidence that the routing sequence processes have been carried out as planned and that we can demonstrate the conformity of products to the requirements that were lined out.
- The program management [(kickoff/risk management) planning of process steps/routing sequence)] will enable PSP to meet the requirements at an acceptable risk, within resource and schedule constraints. If there are any constraints during product realization, communication will occur with the customer to alert them of any on time delivery issues or quality issues that might occur.

Note 2:
All the above are outputs and actions of Gate 1 and are controlled, documented and retained through the Risk Management Form saved within the customer folder (for new parts, new revisions, and repeat parts), and within the ERP System estimates and documents tab. When an order is processed through the ERP System, the above-mentioned information is pulled from the estimates and communicated through the job routing sequence, job notes, etc.

If during Gate 1, PSP determines that some customer requirements cannot be met or can only partially be met (delivery date, manufacturing constraint, missing dimensions, etc.), or if any of the requirements changed during Gate 1, the CSR's will communicate the information to the customer, alert them of the possible delay in delivery (when the customer is accountable for the hold) and negotiate an agreement prior to sending an acknowledgement. All customer requirements shall be reviewed and agreed upon by PSP prior to the CSR's sending an order acknowledgement to the customer. This order acknowledgment finalizes the Gate 1 process.

9.0 Activities if Gate 1 Cannot be Closed Within the Allotted Timeframe:

If a line item on a purchase order is past the Gate 1 time frame for repeat, new, new revision parts and aspects of risk management are still open, the CSR shall send out a notification to the customer (including the sales, scheduling, Gate 1 Team) state that the due date might be compromised due to the open issue. This communication shall be retained within the customer folder under Correspondence.

10.0 Changes:

When a change order is sent to PSP, it is the responsibility of the CSR's to identify if the change does or does not affect the product (price change, qty change, etc. vs drawing change, spec change, etc.). If a change is made to the drawing, spec, etc., then it is the responsibility of the Process Engineer(s) to review the drawing, specs, etc., compare them to the previous drawing, and hold a high priority meeting (reference section 2 below).

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1. **Customer change orders that <u>do not</u> affect the product (job pull in/push out):**
    a. These are changes that affect the delivery schedule, but not the product. These changes shall be handled by the CSR. Actions taken:
    b. Communicate to the customer with a receipt of acknowledgment (soft acknowledgement) for the potential change order.
    c. Check with scheduling to see if the change is within PSP's capability based on capacity and resources (whether the change is a pull in or push out, qty change, etc.)
    d. Scheduler will notify the CSR when or not this change order can be accepted
    e. CSR shall inform the customer of the outcome and issue a new order acknowledgement after the customer and PSP reach a conclusion.
    f. CSR shall implement order entry changes to reflect the outcome of the change order request if it is approved. Scheduling will pull the current travelers from the manufacturing floor and redline the travelers with the respective changes per the change order (if qty changes).
2. **Customer change orders that <u>do</u> affect the product (new revisions, red lined drawing)**
    a. These are changes that affect the manufacturing method or the product and shall be handled by the Process Engineer(s). This type of change must be in writing through an email, redlined drawing, or another form of media that show the customer is requesting/approving a change. Actions taken:
    b. CSR communicates to the customer with a receipt of acknowledgement for the potential change order and log this into the PO/Risk Log.
    c. CSR is responsible for filling out the initial sections of the Up-Rev Change Order Check List (top section of first page), and provide the check list, drawing and associated documents to the Process Engineer(s).
    d. The Process Engineer(s) and/or DOO shall review the changes requested, then pull a high priority meeting with the following personnel where applicable: scheduling team (to change travelers), programming (to change/up rev the program), document control (to up rev the FAI/SPC and drawing), CSR's (to ensure the information is recorded to pass on to the traveler), QA programmer (to change/up rev the program), DOM (to provide feedback in regards to changes and to communicate any information to the appropriate department).
    e. Process Engineer(s) will bring to the meeting the original drawing, the changes/redline drawing, and the Up-Rev Change Order Check List (DOC-8.1.2-001). The Process Engineer(s) will alert the team of the changes they reviewed, and open a discussion for if the change is possible or not depending on the change itself and where in the production run PSP is at to decide if there are any cost and/or scheduling impacts. Re-quoting will occur if necessary.
    f. If the change is accepted by PSP, all purging activities and responsibilities are identified on the Up-Rev Change Order Check List (DOC-8.1.2-001) and MRB activities are outline in the Improvement Process (SOP-10.0-001).
    g. A copy of the Up-Rev Change Order Check List (DOC-8.1.2-001) and associated documents will be provided to each member for the meeting by the CSR's and the original copy will be held at the CSR desk for monitoring and retaining the information in a timely manner. After completion, the document shall be saved in O:\..MASTER CUSTOMER FOLDER\4_PURCHASE ORDER\3_UP REV CHANGE ORDER CHECK LIST for the appropriate customer.

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For change approvals on drawings, routing changes, etc. refer to Control of Documented Information (SOP-7.5-001).

11.0 Method of Determining Process Effectiveness:

PSP measures the length of time it takes for a purchase order to be processed through Gate 1. The process is considered effective if all aspects of Gate 1 are completed and an official order acknowledgement is sent to the customer within 5 business days for repeat parts and 7 business days for new parts.
PSP does not account for any purchase orders that are on hold during the Gate 1 time frame due to a customer issue/hold.

12.0 Product Safety:

PSP ensures personnel and product safety during the product life cycle at PSP through ensuring all hazardous materials are stored/and discarded appropriately (if applicable to use).

13.0 Organizational Knowledge:

All organizational knowledge as well as “tribal knowledge” is documented through written procedures, work instructions, discussed during meetings and sent through emails.
When changes are needed, PSP discusses the current process/knowledge and experience that the company has, and what additional knowledge or required updates PSP needs. This occurs during management meetings, Quality Meetings, kick off/risk management meetings, and during the day to day activities at PSP as things arise.

14.0 Records for Procedure:

Records for this procedure are saved within the secured server in the customer folder.

15.0 Process End:

Process ends when an official order acknowledgement is sent to the customer and Gate 1 is considered closed. The outputs are the communicated risks to the manufacturing floor through the ERP System, work instructions, SPC sheets, FAI and job notes.

2.0 REVISION HISTORY:

DOCUMENT NUMBER	Rev	Description of Change	Rev Date
SOP-8.1-001	1	Initial release	08/01/17
SOP-8.1-001	2	Revised sections regarding changes to purchase orders.	03/11/18
SOP-8.1-001	3	Added information for documenting verbal communication with customers.	11/21/19
SOP-8.1-001	4	Reviewed, updated, and removed unnecessary content	04/06/22

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