1.0 Purpose

The purpose of this procedure is to ensure all customers' expectations are met and proper documentation is maintained.

2.0 Scope

The scope of this procedure is to ensure an appropriate approval process is followed for all new customers and existing customer requirement changes.

3.0 Responsibility

President, Sales, Customer Service and Operations Team

4.0 Safety Considerations

Safety is a condition of employment. Employees are not authorized to work in an unsafe manner and are prohibited from harming the environment of the facility or community.

5.0 Materials/Equipment- N/A

6.0 Procedure

New customer or customer requirement change

1. Sales team initiates a *New Product/Customer Form (P13-PR-100-F083)* in the case of a new customer inquiry or an existing customer's requirement change.
2. Sales team and CSR (Customer Service Representative) fill out the form and price sheets.
3. CSR and/or Sales reviews existing SCR's (Special Customer Requirements) to see if one is applicable.
    a. If one is applicable, it is assigned and the new order can be placed.
    b. If the customer requirements are outside of an existing SCR the *New Product/Customer Form* is sent to the Operations team.
4. Operations Team reviews and approves the form as is or makes suggested edits based upon capability and/or efficiency.
    a. If approved, a new SCR is placed on DOC system and sent back to CSR and Sales team so that an order can be placed.
    b. If not approved, concerns are addressed with CSR and Sales team.
        i. If the Operations Team is uncertain or feels the required specifications cannot be met, the Operations Team will develop experiments, capital projects ideas, or make other necessary process changes to evaluate the capability of the new requirements.
5. The final SCR, New Product/Customer Form (s), Manufacturing Experiment (s), and copies of any Capital Projects will be filed together in the cGMP library.
6. The SCR becomes the manufacturing specification for the product.
7. Specifications sheets and/or Certificate of Analysis will be generated by the Operations team, as applicable, based on new SCR requirements.

7.0 Reference Documents- N/A

New Product/Customer Form *(P13-PR-100-F083)*

8.0 Change Information

Document review- updated format using new template and numbering system.