ION LABS	Standard Operating Procedure Product Quotation Process	SOP Number C-605	Revision 0
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Written by/ Date 12/4/21	Reviewed by/ Date 12/20/21	Approved by/ Date 12-22-21	
Title: Product Development & Engineering Director	Title: VP of Supply Chain	Title: VP of Quality & Regulatory Affairs	

1.0 Purpose

This document outlines the general procedure for generating price estimations for prospective products/formulations that may be manufactured or distributed by Ion Labs, Inc.

2.0 Scope

This procedure applies to all prospective products that are intended for manufacture or distribution by Ion Labs, Inc.

3.0 Responsibility

3.1 It is the responsibility of Sales Associates and Account Managers to compile the necessary information for quotation and enter/attach the information into the Product Development module of Batchmaster.

3.2 It is the responsibility of R&D to convert the concepts and information in the Product Development module of Batchmaster into a hypothetical formulation suitable for cost estimation.

3.3 It is the responsibility of Purchasing/Procurement to provide pricing on the materials specified.

3.4 It is the responsibility of Finance to assess the hypothetical formulations and business opportunities and assign a preliminary sale price to the hypothetical formulation/product.

4.0 Definitions

4.1 **Batchmaster** – ERP software in use at Ion Labs, Inc.

4.2 **ERP** – Enterprise Resource Planning

4.3 **RMID** – Raw Material Identification; identification code in Item Master which codifies the necessary testing and product standards the material will comply with, determined

as follows:

4.3.1 RMC: Raw Material Cosmetic

4.3.2 RMD: Raw Material Drug

4.3.3 RMF: Raw Material Food

4.3.4 RMP: Raw Material Pet

4.3.5 RMS: Raw Material Supplement

4.4 **Shall** – Compulsory; necessitated by this procedure

4.5 **Should** – Recommended; generally standard but not compulsory

4.6 **United States Pharmacopeia** – a pharmacopeia relevant to manufacture within the United States, published annually by the United States Pharmacopeial Convention and referenced by Title 21 of the Federal Code of the United States (21 CFR)

4.7 **Food Chemical Codex** – a collection of international recognized standards for food ingredients published by the United States Pharmacopeial Convention

4.8 **Item Master** – the master list of physical inventory items

4.9 **FIFO** – First In First Out

4.10 **MOQ** – Minimum Order Quantity

4.11 **COM** – Customer Owned Material

4.12 **Direct Labor** – labor, typically paid hourly, involved directly in converting raw materials to finished goods; generally, time spent by machine operators in processing operations

4.13 **R&D** – Research and Development

5.0 References

5.1 C-601, SOP, New Product Approval Process

5.2 C-603, SOP, New Product Realization Process

6.0 Procedure

6.1 Quotation Information Entry

6.1.1 A product quotation is initiated by generating a new Project Identification Number in Batchmaster Product Development. The Project ID is associated with all necessary information to adequately formulate and quote the desired product. All necessary information shall be either input into Product Development or attached to the Project ID.

6.1.1.1 Necessary information to be populated includes, but is not limited to:

6.1.1.1.1 Customer*

6.1.1.1.2 Business Partner Name*

6.1.1.1.3 Customer Address Information*

6.1.1.1.4 Account Manager

6.1.1.1.5 Project Description

6.1.1.1.6 Product Class

- Dietary Supplement
- Cosmetic
- Pet Product
- OTC/Drug

6.1.1.1.7 Product Form

- Powder
- Liquid
- Liquid Capsule
- Capsule-in-Capsule
- Coated Tablet

- Uncoated Tablet/Chewable
- Capsule
- Softgel
- Gummy

6.1.1.1.8 MOQ

6.1.1.1.9 Target Price

6.1.1.1.10 Unit Dose Quantity per Serving (Qty/Serving)

6.1.1.1.11 Servings per Container (Servings/Container)

6.1.1.1.12 Trademark Requirements

6.1.1.1.13 Special Claims

- Halal
- Kosher
- Vegan
- Gluten Free
- Vegetarian
- Organic
- Non-GMO (not bio-engineered)

6.1.1.1.14 COM Materials

6.1.1.1.15 Product Testing Standards

6.1.1.1.16 Packaging Configuration (type of container, closure, required specifications, etc.)

6.1.1.1.17 Supplement Facts Panel Example or Active Ingredient Formulation

6.1.1.1.18 Excipient Limitations

***Note**: A Business Partner may be added to Batchmaster and this information may be auto-populated from the BP Code.

6.1.2 The Project ID status is changed to "Request for Formula Development" in the Product Development module. This populates the quotation on the R&D Dashboard.

6.2 Hypothetical Formulation

6.2.1 R&D Formulators follow a FIFO pattern unless instructed to do otherwise by the R&D Manager, Executive Management, or under special circumstances for which the formulator is made aware.

6.2.2 General Formulation

6.2.2.1 The formulator reviews the necessary information populated in the Product Development module. If any information is missing or if the requested concept is immediately deemed unsuitable for manufacturing for whatever reason, the formulator will change the status in Product Development to Quotation Needs Modification and notify the Account Manager of the reason(s). If the product concept is suitable for manufacturing, the formulator will generate a hypothetical formulation in Physical Property Analysis.

6.2.2.1.1 Populate "Project ID" and "Formula" with the Project ID number.

6.2.2.1.2 Add a description of the formula that mimics the description in Product Development.

6.2.2.1.3 Populate the product type, minimum desired order quantity, and unit dose count per finished good unit.

6.2.2.1.4 Add the customer's desired active ingredients and ensure that the potency and overage fields are correct to the intended formulation. Utilize items in Item Master if available. If an ingredient is to be quoted that does not yet exist in Item Master, populate the Item Code with NA1 or other unique (within the formula) moniker and a suitable description in the Item Description field.

Note: Do not add new items to Item Master during the hypothetical quotation process.

6.2.2.1.5 Add a hypothetical excipient profile that is suitable to produce the customer's desired end product. If excipients are added that do not yet exist in Item Master, follow the same Item Code method described in 6.2.2.1.4.

6.2.2.2 After the hypothetical formulation is complete, utilize the risk tab to provide a categorized risked assessment:

6.2.2.2.1 Risk 1: describes hypothetical formulations which are likely to process either exactly as formulated or with minimal modification. There is no concern with things such as capsule fitment, tablet hardness, solubility, etc.

6.2.2.2.2 Risk 2: describes hypothetical formulations which are likely able to be processed, but for which the hypothetical formulation may not work. Thus, the product will require development.

6.2.2.2.3 Risk 3: describes hypothetical formulations which may work, but will either require extensive development or new information to make a better determination.

6.2.2.3 In addition to the categorized risk assessment, the formulator shall include a small editorial describing foreseen issues, notes, and other relevant information to the development and processing of the hypothetical formulation. Finally, a blending recommendation and process speed estimation should be included if it may be reasonably estimated.

6.2.2.4 Hypothetical formulations designated for peer review remain in this status until the review takes place.

6.2.2.5 Formulations to be sent to Purchasing are designated the status of "Request Price Approval".

6.2.3 Formulations for quotation may be peer reviewed or immediately sent to Purchasing for costing. The determination is based on circumstances and direction from Management. Formulations are designated the status of "Formulation Complete" in Product Development. The hypothetical formula is populated into the Base Formula field in Product Development.

6.2.4 Hypothetical formulation designated for peer review remain in this status until the review takes place.

6.2.5 Formulations to be sent to Purchasing are designated the status of "Request Price Approval", which populates the Project ID on the Purchasing dashboard.

6.3 Purchasing and Price Approval

6.3.1 Buyers follow a FIFO pattern unless instructed to do so otherwise by the Purchasing Manager, Executive Management, or under special circumstances for which the Buyer is made aware.

6.3.2 The Buyer reviews the necessary information populated in Product Development. If any information is missing, the Buyer will change the status in Product Development to "Quotation Needs Modification" and notify the Account Manager of the reason(s).

6.3.3 Packaging Addition

6.3.3.1 The Buyer opens the Project ID in Product Development and right-clicks to open the selection menu, then selects Packaging Details.

6.3.3.2 Packaging information populated under the development tab of Product Development is populated within the Packaging Details module. Packaging details shall be comprehensive within the limitations of the information provided within Product Development, but Item Codes need not be utilized if matrix costing is to be implemented. If matrix costing is not to be implemented, the Item Codes should be utilized so standards costs may be applied.

6.3.3.3 The packaging details should be added to the Project ID with attention paid to the Project ID Revision Number.

6.3.4 Purchase Price Approval

6.3.4.1 The Project ID is opened in the Purchase Price Approval dashboard.

6.3.4.2 Packaging may be matrix costed. Packaging may also utilize standard cost if absolute accuracy is required for the quotation. Matrix costing is maintained by the Purchasing department. The cost of packaging, if not standard cost, shall be added to the Purchase Price Approval dashboard.

6.3.4.3 The raw materials entered into the formulation by R&D should automatically populate the Purchase Price Approval dashboard. Formulation ingredients for which an Item Code exists should utilize standard costing if available. If standard costing is not available, of if the ingredient does not have an applicable item code, the Buyer should obtain a material quotation from a suitable vendor. This cost should be entered with attention to impacts from freight.

6.3.4.4 If an MOQ is established for the material's vendor, it should be entered into the Purchase Price Approval dashboard.

6.3.4.5 Once all pricing has been entered into the Purchase Price Approval dashboard, the status should be changed to "Approved".

6.3.5 Once the purchase price is determined and approved, the Buyer shall generate a cost sheet by right-clicking in the Purchase Price Approval dashboard and selecting Product Cost Sheet. This will generate a Crystal Report which may be saved in PDF format. The Buyer should email the cost sheet and freight estimation to Finance for final costing.

6.3.6 Once the cost sheet has been sent to Finance, the Buyer shall change the product development status to "Purchase Price Approved".

6.4 Costing

6.4.1 Finance shall review the product cost sheet, formulation risk assessment, requested minimum order quantity, etc.

6.4.2 Finance shall use operational modeling to approximate required direct labor (including cleans and changeovers) and overhead to produce the order size requested.

6.4.3 Finance will apply a required profit margin to determine the final unit price at the specified order quantities. The final minimum sale price shall be communicated to the Account Manager.

6.5 New Product Approval

6.5.1 The account Manager obtains approval from the VP of Sales and Business Development (or designee) to onboard a new product based on the completed hypothetical formulation quotation.

6.5.2 The Account Manager obtains credit approval and terms from Finance.

6.6 Refer to SOP C-603 New Product Realization Process and SOP C-601 New Product Approval Process for procedures on converting the approved quotation to an official GMP product.

7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	12/11/21	New procedure.	N/A	C. Fryman