SOP Title:	**Using the Part Number/Master Specification Program to Establish Raw Material Part Numbers and Master Specifications**
SOP Number:	**21903**
Revision:	**08**

TABLE OF CONTENTS

1. PURPOSE

This procedure provides instruction on using the Part Number/Master Specification (PN/MS) software program for establishing or revising Part Numbers and Master Specifications for raw materials and components.

2. SCOPE

This procedure is applicable to Biopharmaceutical Development Program (BDP) personnel who will initiate or revise Part Number requests and establish specifications for raw materials and components.

NOTE: Refer to **SOP 21902 - Requirements for Establishing Part Numbers and Specifications for BDP Components and Materials** for assistance in completing the Part Number and Master Specification forms.

3. RESPONSIBILITIES

3.1 Area Program and Technical Director, BDP

- Defines the procedure.

3.2 BDP personnel

- Initiates Part Number (PN) Requests and determining the Master Specifications (MS).
- Completes the Part Number and Master Specification Request Forms (Attachments 4 and 5) in their entirety and obtaining approvals.

3.3 BDP Manufacturing

- Using the PN/MS program, review and approves PN and Ordering Information found in the Part Number Request and Part A of the final Master Specification. This includes the PN description, product contact/sterile specifications, shelf life and any other information fields found on the Part Number Request tab. Additionally, order quantities/catalog number(s) found on the Order Info tab are reviewed.
- Verifies that duplicate PNs are not established.

3.4 Biopharmaceutical Process Analytics / Quality Control (PA/QC)

- Using the PN/MS program, review and approves the MS as found in Part B of the final Master Specification. This includes COA/COC and COO review (attached as appropriate) found on the Ordering Info tab. COA testing and In-House testing requirements and any other fields found on the Master Specification tab.
- Provides guidance on applicable In-House testing with regard to current BDP resources.

3.5 Biopharmaceutical Quality Assurance (BQA)

- Reviews and approves Part Number Requests and Master Specifications.
- Manages the approved Part Number/Master Specification form and routing it to the requestor and approvers.
- Records approval of the Part Number/Master Specification form in the Part Number/Master Specification program to permit the information to be automatically uploaded into the pcMRP database.
- Uploads the approved form within the Part Number/Master Specification Program.
- Provides Quality oversight of this procedure.

3.6 Biopharmaceutical Quality Assurance Documentation (BQAD)

- Maintains archive copies of PNR/ MS documents

4. ABBREVATIONS

- BQA – Biopharmaceutical Quality Assurance

- PA / QC – Process Analytics / Quality Control
- BQA – Biopharmaceutical Quality Assurance
- COA – Certificate of Analysis
- COI – Certificate of Irradiation
- COO – Certificate of Origin
- MMIC – Materials Management and Inventory Control
- MS – Master Specification
- MSDS – Material Safety Data Sheet
- PN – Part Number

5. OVERVIEW OF THE PROCESS

5.1 Adobe Acrobat 10.0 Standard or Professional is required to have full use of the functions of this program.

5.2 A request for a Part Number and Master Specification is initiated by using the Part Number/ Master Specification program located at H:\BDP_database\partspecs\prg\parts.accdb. This is a Microsoft Access program that allows information to be entered into a form electronically, review of entered information and generation of printed documents for final signature.

5.3 The required information is entered for the Part Number and Master Specification (if required) and routed electronically for review.

5.4 If the request is an A, E or F item, the information is sent for review and approval to BQA only. If a Master Specification is included (needed for B, C and D items), the documents are first routed to PA/QC for review.

5.5 Any BQA or PA/QC comments are incorporated into the form(s) by the requestor. When the information has been approved by the reviewers, BQA sends a hard copy of each form to the requestor for signature. The requestor sends the signed copy back to BQA and it is routed to PA/QC and BQA for signature(s).

5.6 When the approved signed document is received in BQA, the following will occur:

5.7 The approval is recorded, prompting the Part Number/Master Specification program to automatically send an e-mail to the requestor, PA/QC and MMIC.

5.8 The information is automatically uploaded into the pcMRP database. The database may be accessed at \\fr-s-BDP-bms-db\pcmrpw\pcmrpw.exe (**SOP 20309 - Ordering Inventoried Materials Using the pc/MRP Inventory System**)

5.9 BQA scans the approved document(s) within the Part Number/Master Specification program. The scanned approved document can be accessed by selecting “Get Approved PNR/MS Scans” within the program.

5.10 The original is placed in the Part Number folder in the documents room for permanent storage in BQA Archives. This hand-signed form is the GMP controlled document.

6. ENTERING A NEW RECORD

NOTE: Refer to Attachments 1, 2 and 3

6.1 To initiate a request for a new Part Number, open the program located at H:\BDP_database\partspecs\prg\parts.accdb

6.2 The first screen (see Figure 1 below) will have a menu with the following selection of options to choose from: “View/Revise Approved PN/MS Information,” “Create New/Edit Unapproved PN/MS,” “PN/MS Information Search,” “Record Approvals (BQAD USE ONLY)”, “Get Approved PNR/MS Scans”, “Check Status”, “Export Vendor List” and " Obsolete Part (BQA Use Only)”.

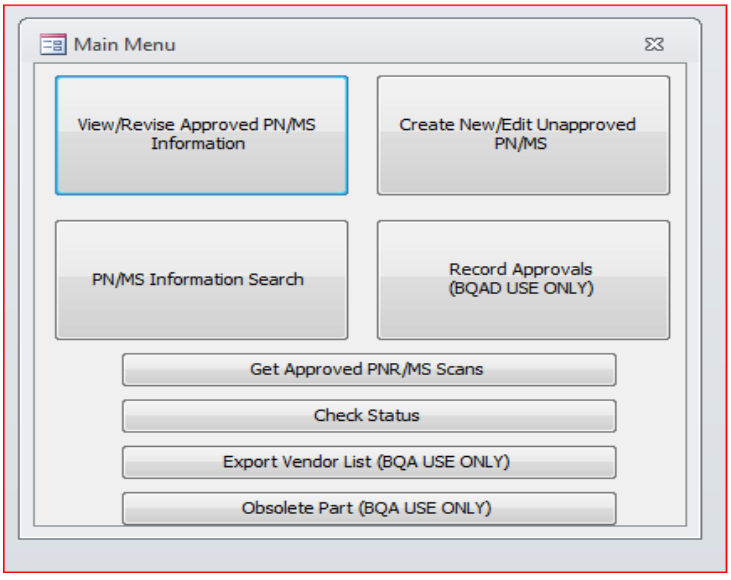


Figure 1

- **View/Revise Approved PN/MS Information** is used to view approved part numbers and make a revision to an approved Part Number/Master Specification.
- **Create New/Edit Unapproved PN/MS** is used to establish a new part number and specification (if required). A revision may be made to an unapproved record from this screen. An unapproved part number may also be any part number that has not been entered into the Part Number program before.
- **PN/MS Information Search** is used to find part numbers based on search criteria with the option to export the information to an Excel file.
- **Record Approvals (BQAD USE ONLY)** is used by BQAD to record the final approval of a part number and/or specification in BQA, pcMRP and the PN/MS Program.
- **Get Approved PNR/MS Scans** is used to retrieve a copy of the current approved Part Number form and/or Master Specification without having to open a record.
- **Check Status** is used to check the approval status of a part number.
- **Export Vendor List (BQA USE ONLY)** is used by BQA to export pre-selected fields from the PN/MS database to an Excel spreadsheet.

6.3 Obsolete Part (BQA USE ONLY) is used by BQA to obsolete pre-selected part numbers from the PN/MS database. Select the “Create New/Edit Unapproved PN/MS” button. On the next screen click on the “NEW” button next to the Part Number field on the upper left of the screen if a part number does not exist. A part entry dialog box will be displayed. The box has a pull-down menu for selecting the Class and a Description. Enter the requested information and select OK.

6.4 Once the information is entered from Section 6.3, the system assigns a new Part Number at revision level "0" and stores the Class and Description.

NOTE: It is helpful to write down the part number for future reference before closing the record.

6.5 A screen is displayed containing two tabs at the top. The first tab is for Part Number request information and the second tab is for Ordering Information (See Attachments 1 and 2). If B, C or D is entered for the inspection level in the Part Number screen, a third tab will appear for Master Specification information (See Attachment 3). All fields are initially empty except for the Part Number, Revision, Description and Class. Only the Part Number field is locked and cannot be changed.

The required information is entered into each screen. When the form is closed without submitting it, whatever information was entered is saved and may be recalled later for additional editing. The following rules apply:

- The description cannot be identical to an existing description within the same class.
- The Abbreviated Description field will only accept a maximum of 15 characters.
- If level B, C or D is selected, a COA is required for each manufacturer listed.
- If level E is selected, a NDC number must be specified.
- If level F is selected, a COA is required for each lot received, but a sample COA may not be available when the PNR is being submitted. Attach if available, but it is not required.
- If the COO-eligible question is "Yes," a COO is required for each manufacturer listed.

NOTE: If a Usage, Sample Size, Retention Sample Size, or Manufacturer is entered that is not already in the list, it will be added automatically to the drop-down box as a selection by the program.

6.6 Proceed to the Ordering Information tab to complete the required Information. To enter a Manufacturer/Size, select the Add button in the Ordering Information field. A window will appear to enter the Manufacturer, Units, and Catalog Number. Select “OK” to save the information. All fields must be filled in. If more than one manufacturer is desired, continue to enter information into the pop-up window (this window will continue to pop-up each time OK is selected). When the fields for Manufacturer and Size populate the pcMRP suffix will be assigned.

6.6.1 In some cases when a custom or special order is placed with a manufacturer and there are multiple sizes or strengths, the manufacturer may not assign a unique catalog number to each item. If this is the case, each item when entered into the PN/MS program must have a unique catalog number.

Assign a suffix to the catalog number for each item when entering the information into the request form.

Example: Ad5 2 X 1011standard and Ad5 5 X 109 standard were issued catalog number 79993 by the manufacturer. Suffix -1 and -2 or other appropriate designation should be added to the manufacturer catalog number.

6.6.2 Any complex, multi-component material (i.e. – dehydrated tissue culture media) should be ordered in quantities below 15kg if at all possible to enable the mixing of the material prior to QC sampling for release. If there is no alternative sizes available, a comment will be made in the master specification that a sample thief will be used for sampling the material.

6.7 When all information in Section 6.6 has been entered, select Cancel to continue filling out the rest of the Order Information form. Selecting Cancel will only remove the pop-up box. It will not delete any entered information.

6.8 In the bottom section of the Order Information form, select from the drop-down menu the release requirements set for each manufacturer. If the part is a B, C or D level select the COA, COO and MSDS (if required) buttons to electronically add the document. Attached files may be verified by clicking on the View button and must be in pdf format.

NOTE: COA's, COO's and MSDS's need to be scanned as an electronic copy if a pdf file is not already available. These documents are scanned to a location of the requestor's choice using one of the BDP scanners. When the COA, COO and MSDS buttons are selected, a screen will open to locate the file path of the scanned document.

6.9 If level B, C or D was selected in the Part Number form, complete the Master Specification form.

6.9.1 Complete the information in the 9 fields at the top of the form. Refer to SOP 21902 - Requirements for Establishing Part Numbers and Specifications for BDP Components and Materials to complete this form.

6.9.2 To enter COA tests, select the Add button next to the COA Tests field.

6.9.3 Enter the test and criteria in the pop-up box that appears when Add is selected. When all COA tests are entered select the Cancel button. Selecting Cancel will only remove the pop-up box. It will not delete any entered information.

NOTE: To add a symbol or character to a test field right click on the mouse and select Character Map. Use the copy and paste functions to add the selection. Characters such as "/, \, [,]" cannot be used in the program.

6.10 To enter an In-House test, select the Add button next to the In-House Tests field. Select the test from the drop-down menu. If the test is not listed, it may be typed in. If the test is selected from the drop-down menu the SOP number will automatically be added to the SOP field. Type in the release criteria for the test.

6.11 When all tests are entered select the Cancel button to continue. Selecting Cancel will only remove the pop-up box. It will not remove any entered information.

6.12 When all the information has been entered select the Submit button to save the information and complete the electronic approval process. The name of the requestor and the date will be linked to the request. If information is missing a pop-up box will appear to indicate what information is still required before the record can be submitted.

6.13 The electronic document will then be routed via email to Manufacturing Managers and PA/QC for review and approval (A, B, C or D level items only). If the requested part is an, E or F item, or N/A, it will be routed to BQA only for review and approval. If Manufacturing and PA/QC approve the document, it is routed electronically to BQA for review and approval.

6.14 If the record is not approved by Manufacturing, PA or BQA, an email is sent back to the requestor with comments and/or requested changes. Refer to Section 9.0 for making revisions.

NOTE: Reviewers may print the forms to review them by selecting the Create Forms button.

7. FINAL APPROVAL

7.1 When the document is electronically approved, BQA creates a digital copy of the part number/master specification and any associated supporting documents for approval signature using a PIV card or other equivalent credential verification method.

7.2 When all reviewers have signed the documentation, it is sent to BQA for processing and filing.

8. RECORDING THE APPROVED VERSION

8.1 The signed approved Part Number and the Master Specification form are uploaded to a file server location.

8.1.1 The Part Number Request file will include the part number, revision page (if applicable), COA, COI, COO and/or other supporting documentation.

8.1.2 The Master Specification form is scanned separately from the part number request and does not include any attachments.

8.2 After uploading the documents, BQA will enter the Part Number/Master Specification program and select “Record Approvals (BQAD USE ONLY)” from the main menu. A list of approved records will be displayed in the pop-up window. BQA will select records that have been received and selects OK, BQA links the Part Number Request and the Master Specification.

8.3 The Part Number/Master Specification program records the approved version as the current version and updates the pcMRP database with the information.

8.4 The PN/MS Program will notify the originator of the document, Manufacturing, PA/QC and MMIC by email that the document has been approved and will supply a link to the location of the scanned copy.

8.5 BQA will place the signed document in the Part Number folder located in BQAD archives for permanent storage.

9. REVISIONS

9.1 Revising a Rejected New Request

9.1.1 Open the Part Number/Master Specification program and select the Create New/Edit Unapproved PN/MS button. The record will be presented with a “Re-Submit” button.

9.1.2 Edit the information and select the Re-Submit button. The document will route again for electronic approval as in Section 6.13. Revising an Approved Record

9.1.3 Open the Part Number/Master Specification program and select the “View/Revise Approved PN/MS Information” button.

9.1.4 Enter the Part Number in the Part Number field and press ENTER. The form will be populated with the approved part information.

9.1.5 Press the Revise button in the upper left corner of the form. A new, editable record is created with the revision number incremented to the next sequential number.

9.1.6 When all revisions are completed select the Reason for Revision/Revision Summary button at the bottom of the screen. A revision box will appear to record the revisions made. Record what revisions were made in the lower section of the box. Once the revisions are recorded, click OK. The Submit button may now be selected to route the document for approval. The document will route for electronic approval as described in Sections 6.12 to 6.13.

NOTE: (For all revisions)

- Buttons are available on the upper left side of the record screens to view the approved part number form or master specification form.
- If the record is closed without submitting, the edits are discarded and the record remains in its previous state.
- Upon re-submission, all previous reviews and rejections are rescinded and the review process starts over as specified in Section 6.12 to 6.13.
- If a manufacturer is removed, the size information for that manufacturer will remain in the size field. It cannot be removed by the requestor.
- For B, C and D level items the COA, COO (if required) and MSDS (if required) will need to be re-scanned if the revision being made is a reflection of a change in one or more of these documents. If the revision was not done previously in the PN/MS Program all supporting documentation must be scanned in again.
- To change the order of the manufacturers, select the Up or Down buttons.
- If the record was initiated previously by someone other than the person editing the record, the person who performed the most recent previous edit to the current session is notified by email that the information has been changed.

10. CLONING THE RECORD

In some instances, a series of raw materials may vary only slightly. An example of this would be color, material of construction or description. To save time entering all the information for each part a record may be "cloned" so that only the difference between each item is changed in the cloned record. Cloned records must be in the same class as the original part number.

10.1 To reproduce (clone) a record, use the Clone button available in the Create New/Edit Unapproved PN/MS screen or the View/Revise Approved PN/MS Information screen on the lower left side of the record.

10.2 When all information is entered for the new or revised part number, select the Clone button. A new record will be generated with the next available part number.

10.3 Enter the information. If more than one cloned record is needed continue to select "Clone."

10.4 As each record closes when it is submitted for approval the previous cloned record will appear. Each record can be submitted when completed or all records may be completed first and then submitted.

NOTE: Record the PN of each record for future reference before closing the screen.

11. VIEWING APPROVED PART NUMBER/MASTER SPECIFICATION INFORMATION

11.1 Open the Part Number/Master Specification program and select the "View Approved PN/MS Information" button.

11.2 Enter the Part Number in the Part Number field and select Enter. The form will present the information on the approved Part Number. If the Part Number entered has not been approved using the PN/MS program a message will be displayed "Approved information does not exist".

11.3 To view the scanned copy of an approved part number and/or master specification they may be accessed by using the main menu button labeled "Get Approved PNR/MS Scan".

12. SEARCHING FOR AND EXPORTING PART NUMBER INFORMATION

12.1 Open the Part Number/Master Specification program and select the "PN/MS Information Search" button.

12.2 A pop-up window will appear with search criteria for Part Number, Description, Manufacturer, Manufacturer's Part Number, Class and Inspection Level.

12.3 Enter the information for the search into the field(s) and click OK.

12.4 The program will display a list of matches, containing the search criteria and number of records returned. The list itself consists of the Part Number, Description, approved revision number and pending revision number. The current approved revision and pending revision (if the document is being revised) may be viewed by selecting the corresponding buttons on the right side of the list.

NOTE: If the part number was initiated or revised through the PN/MS Program the complete information will be available. If the part number was initiated or revised prior to the initiation of the Part Number program, only partial information may be available. If this occurs the information on the part is available by looking at the scanned copy on BDP Public. The search field is not linked to existing scanned documents.

12.5 If only OK is selected in the search window a list of all the Part Numbers will appear.

12.6 The list of Part Numbers that result from a search may be exported to an Excel file by selecting the Export button at the bottom of the screen.

13. REFERENCES AND RELATED DOCUMENTS

Document Number	Title
21902	Requirements for Establishing Part Numbers and Specifications for BDP Components and Materials
20309	Ordering Inventoried Materials Using the pc/MRP Inventory System

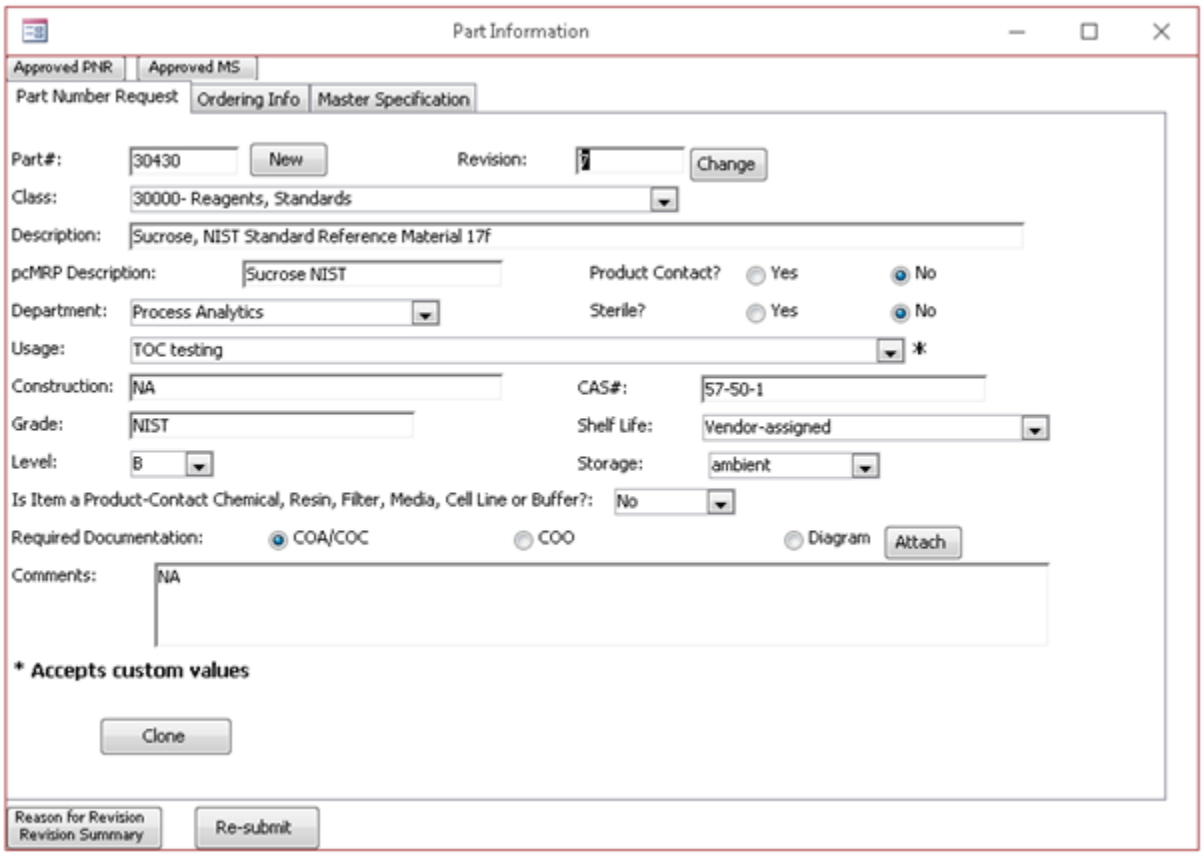
14. ATTACHMENTS

Attachment 1 Part Number Screen

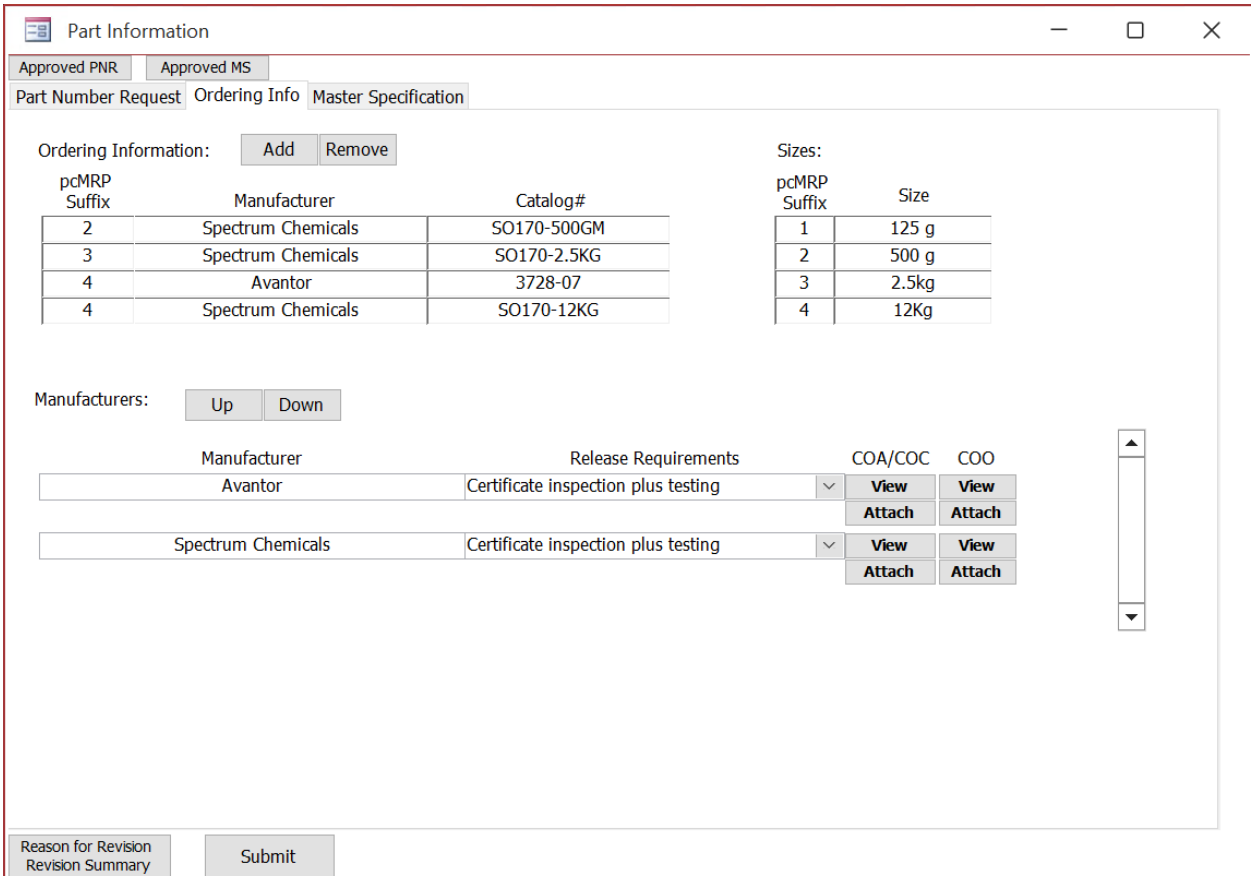
Attachment 2 Ordering Information Screen

Attachment 3 Master Specification Screen

Attachment 1 Part Number Screen



Attachment 2 Ordering Information Screen



Attachment 3 Master Specification Screen