

# RHÔNE-POULENC RORER

## Software Requirements Document

VALIDATION TEAM APPROVAL	
Signatures: <i>Your signature below indicates acceptance of the proposed plan.</i>	Date
Manager, Computer & Control Systems Validation	
Project Leader, IS - Systems and Programming	
Manager - Plant Services, Barcroft	
PRISM Project Manager, Barcroft	
Manager PPIC, Barcroft	
Quality Control Supervisor, Barcroft	
Purchasing Coordinator, Barcroft	

Software Requirements Document

**Table of Contents**

**Background .....3**

**Objective.....3**

**Description of Organizational Function .....3**

**Description of Functional Requirements.....4**

**Lot Control .....4**

**Product Specification Information .....4**

**Lot Recall/Trace.....4**

**Customer Specification Information .....5**

**Customer Specification/Product Characteristics/Available**

**Inventory .....5**

**Purchasing .....5**

**Warehouse Management / Inventory Management.....6**

**Drum Accountability.....6**

**Financial Reporting.....7**

**Security .....7**

**Database .....7**

**Platform / Technical.....7**

**Interfaces .....8**

**Information Retrieval .....8**

**Overall System Consistency.....8**

**Revision Control.....8**

## Background

The Fort Washington Facility recently embarked upon an implementation of the PRISM Software Package. This software is marketed by MARCAM and will reside on an AS/400 located in the Fort Washington Facility. As part of this project it was expected that the Barcroft personnel would also be provided access to the PRISM Software on the same AS/400.

Fort Washington recently has taken the position to treat Barcroft as though they were any other supplier. This changes the scope for the Barcroft part of the Ft. Washington Project. It alters the degree to which Barcroft will need to be involved in the Fort Washington project.

Barcroft is currently running their operations with a significant number of manual processes. Access to information is also through manual paper tracking systems. A local area network has recently been installed and became operational December 6, 1993. This will begin the automation process at Barcroft.

The money originally placed into the Fort Washington IAR to accommodate Barcroft access to PRISM will be used to provide the Barcroft facility with Inventory Management, Warehouse Management and Purchasing capabilities through the PRISM system.

## Objective

It has been determined that PRISM will be used at Barcroft. Therefore, the objective of this document is not to select the software but to describe the short term tactical needs for the Barcroft Facility in the areas of Purchasing, Inventory Control and Warehouse Management.

These areas will be addressed first (Phase I) and will be followed by a Phase II to address the Manufacturing, Planning, etc.

This document will also be used to measure the effectiveness of the PRISM software when its functionality is compared to Barcroft's requirements.

## Description of Organizational Function

The Barcroft Facility is located in Lewes, DE. The facility provides raw material for the manufacture of Maalox suspension and tablet formulations for the Consumer business. The Barcroft facility is the single source of these raw materials and ships directly (or through their Milford warehouse) to the Ft. Washington Plant.

In addition, Barcroft provides these same materials (and others) for sale to International RPR affiliates as well as domestic and international third party customers.

As a result, the ability to manage inventory to the best advantage of RPR-Barcroft as well as appropriating raw materials to produce these products at the best price possible is key to the continued success and growth potential for this manufacturing plant.

## Description of Functional Requirements

### *Lot Control*

As the system captures, maintains and manages inventory information, data describing the associated Lot Number and Quality Control Status must be maintained in the system with proven integrity. Since the FDA scrutinizes the Pharmaceutical Business, Lot Control is necessary to comply with FDA's GMP regulations as well as internal RPR standards and guidelines. Subject system must be able to consistently provide adequate Lot Control. The system must be able to be configured such that UNIQUE Lot numbers are required during Lot number creation. The system must be able to prohibit/allow use of materials based on QC status and expiration date. QC status must be assignable at the drum/container level. The mechanism for assigning status should allow individual drum/container assignments, or whole lot assignments in a single transaction.

### *Product Specification Information*

The Barcroft facility produces its material by way of a continuous flow process. As a result product characteristics vary. This diverse information must be captured within the system. The ability to subsequently access product [inventory] utilizing these characteristics must also be present.

This is particularly important as each third party customer's specifications can vary. The ability to efficiently locate the appropriate product [inventory] to match customer specifications is key.

### *Lot Recall/Trace*

The system must be able to provide full lot trace and recall capabilities for those products with lot trace requirements. This is key functionality for the Pharmaceutical industry and is important when meeting FDA regulations. FDA audits may require this information and the ability to locate it quickly and with consistent accuracy and completeness. The system as part of the Lot Recall should facilitate the reconciliation process when inventory for a specific lot is in various stages. The product may have been distributed to the Milford Warehouse, Customers (Third party or RPR), still be in the manufacturing area or warehoused at Barcroft (waiting for distribution). System must be able to effectively perform Product Recalls by Lot, Product, Date (Date Range) or combination of above. Lot tracing must be able to report both all lots made from a given material and all materials that were used to make a lot. The tracing must be able to progressively step through multiple generations of materials/lots.

## ***Customer Specification Information***

Fort Washington, RPR International Affiliates, International and Domestic Third Party are all customers receiving Barcroft produced product. These customers have different needs and therefore different specification requirements. The system must provide a place in which to store information relative to customer / product specification information.

## ***Customer Specification/Product Characteristics/Available Inventory***

Once the system provides a place to store Customer Specifications (or requirements information) and the product [inventory] characteristic(s) information, the key capability that must be present is the ability to locate available inventory that meets the Customer's Specifications.

Since it is not the position, or the objective, of this project to provide an Order Management system, at this time, it is believed that to completely fulfill these requirements it may necessitate the purchase of an Order Management System. Some aspects of the requirements, however, will be met within the installed software, others will not. It will be through SOPs or the continuation of existing manual processes that the shortfalls will be addressed. It is important to describe the requirements however so that when developing the SOPs these requirements can be met.

## ***Purchasing***

The Fort Washington Facility has installed PRISM. The planning modules are being used to determine raw material demand. These requirements become Barcroft demands. The system must be able to accept (an order) into the system to represent these material requirements. There must be one inventory. Therefore it is an expectation that when a receipt against a PO occurs that the inventory is immediately updated. However, it is key that the status of the inventory be configurable, in other words, RPR(Barcroft) will decide by item number/supplier combination what status the material will carry when received into the system.

System must effectively portray Cash Flow (Projections) and Purchase Price Variance information.

It is key that the ability to monitor Vendor Performance is provided. Material rejection rate(s) must be captured especially as they relate to GMP [FDA] controlled materials and/or high volume or high cost items.

The System must provide the ability to inquire about purchases by various selection criterias. Some examples would be: by date, by date range, by product, or by buyer. System must be able to control purchase of materials from only approved suppliers.

## ***Warehouse Management / Inventory Management***

The Barcroft Facility has warehousing facilities. However, these are not adequate. The Milford Warehouse (also located in Delaware) is used for storage of Feed Stock, Finished Goods and Intermediates in addition to the Barcroft facility. Due to this fact, the system must be able to facilitate the creation of two Warehouse entities that easily interact with one another. Material movement between the two warehouses must be facilitated.

The system must support product shipment between warehouses, third party customers, Ft. Washington and RPR affiliates. As part of this functionality it must facilitate the creation of a Bill of Lading (BOL). The ability to "tailor" a BOL to Barcroft's specifications must be allowed without the need to modify the software. The system must also provide some of the paperwork required to effectively ship Third Party Customer Orders as well as Fort Washington and RPR Domestic and International Affiliates.

Since the Order Management module is not part of this implementation, the production of invoice information will continue to be performed manually. However, the system must be able to track and report on product distribution information.

Cycle Count Management must be user defined and able to be based on type of material, type of location, or dollar value. Cycle count accuracy reporting should be provided with the ability to compare last period (cycle) accuracy shifts. System assisted pick, move and put-away transactions must be part of the system. The Fort Washington Facility currently is utilizing Radio Frequency throughout Plant Operations. It is key that this technology effectively interacts with the system such that when Barcroft is ready it can take full advantage of this functionality. System must accommodate the use of and/or creation of bar-code information

The ability to define (for any item) the default location/location type is preferred. Upon receipt of inventory, the system should automatically indicate (suggest) the location for put-away. The ability to override the suggested location must also be allowed if another one is preferred upon initial receipt.

The system must provide the ability to enter information for multiple accounting periods (if still open) simultaneously. Unit of Measure (UOM) conversion processing must be able to be "configured" by item number. For example Item #123 a case equals 12 units, Item #789 a case equals 10 units, and so on. System must not allow unapproved and approved material in the same location at the same time.

The ability to retrace material movement is key. Inventory adjustment activity must be facilitated by item or location. The ability to summarize this information will also be required.

The system must be able to determine dry tonnage / weight based on variable factors. The system must allow for transfer of approved or unapproved material between warehouses or facilities.

## ***Drum Accountability***

It is important for the plant to be able to monitor the manufacture of and distribution of product down to the drum level. Composite testing at times identifies variations in quality of product. This may require segregation of specific drums from the rest of the drums within a given

lot. In these scenarios, the ability to identify these drums in the system and physically segregate them from the remainder of the drums within the Lot is key. Also, the system should facilitate the entry of a range of drum numbers as opposed to needing to enter all drums individually. For example; if there are 288 drums within a lot, in order to enter the lot the system should facilitate entering 288 in one transaction as opposed to requiring 288 transactions.

### ***Financial Reporting***

System must provide for monthly reporting of Total Inventory Balances by Warehouse and in total.

### ***Security***

Within the system, diversity in access needs to be managed. The ability to restrict or allow access (which ever seems more appropriate ) should be available for each function. The ability to "group" functions for the purposes of supplying access is preferred. The ability to define a type of access and copy from one user (profile) to another is required. This must be facilitated within the software.

### ***Database***

There is one shared F50 AS/400 machine physically located in the Fort Washington Facility. On this box is the PRISM software. The Barcroft operation will share this software with the Fort Washington facility personnel. It is a requirement that a separate database be maintained specifically for Barcroft inventory management, warehouse management and purchasing activities without interfering with the Fort Washington operation and vice versa. The associated data that will result must also be segregated from the Fort Washington data to ensure data integrity and securability.

### ***Platform / Technical***

It is RPR's current direction to pursue PRISM as the standard for Manufacturing, Planning and Inventory Management Systems throughout the RPR world. This software is currently proposed to be placed on the AS/400 box, sized to fit the needs of the facility.

Workstations throughout the Barcroft facility are standard RPR configurations with Windows (OSCARD) and LAN connectivity. Given these workstations, the software must be able to work effectively in this environment.

## ***Interfaces***

This project will not initially automate any interfaces. However, it is important to note, as the project proceeds, that none of the following interfaces should be hampered as there may be a need to automate them in the future. What this suggests is that no piece of data be eliminated from data entry if it will facilitate one of these interfaces. This also coincides with RPR's philosophy to implement packaged software in a "Vanilla" or "unmodified" mode.

- Accounts Payable
- LIMS
- Bar-coding/Radio Frequency
- EDI (Customer Purchase Order-Inbound)
- EDI (Requisition/Purchase Order-Outbound)
- BDP or other Freight Forwarding Company and/or System

## ***Information Retrieval***

The ability to retrieve information in a variety of ways is critical to Barcroft. It is particularly important and at times may be required to provide information (in a timely fashion) to the FDA during an audit. The ability to retrace product distribution will remain a key piece. If this process is automated it must provide the accuracy levels associated with the existing paper system.

The system must be able to retrieve key data (i.e., lot tracing and transaction history), for up to seven years after lot manufacture, in a timely fashion (less than 24 hours).

## ***Overall System Consistency***

Within the Barcroft facility, job rotations occur frequently. To support the feasibility of this remaining an ongoing practice, the system must be developed with certain consistencies throughout.

Methods utilized throughout the system should remain constant to allow for ease of use. Examples might be PF1 always is used for help, etc. Help should be provided for each screen with field level help available (where appropriate).

## ***Revision Control***

System must have adequate configurability features so as to limit the need to revise or modify the software. Once the software is configured, the system must provide that ability to view and/or print this information. The system must have some reasonable safeguards built

inherently into these features. For example, you may not want to change some things on the fly in the middle of the working day but have them take affect the next "cycle", whatever that might be. The ability to initially configure or subsequently re-configure must be securable.