
USAF Pharmacy Automation Project
PharmASSIST Enterprise Software
Pre-Implementation Guide
Version 2.0

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1 Purpose

Innovation Associates has been contracted to provide the PharmASSIST Enterprise System to pharmacy operations throughout the United States Air Force (USAF). The purpose of this guide is to provide a short description of the system and familiarize key personnel with general requirements for system implementation. A detailed schedule of milestone events and tasks that must be completed prior to and during the system implementation (The Implementation Plan) will be provided to the designated Project Manager at each receiving installation. Generally, the Implementation Plan commences 12 weeks from the scheduled installation date. The Master Rollout Schedule is created and managed by the Office of the Air Force Surgeon General

1.1 Proposal Specifics

The PharmASSIST Enterprise System will be installed at all major USAF pharmacy locations processing new prescriptions (POE or paper) and/or refills for existing prescriptions. As part of the 601 submission process, each facility received a site proposal generated from a site survey conducted by a representative of Innovation Associates. These proposals outline the recommended system configuration, including the number and type of computer workstations, peripherals, and number of PharmASSIST Standard Cabinets. In addition, a conceptual drawing of the pharmacy layout was included to illustrate the proposed location of the system equipment.

NOTE: These drawings are provided only to illustrate the proposed workflow description and diagram the location of supporting equipment for each Enterprise System. They are only to be used as a reference for planning the setup and installation of the respective systems and should not be held as a final construction build. Depending on the remodel plans of the local facility, these drawings may be modified by local agencies to accommodate site-specific requirements.

A copy of this proposal was provided to each facility and should be referenced by the Information Systems Agency as part of the system implementation. Contact Innovation Associates in the event your facility requires additional or replacement copies.

1.2 Project Schedule

As mentioned above, the site proposal serves as a recommendation for system configuration. As the scheduled installation date nears, Innovation Associates will initiate a detailed planning process to finalize the facility implementation plan. While the Pharmacy Operations OIC will serve as the primary point of contact for each facility, separate responsibilities will be delegated to various departments.

2 PharmASSIST Enterprise System

The PharmASSIST Enterprise System is a commercial-off-the shelf (COTS) software/hardware package that provides automated prescription dispensing and workflow management for pharmacy operations. It is used in the commercial sector as well as within the DOD. The PharmASSIST Enterprise System operates both the Windows NT and Windows 2000 operating systems. The dispensing cabinets utilize custom software controls and maintain a local drug database for drug specific calibration, inventory control, lot tracking, and bar-coded replenishment.

2.1 General Description

There are eight major functions in the PharmASSIST Workflow Software. These functions include the capability to receive prescription data from the Combined Healthcare System (CHCS), scan and store an image of the prescription, fill orders using high quality automated dispensing equipment or through software-controlled procedural checks, verify prescriptions at the end of the filling process, and report on a variety of system functions, prescription statuses, and statistics.

The PharmASSIST system consists of a set of computer workstations, the CHCS system, and the pharmacy staff. Once prescription data is transmitted to PharmASSIST, the user follows various system prompts displayed at each workstation monitor. These prompts guide the user through filling and checking a prescription, including performing bar code scans, data entry, and other required actions. PharmASSIST will notify the user if an incorrect drug is scanned and will prohibit the user from putting medication into the wrong dispenser or labeled vial.

A base system consists of one (1) Standard Cabinet of fifty (50) dispensers, one (1) database server, one (1) disaster recovery backup station, and a variable number of supporting workstations (Order Entry, Auto-Fill, Manual Fill, and Verification), one of which is designated to interface with the Pharmacy Management Software System (PMSS). Workstations and Standard Cabinets can be added or subtracted to customize the workflow for any pharmacy. An itemized equipment list for system is provided in Schedule A, Equipment and Software List, of the site proposal.

2.2 Interface and Connection to CHCS

The interface with CHCS is via the local area network and is a one-way interface only. PharmASSIST connects to the CHCS network in one of two ways; either each computer is placed on your network, or the computers are networked together through a hub and connect through a switch to your network. Workflow through the PharmASSIST System begins once prescription information is transmitted to the system database from CHCS. The pharmacy staff or physician enters patient prescriptions into CHCS. The prescription information is transmitted electronically to the PharmASSIST system when the CHCS user processes the prescription batch.

As part of the PharmASSIST hardware installation, Innovation will require connection to CHCS. Innovation or its responsible subcontractor will provide any and all unique cabling necessary for connection to the pharmacy computer/server running CHCS. The Customer is responsible for providing access to network connections. At contract award, the Customer will identify system, facility, network, or command security requirements necessary for connection to the CHCS computer/server.

PharmASSIST workstations do not necessarily replace existing CHCS terminals. However, to save space at the prescription drop off window, a terminal emulation software application can be installed on the Order Entry workstations.

2.3 Electrical Requirements

PharmASSIST Standard Cabinets draw a maximum of 1.5 Amps at 120VAC. When idle, the load is well under 1 Amp. The workstations are standard PCs, and draw approximately 2-3 Amps each. As a general requirement, one (1) dedicated 15 Amp service for the cabinets and the workstations to be placed on "Clean" power.

Cabinets come equipped with a surge protector and are usually secured to the floor and to the wall, rendering floor and wall outlets inaccessible. Suggested locations for power outlets are either immediately to one side of cabinets, on the wall above the cabinets, or power poles dropped from the ceiling. PharmASSIST Standard Cabinets require a four-plex electrical outlet.

At each workstation location, there should be at least one four-plex electrical outlet. Normally, workstations are comprised of a computer, monitor, and one or two bar code readers. However, the Order Entry workstation has a computer, monitor, bar code reader, prescription scanner, and label printer, so each Order Entry workstation requires two, four-plex electrical outlets.

2.4 C2 and Y2K Compliance

US Air Force Policy requires that the Air Force Chief Information Officer accredit all software used on Air Force bases. The PharmASSIST Enterprise Software was awarded a Certificate of Networthiness (CON) on 24 DEC. Since that time, each MAJCOM has granted Certificates to Operate (CTO's) for the PharmASSIST Enterprise Software. Official copies of the CON are available if requested.

The issuance of the Certificate of Networthiness will allow all bases running the AF-EMIS software to be assured that PharmASSIST meets or exceeds all the security requirements of the Air Force. The Certification and Accreditation Package, along with a copy of the Certificate of Networthiness, will be made available to each base for their certification of the software.

While every system is ghosted with a C2 certified and accredited hardened image before it ships from our production facility, it is the responsibility of every receiving agency to ensure that their PharmASSIST Enterprise System remains compliant. Any local applications loaded onto workstations after installation, such as anti-virus, intrusion detection, terminal emulation, etc., should not conflict with the requirements for network security. Additionally, it is each agency's responsibility to check for and load all recently released patches and hot fixes. Answers to further questions concerning the Security Policy and System Design Document can be found by referencing the SSAA.

The PharmASSIST Enterprise Software uses Y2K compliant time and date functions provided by Microsoft Visual Basic. It supports input for all dates up to the year 9999. Dates are stored in a SQL Server 7.0 database, which is also Y2K compliant. All of the hardware and utility programs used to support PharmASSIST are Y2K compliant.

2.5 Warranty and Maintenance

A basic one-year warranty for parts and labor covers the PharmASSIST Enterprise System from the date of installation. Innovation Associates may provide technical direction, but Customer is responsible for reasonable troubleshooting of all minor mechanical and electrical issues and/or repairs.

Warranty coverage includes software updates (excluding new software modules), counting parameter updates, quarterly drug image updates, and all replacement parts. Innovation, at its option, will repair or replace the equipment or any part of the equipment that is not properly functioning. Each facility is responsible for basic and routine system maintenance to include the purchase of consumable supplies such as printer ink, paper, and toner cartridges.

During the warranty period, Innovation Associates will provide emergency maintenance service between the hours of 8:00 AM and 5:00 PM EST, Monday through Friday, excluding national holidays. Innovation Associates will respond by telephone to emergency calls for service within one (1) hour after notification by Customer. If during the response to an emergency call, Innovation, at its sole discretion, determines that a technician is required to travel to Customer site to repair or replace Equipment under Warranty, Innovation shall dispatch a technician within a reasonable period of time. Warranty service requested by Customer during other than normal working hours will be completed at the rate of \$75.00 per hour.

While PharmASSIST Enterprise System has built in disaster recovery routines, it remains the responsibility of the end-user to ensure that proper backups are performed on a routine basis. Innovation Associates recommends a daily backup for the PharmASSIST Enterprise System.

3 Key Areas of Responsibility - Pharmacy

While the USAF Pharmacy Automation Project is centrally funded, the responsibility for completing the required paperwork to be scheduled for installation rests at the local level. Provided all elements are included and the proposed vendor quote and site configuration is in line with the Central Pharmacy Automation Project Plan, the package should be expedited through the MAJCOM, AFMLO and the SG Clinical Consultant. Once approved the requirement will be executed according to the project schedule.

For those sites that have packages that have been submitted and put on hold, they have the option of submitting a new vendor quote (even if the original was through a different company) through AFMLO FOE and it will be processed.

As part of the 601 submission process, each facility is to receive a site survey completed by a representative of Innovation Associates. This survey is used to complete a suggested system configuration, to include the number and type of computer workstations, peripherals, and number of PharmASSIST Standard Cabinets. This survey is an excellent opportunity to re-engineer any aspect of your current workflow. Innovation Associates will work closely with the Air Force to lend insight to questions regarding workflow modifications, layout changes, and fixture remodeling, but the final responsibility rests with the Pharmacy Supervisor of each individual facility.

3.1 Workflow Modifications

The proposal created by Innovation Associates for inclusion in the 601 packet is based upon analysis of the information submitted by each respective facility. As such, the proposed systems are designed to meet existing requirements and accommodate prescription volume growth. Due to the modularity and scalability of PharmASSIST, you can easily upgrade your systems to automate additional elements of prescription fulfillment, so plan for growth.

Careful consideration should be given to how the PharmASSIST Enterprise System will impact your current workflow. Existing constraints such as physical layout, staffing, patient types, and peak times, may create new challenges after system installation. Use this time to consult with your peers, supervisors and the Innovation Associates Team, to identify potential problems and develop the best possible solutions.

3.2 Pharmacy Layout

Included with each proposal are draft layouts. These drawings are provided solely to illustrate the proposed workflow description and diagram the anticipated location of computer workstations and dispensing cabinets. These layouts are conceptual in nature not intended to be in final form. If a remodel or reconfiguration of the current pharmacy is planned, consult with the Innovation Associates for suggested layout to accommodate equipment and anticipated impacts to workflow. These ideas can be explored during the proposal site visit, or if the 601 packet has already been submitted, follow-up site visits can still be scheduled and are encouraged. The goal is to create an environment that promotes safe and efficient workflow.

Each facility is responsible for all site preparation and modification of premises. Site preparation is not included in the System pricing. More detailed space, electrical, and communication requirements will be provided within the Implementation Plan for each facility.

3.3 Druglist Submission

To identify the appropriate drugs for automated dispensing through the PharmASSIST Cabinets each facility is required to submit a druglist of their top 200-300 movers. The timely submission of this list is required for coordinating the production and delivery of the dispensing cabinets at time of the implementation of the PharmASSIST Enterprise System. This report should be the results of a query of the number of prescriptions filled over the most recent 6 months, including the NDC, and exported into MS Excel Format.

4 Key Areas of Responsibility – Information Systems

Innovation Associates is responsible for delivering the appropriately configured system to the pharmacy and coordinating with the respective Information Services agencies to complete the necessarily required tasks for installing the system. The specific areas that need to be addressed during the implementation of the PharmASSIST Enterprise System are addressed in detail below.

A detailed description of the architecture of the PharmASSIST software and hardware is available in the PharmASSIST System Security Authorization Agreement (SSAA). Information about the system is also available on the Innovation Associates website (www.innovat.com). Questions may also be directed to the below listed individuals:

<u>US AIR FORCE</u>	<u>INNOVATION ASSOCIATES</u>
LTC Scott Sprenger Directorate of Medical Programs and Resources Office of the Surgeon General (703) 681-4445 x3049 or DSN 761-4445 x3049 scott.sprenger@pentagon.af.mil	Jeff Castille National Implementation Manager (607) 798-9376 x350 jeffc@innovat.com

4.1 Computer Workstations

The number of computers delivered with the PharmASSIST Enterprise System varies from two to twelve, based on a variety of factors such as pharmacy layout, workflow, number of staff, and prescription volume. Local Information Systems agencies are responsible for assigning static IP addresses prior to or during system installation.

The Innovation Associates installation team will setup and network the system workstations, peripherals, database server, and the automated dispensing cabinets. After delivery, these computers and their system software (i.e. Windows 2000, Internet Explorer, etc.) become the property of the U.S. Government, to be controlled and maintained by the local Information Systems agency. Innovation Associates' responsibility for these computers is limited to the PharmASSIST application. A member of the local Information Systems agency must be identified prior to delivery and available for support during the installation of the system. If requested, Innovation will send the PharmASSIST Enterprise System computer workstations to the Customer's designated representative for set-up prior to their installation and connection to CHCS.

4.2 Network Requirements

As part of the system installation the PharmASSIST Enterprise System, computers will be integrated into the local Microsoft Windows domain. The system bandwidth requirements for connectivity are 100 mbps. Users of the PharmASSIST Enterprise System require no special privileges on the computer outside of access to the installation subdirectory (C:\Program Files\PharmASSIST). The common software platform is either Windows NT 4.0 (Service Pack 6.0a) or Windows 2000. Other system software includes MS SQL 2000 Server, SQL Client, PharmASSIST TCD Controller Software, and PharmASSIST Workflow Software.

In addition to managing workflow, PharmASSIST collects data regarding the performance of the software and counting devices. To properly analyze this data, the system requires the ability to transmit the data to an FTP server for secure retrieval. This is a manual processes initiated by the pharmacy staff. The IP address will be provided during system installation. To comply with local network security requirements, there is no dial-in capability, and thus no need for modem lines.

4.3 Interface to CHCS

Per the network security requirements set forth in the CON, the PharmASSIST application does not send any data to CHCS; communications between the two application are one way only: CHCS to PharmASSIST. The PharmASSIST system receives data from the CHCS system at the pharmacy through what is commonly referred to as the Baker2000 or B2K Interface. This interface must be installed and configured prior to the installation of the PharmASSIST System.

There are two different packages that implement the interface between PharmASSIST and CHCS. The old one, LPO B2K still exists but is not supported and is not baseline CHCS code. It may be the only option available to your site if your facility has not yet implemented the latest version of CHCS. If this applies to you, endure you have version 3.1. The new interface, known as the BPL or Batch Print Label, is part of change package 111 for CHCS. Complete setup details can be found in the support document entitled "Implementation Update Guide Pharmacy LPO Enhancements CHCS S/W Version 4.630" (SAIC GSA Doc. GS-PPVC 08 Feb2003).

4.4 Outbound FTP

In order to provide proactive systems management and customer service, Innovation Associates requires the ability to collect performance data from the PharmASSIST Systems installed at customer sites. This data does not contain any patient identifying information and used by Innovation Associates to monitor the performance of the system and resolve customer calls. This data is automatically collected and transmitted to IA headquarters using standard FTP protocol. Details of this data collection process can be found in the System Security Authorization Agreement submitted as part of the Certificate of Noteworthiness evaluation.

The Innovation Associates software was written taking advantage of Passive FTP connections, which allows for better network security. Passive connections require no inbound port access, but do require a large range of out-bound ports to be available. With a passive network connection the client-side software initiates all network connections. Unfortunately, the local port that is used by FTP Sockets when making a connection to an FTP server is random. This random port can be any outbound port from 1024 to 65535.

As a result, Innovation Associates requires access through all Firewalls located between an Innovation Associated Server and the Internet. The required holes are through Port 21, and the port range of 1024 to 65535. It should be noted that these holes should be placed in the firewall for outbound traffic only; all inbound traffic from the Internet via these ports should be blocked.

5 Installation and Setup Checklists

5.1 CHCS and Lexmark Software and Hardware Setup

The following checklists have been created to assist in tracking the necessary actions in configuring a facility for the PharmASSIST Enterprise System.

-Confirm the site has the current versions of the following software

- CHCS version 4.6 or B2K Version 3.1
- KP Common
- KT Common

-Procure and install the following CHCS files (verify the latest version by contacting the MHS help desk at 1-800-600-9332)

- KP_LPO_3-0.PKG;1
- KP_LPO_B2K_2_0_MU_000918.PKG;1 (CHCS interface driver package)
- KP_PLC_3_0.PKG;1
- KP_PLC_3_0_MU_001227;PKG;1

-Confirm the site has the barcoding/auxiliary label card (DIMM5.3) for each Lexmark printer.

- DIMMS for Lexmark printers (Available thru Pharmex 1-888-742-7639)

5.2 CHCS Application Setup

- Setup a separate site for each PharmASSIST system. In most cases, separate dispensing lines are an indication of separate PharmASSIST systems.
- Setup the site parameters (SFM-OMM-DLS) to enable barcoding
- Setup an HDR menu to identify your clinic
- Setup an OUT menu to enable the use of Lexmark labels

5.3 CHCS User Setup

- Setup a couple of users with the ALPO option in CHCS to allow edit access to key menus in CHCS
- Setup each remaining user with the LPO option in CHCS
- Setup a UDK for the users with the ALPO option
- Setup a UDK for the users with the LPO option

5.4 Network Connectivity Setup

- Assign Static TCP/IP addresses for each Workstation; ensure they are active in the switch.
- Setup the gateways
- Confirm the PharmASSIST.ini file on each desktop is setup correctly

The concept of operations (CONOPS) of the PharmASSIST system is to provide a processing environment that supports processing patient prescriptions in an error-free, quality-focused manner without impacting overall patient wait times.

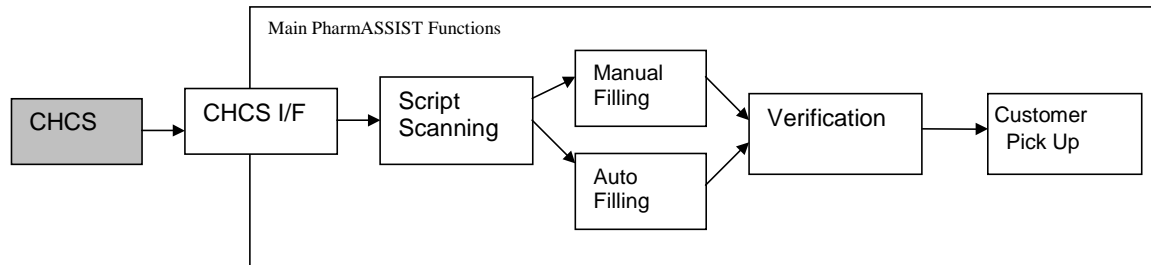


FIGURE 2. MAIN PHARMASSIST FUNCTIONS

In general, prescription information is received from the CHCS system over a local area network. The user scans new paper prescriptions at the Order Entry Station. If the prescription is for a medication located in the automated dispensing equipment, the Auto Fill Station awaits an on demand request by the filling technician before releasing the counted order. The Manual Fill Station verifies the proper retrieval of medication from the pharmacy shelf. Completed prescriptions await final check at the Verification Station to ensure that the physician's script and the data from CHCS match the properly labeled and dispensed medication.

Each authorized user must enter an appropriate Identification and Authentication (I&A) before being authorized access to the PharmASSIST system. Operations performed within the system are tagged with the ID of the user that is signed onto the workstation. Users can be given subsets of all privileges by the PharmASSIST system administrator.

APPENDIX B FUNCTIONAL DESCRIPTION

The PharmASSIST system is composed of a set of workstations, software, and dispensing cabinets. The workstations run the PharmASSIST Workflow Software that guides the pharmacy staff through the process of filling a prescription in a high-quality manner with and without utilizing the dispensing cabinets. The figure below depicts the PharmASSIST Software menu structure.

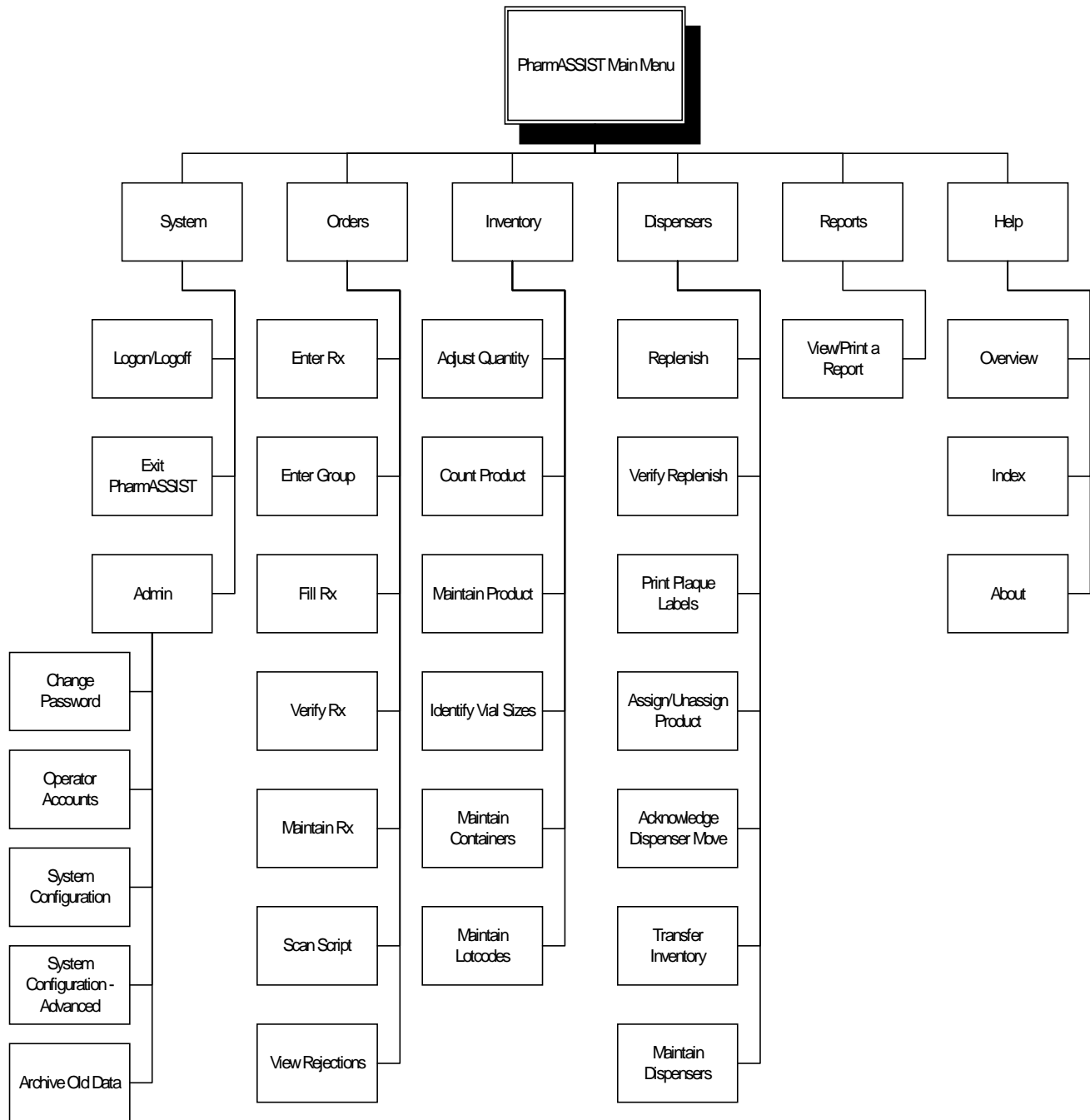


FIGURE 1. PHARMASSIST SOFTWARE MENU STRUCTURE