
Setting up a computerized drug registration & allied information system



A User's MANUAL



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ANNEX A: GENERAL OUTLINE OF THE SYSTEM

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INTRODUCTION

There are three parts to this user manual: Part 1 outlines the minimum requirements needed before setting up to computerize the drug registration system. It then describes the drug registration and information system in general. An overview of the drug registration system with emphasis on the hardware and the software needed to install a computerized drug registration system and finally, the data preparation requirements is presented; Part 2 presents, in detail, how to install the application systems. A step by step guide is presented to aid the user during the actual installation process; and Part 3 explains the details of the three subsystems under the **DRUG REGISTRATION SYSTEM AND INFORMATION SYSTEM** and it provides in depth illustrations on the use of the installed subsystems.

Introducing a computerized **DRUG REGISTRATION AND INFORMATION SYSTEM** in a drug regulatory authority will entail investment in terms of time and energy. The benefits derived in using such a system however, cannot be overemphasized. Not only will the system facilitate the systematic organization of data, a computerized system can also help the drug registration staff reduce the amount of time spent on clerical work. The drug registration staff can thus concentrate more on the technical evaluation of product applications.

A computerized **DRUG REGISTRATION AND INFORMATION** system will greatly reduce the amount of clerical errors that abound in most manual systems. Management information reports can easily be prepared when using a computerized system. Preparation and printing of the certificates for product registration (CPR) and the licenses to operate (LTO) for establishments may be automated. The tremendous reduction in the time for the staff in preparing certificates results in a more efficient management of resources. Preparation of reports is a keystroke away and can be redesigned using *MSWord™* or *MSEXcel™* to suit user preferences. Ultimately, this results in a more professionally run drug regulatory agency.

Users of the system will also appreciate that moving from a manual to a computerized drug registration and information system is an investment well spent in the long run.

Developed as a tool for Drug regulatory agencies (DRA) implementing a computerized system for the registration of pharmaceutical products, the system is designed to aid the DRA in countries in the management of drug registration data. The system was developed to provide for a fast and efficient way for recording and retrieving data. With the information generated by the system, sound management decisions may be enhanced which may help countries regulate and ensure the quality of drugs available in the market.

The system was purposely made as simple as possible and has been pre-tested in several installations for user-friendliness. It is also designed to encourage the DRA to implement a computerized system with resources that may already be available. No other special equipment or software other than the basic windows office suite is required. Because Microsoft Office Suite is commonly used in most drug regulatory offices, the **DRUG REGISTRATION AND INFORMATION SYSTEM** was developed using one of the office suite packages: *MSAccess*[™]. Another version of the same system may also be available, with the same user interface, recoded in *Visual Basic*[™]. The recoded version of the system can be used in a multi-user environment in a true client-server relational database management system such as Microsoft SQL[™] server, where tighter security may be a prerequisite.

The primary reason for using *MSAccess*[™] as the database management system was to simplify future maintenance. With the system, the user can easily transport the data to another database management system. The entire dataset can then be moved to *Dbase*[™], *FoxPro*[™], *SQL*[™], *MS Excel*[™], or *Oracle*[™]. Abandoning the database will not be necessary in the event of a policy change to use another database management system. This will save the user countless time and resources in reentering the data.

A generic report preparation scheme is employed in the **DRUG REGISTRATION AND INFORMATION SYSTEM**. The *MSWord*[™] word-processing and the *MSEXcel*[™] spreadsheet programs are utilized to maximize user familiarity with these programs - a plus for user acceptance of the drug registration system.

Data can easily be exported to other *Microsoft*[™] office products as well as to similar database engines. Thus, upgrading to a true client-server database management systems like *SQL Server*[™], *Oracle*[™], or some other highly scalable database management system as the back-end database will be less daunting. The main database was purposely not split into smaller tables, as would normally be done, for the very same reason.