Synergy Medical

AUBURN LONG TERM CARE

USE OF SYNMED® TECHNOLOGY FOR PRODUCTION OF BLISTER PACKS

POLICIES AND PROCEDURES

Synergy Medical

AUBURN LONG TERM CARE

SYNMED® SYSTEM

This document is intended mainly for the pharmacist-owner(s) and the SynMed® Pharmacist Manager designated to SynMed® system support. It can also prove useful to staff involved in producing blister packs with the SynMed® system.

This document was produced by AuBurn Pharmacy and Synergy Medical. It is the policies and procedures for use of SynMed® technology in the production of blister packs. This guide aims to provide guidelines to implement safe working practices and to ensure optimal productivity in a pharmacy setting.

It also provides a checklist of various elements to consider and to put into practice in order to ensure optimal production of blister packs in the transition to an automated environment.

This guide should be retained for all stages of the installation, training and production cycles.

This guide is an important tool to ensure that SynMed® technology is implemented as smoothly as possible.

Synergy Medical

AUBURN LONG TERM CARE

***SYNMED® PROJECT DOCUMENT CHECKLIST**
USE OF SYNMED® TECHNOLOGY FOR BLISTER PACK PRODUCTION

#	DOCUMENTS	
1. SYNMED® SET UP – NEW SYSTEM INSTALLATIONS		
1.1	DECISION SUPPORT TOOL FOR INITIAL SYSTEM SET UP	
1.2	ACTION PLAN FOR SUCCESSFUL SYNMED® INTEGRATION	
1.3	DESCRIPTION OF SYNMED® TRAINING STEPS	
1.4	PRODUCTION TECHNICIAN COMPETENCY ASSESSMENT MATRIX	
1.5	PRODUCTION TECHNICIANS TRAINING LOG	
1.6	PRODUCTION TECHNICIANS AND ACCESS MANAGEMENT LOG	
1.7	RETENTION PERIOD FOR VARIOUS DOCUMENTS	
1.8	LIST OF DANGEROUS DRUGS AS LISTED BY NIOSH	
2. SAFETY OPTIMIZATION		
2.1	SAFETY TOOLS FOR SYNMED® PRODUCTION	
2.2	SUMMARY OF SYNMED® SAFETY PRECAUTIONS	
2.3	PROCEDURE – FOR CUTTING PILLS AND BLISTER PACKS	
2.4	PROCEDURE FOR SECURE SYNMED® SET UP	
2.5	SECURE SYNMED® REPLENISHMENT PROCEDURE	
2.6	SYNMED® ERROR SHEET	
2.7	RECORD OF ACKNOWLEDGEMENT OF SYNMED® PROCEDURES	
3. OPTIMIZING PRODUCTIVITY		
3.1	SUPPORT TOOL FOR SYNMED® PRODUCTIVITY	
3.2	CHART OF PERIODIC TASKS	
3.3	DAILY TASKS CHECKLIST	
3.4	WEEKLY AND MONTHLY TASKS CHECKLIST	
3.5	SYNMED® WEEKLY PRODUCTION SCHEDULE	
3.6	SYNMED® PRODUCTIVITY LOG	

Synergy Medical

AUBURN Long Term Care

1.1 DECISION SUPPORT TOOL FOR IMPLEMENTATION

NAME OF PHARMACY: _____

PERSON IN CHARGE: _____

This chart contains important information that will assist users in advance planning of SynMed® robot set up. Certain decisions will have to be made around initial system configuration and modes of operation. These decisions will make set up smoother and provide uniformity in work methods and processes, which will ensure operational safety, improve efficiencies and reduce the risk of errors.

Please take the time to review each of these steps, so as to familiarize yourself with the advantages and drawbacks associated with various options.

#	DESCRIPTION OF PLANNING ELEMENT	DECISION	SPECIFIC COMMENTS
1	**PLANNING PHYSICAL SET UP**		
	- Anticipating physical space needs for installation of robot - Following Synergy Medical guidelines, balance space needs in such a way as to give Production Technicians space to operate without creating too much space to move around, which can diminish productivity. Each time a technician has to move from one area to another, time is lost and this has an impact on productivity.		
	- Plan to have two (2) work stations so as to provide both a pre- and a post-production space. Preferred options include: 1) A U-shaped work station (one counter constituting the first leg of the "U", with the robot at the base of the "U", and another counter as the second leg of the "U").		

	2) Or: A T-shaped work station if the space configuration does not allow for a U-shaped work station. 3) Or: a linear work station in front of the robot.		
	- When setting up dispensaryspace and furnishings, allow for: 1) Space for computers and printers supplied with SynMed®. So as to avoid undue traffic and staff interruptions, these printers should be reserved exclusively for the use of the SynMed® robot. 2) Space beneath the counters (for garbage and plastic recycling containers, storage of confidential papers to be destroyed, as well as shelving for documentation to be conserved during the production cycle, blister packs, etc.). 3) An ergonomic environment is essential. Counters should be a maximum of 36 inches in height. This is the optimum height to ensure that Production Technicians are able to efficiently complete the post-production cycle (i.e. conduct a cell count and check blister packs without having to move them). 4) Shelving for drugs added manually, as close as possible to the pre-production space. If the dispensaryis not within easy reach, a second inventory should be considered. 5) Shelving to arrange jars to store drugs used for replenishing the robot. These jars can be stored alphabetically or numerically by container in the SynMed® store. A numerical system speeds up work during the replenishment process, but does slow down the placement of drugs on the shelves, since a checklist will have to be cross-referenced in the shelving process. 6) A space to receive prepared blister packs, as they transit to the quality control area (a counter that is larger than the space dedicated to trays or an additional shelf). 7) A space sufficiently large to accommodate any tools needed for sealing the blister packs according to the types of blister packs being used.		

2	**DESIGNATING A SYNMED® PHARMACIST MANAGER ASSIGNED TO A SUPPORT ROLE**		
	- To ensure proper implementation of the new technology, it is recommended that a SynMed® Pharmacist Manager be designated as a support person for technology projects pertaining to pharmacy processes. - This pharmacist will participate in meetings with the Synergy Medical team and in all training of the technical team. - This person must be proficient in all of the functionalities of SynMed®. <u>Qualities needed in a SynMed® Pharmacist Manager</u>: - Ability to make oneself available to provide overall supervision of SynMed® operations, in addition to other work duties - Ability to analyze processes - Ability to organize - Efficiency - Computer skills - Ability to delegate tasks - Aptitude for supervising/training/coaching a team - This pharmacist's role is to surround himself with a team that can support him in his duties, but will still be the point person who ensures follow-up on action items by the various staff members. The operation of the robot is primarily a technical task that must be rigorously supervised by a qualified pharmacist.		
3	**DESIGNATING A SYNMED® OPERATIONS TECHNICIAN MANAGER**		
	If more than one operator has been assigned, it is recommended that a Technician Manager be assigned to supervise the production cycle, in addition to his/her operational role.		

	Qualities required of a Technician Manager: - Technological skills - Ability to make oneself available to supervise SynMed® operations, while completing his/her regular tasks as a Production Technician - Ability to second-guess processes - One who highly values work well done - Interpersonal communication and staff training skills - Ability to organize - Efficiency - Ability to identify and resolve problems - Computer skills The Technician Manager is the point person to ensure follow up on actions related to operation of the robot. This person may also participate in training of other Production Technicians in support of the designated SynMed® Pharmacist Manager. This person will be responsible for executing high level tasks (e.g., adding drugs, optimizing SynMed System), determining picking attributes, analyzing production reports, etc.). Avoid assigning your lead technician to this task since this person will already have a full workload, and the addition of these tasks may prove counter-productive.		

4	**DESIGNATING PRODUCTION TECHNICIANS**		
	Some of your Production Technicians will be trained specifically in the operation of the SynMed® robot. Such training will be essential for ensuring proper equipment functioning. Qualities required of a Production Technician: - Technological skills - Ability to work independently - Attention to detail - Ability to focus - Thoroughness - Sense of responsibility - Reliability - Observant - Ability to organize work efficiently - One who completes tasks assiduously - One who follows procedures closely - Avoid choosing someone overtly communicative who requires social interaction and validation. Give preference to a candidate who is detail oriented and has an ability to concentrate. - Choose a Production Technician who will devote his/her time and efforts to the operation of the robot and who will not be distracted by other dispensarytasks to be performed.		
5	**OPERATION OF ROBOT**		
	A single person should be assigned to perform all tasks related to SynMed® operation (e.g. analysis of SynMed® software files, manual insertion at the		

	pre-production phase, cell count and sealing of blister packs during post-production, container replenishment, etc.). The robot has been designed to take into account the time required to complete pre- and post-production tasks in relation to automated functions. <u>Role of 2nd Production Technician if needed</u>: A second Production Technician can be assigned tasks related to file transmission to SynMed® via the Pharmacy Software, to renewals, to change and order management, etc.		
6	**NUMBER OF PRODUCTION TECHNICIANS TO BE TRAINED**		
	- The number of Production Technicians to be trained should be assessed in terms of the volume of blister packs to be produced and the number of hours required for daily and weekly production purposes. - It is mandatory that the Technician Manager participate in initial training offered by the Synergy Medical team. - From the outset, two Production Technicians should be assigned who are qualified to operate the robot and who can share production of blister packs on a weekly basis. It is important to ensure maximal staff coverage to avoid dependence on one sole staff member. Having two trained Production Technicians allows to make up for staff absenteeism and vacations. - Additional Production Technicians can be trained in-house once the production cycle is well established and as needs dictate. (It is strongly recommended to wait one month before training other users). - Production Technicians selected to train to become system operators should be reliable team members; in other words, avoid training staff members who may quit within a short period of time. - A log of trained Production Technicians should be kept.		

7	**SELECTION OF DRUGS FOR THE ROBOT**		
	Drugs to be included (internal) Most of the drugs ordered in volume will be placed within the robot. Drugs to be excluded (external) Certain drugs are to be automatically excluded from the robot: 1- Drugs requiring refrigeration 2- Cytotoxic or other dangerous drugs[1] 3- Allergenic drugs such as penicillin and sulfates 4- Pills sensitive to humidity 5- Drugs that dissolve rapidly 6- Drugs in powder form, whenever possible		
8	**ACCESS RIGHTS TO SYNMED® SOFTWARE AND PRIVILEGES**		
	A unique user code and password will be assigned to each staff member working with the SynMed® robot. Access levels (tabs) should be assigned to each user. - Production Tab: Applies to Production Technicians. This tab is used to manage patient/prescription files and to launch blister pack production. This is the basic access level required for SynMed® operation. - Inventory Tab: Applies to all Production Technicians and all other personnel authorized to replenish SynMed® containers or to access		

[1] Cytotoxic and other dangerous drugs (teratogenic drugs, immuno-suppressors, abortives, hormones, etc. as listed by NIOSH) should not be stored in the SynMed® store. They must be handled separately. They will be included through the SynMed-Assist or the Exception Drugs Report (manual insertions). A strict handling procedure for these drugs must be put into place to avoid contamination.

	the SynMed® store. This tab is used to re-supply containers, print labels, manage drug expiration dates and inventory reports. - Drugs Tab: This tab is for managing drugs listed in the SynMed® database software (create, remove, modify, etc.). Access to this function should be restricted to a qualified pharmacist. Access may be granted to a Production Technician but only if his/her work is double checked by a pharmacist. Any additions to the SynMed® database software can be printed for a given period to be verified by a pharmacist (i.e. *Registry of Drugs Added to SynMedSoft Database*). - Users Tab: This tab manages various levels of access for each system user. The Users Tab lists all those with user access along with their access levels. The SynMed® Pharmacist Manager should be given access to this tab. - Parameters Tab: This tab allows for various SynMed® software configurations. It is recommended that a log be kept listing all personnel authorized to operate the SynMed® robot along with their access levels (Document 1.6 – SynMed® Log of Production Technicians and Access Levels).		
9	**SEALING OF BLISTER PACKS BY PRODUCTION TECHNICIANS**		
	Once the production tray is filled, the Production Technician completes a cell count of the units in each blister pack. All blister packs should then be sealed. - Once the blister pack is completely sealed, there should be no accidental displacement of drug units during handling and transport following the cell count. The container-contents verification is performed once the blister packs have been properly sealed. This is the best way to ensure that the blister pack has not been compromised after the cell count. - If the blister pack has been partialy sealed, the risk of error after the cell count is greater due to required handling and transport.		

	However, the container-contents verification is to be completed with non-sealed blister packs. - Several pharmacies seal most of their blister packs, but do keep a list of exceptions for those packs that cannot be verified once they have been sealed (blister packs that are too large). - The verification of sealed blister packs allows for moving of contents without risk of error. Each unit can be viewed and counted from five different sides. - Verification of non-sealed blister packs allows for manipulation of units with tweezers. A single side is available for viewing and counting each unit. Units can move around, displace and fall out. - Keep in mind that blister pack production is automated, which minimizes risk of error as long as all safety procedures have been followed.		
10	**MANAGING LOTS**		
	Managing Lots — Additions or Replacements/Number of Approved Lots During the set up phase, the maximum number of lots to be stored in memory should be determined and programmed. When a drug is being replenished, the system will not authorize production of more lots than have been programmed. **The number of accepted lots should be limited in order to ensure data accuracy**. Replenishment with the SynMed software offers three options: that of KEEPING existing lot(s), ADDING a lot or REPLACING existing lot(s). <u>KEEPING EXISTING LOT(S):</u> - When replenishing a container, "Keep Existing Lot(s)" should be selected if the number of the drug lot being added matches the lot number(s) already registered in the SynMed® software. <u>ADDING LOTS:</u>		

	- When replenishing a container, click on ADD if the drug lot number being added is different from the lot number(s) registered in the software, and in order to save lot numbers already registered. - If there are units left in the container, a new lot number should in theory be ADDED. <u>REPLACING LOTS:</u> - When replenishing a container, click on REPLACE ALL LOT(S) if the lot number(s) of the drug(s) being added is(are) different from the lot number(s) registered in the software, and if lot numbers already registered need to be replaced by new ones. It is not possible to replace a single lot if there are more than one. Replacement automatically erases all preceding lots (i.e. all lots will be deleted and replaced). - If the container is empty, REPLACEMENT can occur without the risk of mixing lots. - It is necessary to completely empty a container in order to REPLACE all lots.		
11	**PRODUCTION once a week or once every two weeks**		
	<u>Once a week</u> - <u>Advantages</u>: lower inventory, less storage space used, lesser probability of having to alter blister packs already produced, less waste if a patient leaves after his blister pack is produced. <u>Once every two weeks</u> - <u>Advantages</u>: productivity gains at every stage of the blister pack production cycle (sending files, handling jars for manual insertions, lower selection of drugs when production is completed by the robot, ability to check two blister packs at a time, etc.).		

	- Drawbacks: Managing changes to blister packs, required inventory, space needs, recuperating blister packs produced but not required incurring risk of error and/or contamination.		
12	**USE OF PATIENT FILE LIST REPORTS – PHARMACY PREPARATION/DISPENSING**		
	Automatic programming of this function is strongly advised. - The Patient File List – Preparation Report is a useful tool for preparation and verification purposes, for ensuring proper tracking of sent files, preparation and verification. - This report should be automatically printed out at the beginning of the production phase when all other reports are being printed. - The Patient File List – Dispensing Report is useful when preparing blister packs for another pharmacy, through central filling. This report is use as a delivry sheet.		
13	**PROGRAMMING INITIAL PARAMETERS AND BEST PRACTICES**		
	Expiration Date: - When SynMed® containers are being replenished, the Production Technicians must register an expiry date of all drugs entered into the system. - This date is the one printed on the original container from the manufacturer. Assigned Date: - The number of days assigned to the expiry date is a parameter which allows for specifying the maximum expiry date that should be indicated once the manufacturer's original drug packaging has been opened. **It is advised to attribute a period of 365 days (one year).** - The closest date (expiry or assigned date) is the date chosen by the system to generate an alert. (If the drug has already expired once		

	administered to the patient, the container production file of the drug should generate an error message.)		

14	DELEGATION OF CONTAINER-CONTENTS VERIFICATION (DCCV)		
	**Applies only to regions where such delegation is allowed.* Automated production of blister packs by SynMed® is highly secure. - This option saves a great deal of technical preparation time. When production is automated, DCCV is easier to put into place, since many production cycles are standardized when setting up automated technology. - DCCV frees up the pharmacist from conducting technical checks, and to focus on quality control. He/she will have more time to devote to his/her official duties.		

Synergy Medical

AUBURN Long Term Care

1.2 ACTION PLAN FOR SUCCESSFUL SYNMED® INTEGRATION

NAME OF PHARMACY: _____

PERSON IN CHARGE: _____

Setting up an automated function in a pharmacy environment necessitates thorough planning and restructuring in the workplace, as much in terms of human and material resources as in work methods and process management. The success of the implementation depends greatly on the preparatory steps taken in advance of launching the automated operation.

This table outlines tasks to be undertaken to ensure the success of the set up procedure. Take the time to prepare and to surround yourself with qualified staff to ensure the success of your implementation phase.

#	TASKS TO BE PERFORMED	POINT PERSON	DEADLINE	DONE
1	**PRE-SET UP DECISIONS**			
	Take all pre-system installation decisions with the help of Document 1.1 – Decision Support Tool for Initial System Set up.			
2	**PLANNING PROJECT RESOURCE ALLOCATION AND SUPERVISION**			
	Designate a SynMed® Pharmacist Manager tasked with planning, follow up and execution of SynMed® integration.			
	Designate a Technician Manager to assist the Pharmacist Manager in SynMed® deployment and integration.			
	Identify Production Technicians with the skills and competencies to operate the robot. (Refer to Document 1.1 – Decision Support Tool for Initial System Set up, Section 4 – Designating Production Technicians)			

#	TASKS TO BE PERFORMED	POINT PERSON	DEADLINE	DONE
	With the help of SynMed® personnel, create a schedule for the implementation of the automated system. This schedule should include: 1. Preparatory training: conversion of patient profiles 2. Initial replenishment of containers (about 20 hours) 3. Installation 4. Training 5. Last date when blister packs are to be prepared manually			
3	**PREPARING THE ROBOT AND SELECTING DRUGS**			
	Identify internal drugs (molecules) to be included in SynMed® based on computer sales reports for patients receiving blister packs.			
	Send list of selected drugs to Synergy Medical following the agreed to 45-day advance schedule, once all final decisions have been made concerning the inclusion or exclusion of certain products.			
	Order blister packs adapted for automatic production and all sheets used to print photos, if required, from the blister pack supplier. Item Numbers: <u>Dispill Canada:</u> - Permanent: 32-11 - Removable Sheets: 4-11 <u>Dispill USA:</u> CARDINAL: - Color label: 4860250 - White label: 4860318 - Blister pack: 4147989			

#	TASKS TO BE PERFORMED	POINT PERSON	DEADLINE	DONE
	- 32 days label: 4940862 - 32 days blister packs: 4940458 PARMED: - Color label: 993729 - White label: 993731 - Blister pack: 992780 KINRAY: - Color label: 911602 - White label: 911669 <u>Drug Package label: LASCL-43</u> <u>Jones Qubit :</u> T12F269: 7 Day Auto-Fill Single Panel Grid Card. Packed 1,000/case. T12F270: 7 Day Auto-Fill Double Panel Cover Card. 500/case. T12234: 7 Day Auto-Fill Blister. 1,000/case F119.07.00: 7 Day Laser Label 3-partAuto-Fill Blister. 800 sheets/case			
	- Determine the quantity or number of inventory days to be maintained for the units to be included in SynMed® (e.g.: 14, 21, 28 days). - Containers should be supplied initially according to the recommended required number of inventory days (for example, the quantity needed to prepare 14 days' worth of blisters packs).			

#	TASKS TO BE PERFORMED	POINT PERSON	DEADLINE	DONE
	In the initial week of system implementation, plan for a maximum number of blister packs to be produced with SynMed®. With Synergy Implementation Reprensetative, draw up a group deployment plan to gradually include each group and balance production (and build in time needed to make adjustments).			
	If the volume of blister packs warrants (over 400 units per week), keep manual production running continually until all of the groups are automated and optimum productivity is reached (plan for about 25 blister packs per hour, which could take a few weeks to accomplish).			
	Replenish SynMed® drug containers according to the procedure laid out by the Synergy Medical team. (This document named "Initial Replenishment of SynMed®" is provided by Synergy Medical.)			
4	**PREPARING AND PROGRAMMING PATIENT PROFILES**			
	Designate one Technician Operator and one pharmacist who will be in charge of patient profiles and master records according to the new pharmacy software programming guidelines (INSTRUCTIONS) governing patient dosages. A detailed guide will be provided by the Synergy Medical team during preparatory training (the document is called "SynMed Preparation").			
	<u>In each patient profile</u> Determine name of the generic drug brand provider to be included in the SynMed® for each drug and program the information in all patient profiles they apply to. Refer to the list initially selected.			
	<u>In each patient profile</u> Eliminate, where possible and with the help of the pharmacist if applicable, ½ (or ¼) sized pills if a half dose is available in one pill. (The ½ or ¼ sized pills will not fit in the SynMed®.)			

#	TASKS TO BE PERFORMED	POINT PERSON	DEADLINE	DONE
	In each patient profile Program the variable dosages by calendar dates (every other day, one day a week, once every two weeks, etc.) by a method compatible with SynMed®.			
	In each patient profile Eliminate all dosages with all calendar dates indicating ODD/EVEN DAYS. Replace them with calendar dates marked EVERY OTHER DAY. This way, sequencing will always conform to the starting date.			
	In each patient profile When a prescription needs to be in a distinct blister pack, it is possible to program the dosage in order to minimize handling, loss of time and risk of error. - It suffices to enter @@ at the beginning of the dosage field (INSTRUCTIONS).			
	Managing/Configuring Groups Within any one group, all patients must have the same starting date, must be on the same number of weeks in the production schedule, and must use the same type of blister pack. Program all patients in each corresponding group.			
	Managing/Configuring Groups Retain active patients in each group exclusively. This will save many minutes per week and ensure better system stability. This programming approach will ensure that all patient orders will be relayed automatically without having to sort active from inactive patients for each delivery schedule.			
	As much possible, eliminate all other drug distribution protocols (single-dose packs, partial doses, etc.). Patients whose profiles cannot be converted into multi-dose blister packs will have to be re-organized into different groups.			
	Try to standardize modes of distribution of particular drug orders (e.g., by affixing an identifying a marker to the blister pack).			

#	TASKS TO BE PERFORMED	POINT PERSON	DEADLINE	DONE
	Work on mastering transfer of profiles in batches.			
	Ensure that designated staff are well trained in entering uniform scheduling data that can be easily transferred to SynMed® software.			
5	**CROSS-CHECKING, QUALITY CONTROL AND RESPECTING GUIDELINES**			
	Plan the assessment of Production Technicians. Conduct the assessment of Production Technicians (refer to Document 1.4 – Production Technician Competency Assessment Matrix and Document 1.5 – Production Technicians Training Log.).			
	Make sure that Document 2.7 – Record of Acknowledgement of SynMed® Procedures is signed by all concerned parties.			
6	**RETENTION OF DOCUMENTS FOR RETRACEABILITY PURPOSES**			
	Plan for document retention (e.g.: Patient List – Originating Pharmacy). <u>Numbering System</u>: - Does not occupy physical space, but is housed within the memory of the computer system. - Need to adopt an efficient method of document classification. - Need to ensure that all files are protected and stocked in a secure manner for the required period. - Need to set aside time to create a numbering system. <u>Hard copies</u>: - Requires considerable physical space allocation.			

#	TASKS TO BE PERFORMED	POINT PERSON	DEADLINE	DONE
7	**PLANNING FOR PRODUCTION, TRAINING PURPOSES AND VARIOUS ASSOCIATED TASKS**			
	Conduct precise analysis of the total number of patients who will receive blister packs, weekly, every two weeks and every four weeks in order to set a production schedule, productivity goals and number of production hours required.			
	Allow for a period of 30 minutes either at the beginning or the end of the day to replenish containers. Include this task in the productivity index.			
	Determine by who and when the following tasks will be performed: ✓ modifying blister packs ✓ ordering drugs ✓ equipment upkeep ✓ packaging orders ✓ finalizing deliveries SynMed® productivity is optimal when the Production Technician works exclusively on production. Plan schedules accordingly.			
	Put together a robot production schedule that takes into account daily replenishing periods, number of blister packs to be produced for each group, daily/weekly/monthly tasks, and tasks assigned to Production Technicians. (See Document 3.5 – SynMed® Weekly Production Schedule.)			
	Determine timing for training of staff with Synergy Medical team, according to proposed training schedule.			
	Determine timing for training staff by SynMed® Pharmacist Manager according to proposed training schedule. (See Document 1.4 – Production Technician Competency Assessment Matrix, Document 1.5 – Production Technicians Training Log, Document 1.6 – Production Technicians and Access Management Log, Document 2.3 – Procedure for Cutting Pills and Blister Packs, and Document 2.7 – Record of Acknowledgement of SynMed® Production Procedures.)			