Synergy Medical

AUBURN LONG TERM CARE

## 2.1 SAFETY TOOLS FOR SYNMED® PRODUCTION

The following chart lists essential safety standards to be incorporated in all work practices adopted for automated SynMed® blister pack production. Proper use of technology will serve to minimise errors, as long as all operational rules and safe work practices are adopted and followed, and safety processes/tools already in place are never overridden or de-activated.

| # | SAFETY STANDARDS | RATIONALE |
|---|---|---|
| 1 | **REPLENISHMENT OF SYNMED® ROBOT** | |
| | Only sealed jars can be used for replenishing the robot. | It is essential that correct drugs are placed in SynMed® containers. There is no way to guarantee that the contents of unsealed (open) jars have not been compromised. The wrong pills could have been mixed together and this compromises the precision and safety of the SynMed® process. |
| | When the contents of an original container cannot fit into an identical SynMed® container, it must be immediately resealed with a safety seal designed for this purpose. | This simple measure ensures that nothing has been added to the container and that only those pills placed in it by the manufacturer during production are present. |
| | Each vial must be validated by a barcode scanner during replenishment. This is also the method to be adopted with pills available in 28/30 format blister packs. If pills are removed from the blister in advance, a clear procedure must be adopted. | Barcode scanning validates with 100 percent accuracy that the jars/boxes of a particular molecule correspond with the SynMed® container content. By scanning all packaging (jars, boxes, packs), errors of inattention can thus be avoided (for example, 100 mgs of Cozaar are found in a 50 mg Cozaar container, because one 100 mg jar has been included by mistake with four 50 mg vials). |
| | No drugs may be returned to their jars or directly into SynMed® containers (drugs from blister packs that have been damaged or otherwise compromised). | This prevents two different types of pills or twodifferent drug strength from being included in the same SynMed® container, which would compromise safety standards. Despite good intentions and all necessary precautions, this risk increases if SynMed® drugs are allowed to be returned to their original jars or containers. |

| # | SAFETY STANDARDS | RATIONALE |
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| | During the replenishment phase, in order to ensure proper inventory turnover, new pills must be placed BENEATH old ones in the SynMed® containers. | This allows for selection by the SynMed® system first of those pills with a later expiry date. |
| | When replenishing a SynMed® container, make sure to use a pill counter sterilized with isopropyl alcohol and then add pills already present in the SynMed® container. Then add the pills from the manufacturer into the SynMed® container, followed by the contents of the pill counter. Make sure to clean the pill counter for each drug. | This avoids risk of cross contamination between different types of drugs and reduces potential harm to patients. |
| | When adding new pills into the SynMed® drug container in which there are already pills from another lot, pay close attention to the expiry date of the existing lot. Make sure you understand the ADD vs REPLACE functions. When in doubt, consult a supervisor. | It is important to document, from the start, steps to follow for keeping data up to date in the robot and for standardizing team work practices. If the REPLACE function is first activated, lots being processed will not automatically be stored in memory. In the event a drug is then recalled, omissions could occur. It is best to use the ADD function when processing different lots, but not to process more than two or three different lots at a time. |
| | When replenishing a container, if you must REPLACE all lots, the SynMed® container must be completely empty before adding drugs from a new lot. Pills removed from the container must be returned to the dispensary, in a vial well identified with the name of the drug, the strength, the expiry date, the lot number and the current date. The vial is then attached to the original container with an elastic band, and the drugs from this vial will be dispensed first to the patient when their next prescription is being filled. | This allows for continuous tracking of lots contained in the SynMed® store and for risk- and loss-free handling in the event of product recall. |
| 2 | **PLACING DRUG CONTAINERS IN THE SYNMED® ROBOT** | |
| | When inserting SynMed® drug containers in the robot, barcode scanning technology must be used to ensure proper positioning of containers. | Dispensarytechnicians must never be permitted to manually retrieve drugs from the SynMed® store, except under extreme circumstances.<br>There is an elevated risk of error if containers are replaced without using the Validate Containers button (activated by the barcode scanner).<br>As well, this compromises accuracy of drug inventory and replenishment reports while adding to the daily replenishment schedule workload. Production Technicians could as a result take short cuts if the process becomes too onerous because established work procedures have not been followed by the team. |
| 3 | **MANUAL INSERTION OF EXTERNAL DRUGS** | |

| # | SAFETY STANDARDS | RATIONALE |
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| | Safety gloves or tweezers must be used to handle all drugs. | Repeated direct exposure of skin to drugs can cause sensitivities and allergies. The list of dangerous drugs compiled by NIOSH, which require careful handling, has increased in length over time. This list is included in this binder (see Document 1.8 – List of Dangerous Drugs as Listed by NIOSH).<br>As well, it is important to follow proper hygiene guidelines. |
| | Returning drugs to their jars is to be avoided, unless handling external drugs (drugs inserted manually). Proper steps must be taken to ensure that the correct drugs have been placed in the proper containers, by verifying the contents of the original container and comparing them with the list of drugs to be added. | Since this stage is done manually and each inserted pill is handled by a Production Technician, anomalies are more easily spotted by the technician, or the manager, who will perform the initial check of external drugs (manually inserted) in each blister. |
| 4 | **POSITIONING AND SEALING BLISTER PACKS** | |
| | Print out and check the *Production Events* Report after each tray is produced. This report must be double checked before the labels are affixed to the blister packs. | This allows anomalies in the production cycle (manual insertion of drugs, for example) to be corrected and for avoiding processing errors. |
| | Use of barcode scanners is mandatory to ensure proper labels have been affixed to the blister packs. | This is a safety feature which allows for smooth delegation of the blister pack production cycle. It also helps to avoid patient error, among other things, as well as wasteful duplication of efforts in the event blister packs have been improperly positioned from the start (i.e., positioned without being validated with a barcode scanner). |
| | Blister pack labels must be affixed to the packs once all blister packs are properly in place. | This ensures that the proper label has been affixed to the correct pack, and prevents units falling to the floor during the final count. |
| | Drug bags or vials must be attached to the blister packs as quickly as possible in the production cycle. | This allows for accurate cell count of drugs included in the blister packs while eliminating manual handling. |
| | All blisters for each blister pack and each tray must be carefully counted and checked. | Careful (or photographic) cell count is the only way to trace jumpers, duplicates, and breakages before all blister packs have been sealed. This step must be carefully executed to minimize risk of error and avoid alterations to blister packs that have been sealed. All ½ sized pills must also be accounted for at this stage. |

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| | Blister packs must be sealed once cell count has been completed and trays checked, so as to avoid jumpers resulting from handling of unsealed blister packs. | Sealing blisters packs immediately following cell count ensures that the integrity of the contents has not been compromised during handling.<br>If some of the packs cannot be checked once sealed, affix three paper clips (on each side) to limit pill displacement.<br>Limit number of unsealed blister packs as much as possible. |
| | Fill out the SynMed® Error Sheet (Document 2.6) as soon as an error is spotted during the verification phase. Take swift action to correct the sources of the problem (e.g., in the case of duplicates, lid size must be checked). | Compiling a list of errors allows for follow up and identifying the source of the problem. Action must be taken swiftly to solve the problem at its source, as this will prevent the same problem from re-occurring. This also serves to improve production efficiency. |
| **7** | **RETRIEVING DRUGS FROM PATIENTS** | |
| | Due to elevated risk associated with this work practice, retrieving drugs from patients must be done on an exceptional basis. | Retrieved drugs should never be replaced in the robot. |
| **8** | **ERGONOMICS** | |
| | Counter height for preparation and checking of trays (for manual insertion and counting of drugs) must be adapted so that each Production Technician has a clear view of the blister packs being worked on, including those in the upper rows. | This avoids risk of error when counting cells or drugs due to lack of access to all blister pack cells (i.e., a technician cannot see properly without standing on the tips of his toes). This also avoids risk of injury resulting from the use of a low stool. |
| **9** | **INTERRUPTIONS** | |
| | Limit as much as possible any interruptions to the system production schedule or by work colleagues. Working in silence also enhances the ability to concentrate on tasks. | Interruptions are one of the chief causes of error. When concentration is broken, the human brain loses its ability to follow a logical train of thought. The task at hand then needs to be started over to ensure that it is properly executed. |
| **10** | **COMPLIANCE WITH WORK PRACTICE PROCEDURES AND STANDARDS** | |
| | All Production Technicians should have their own user name and password. | It is essential to trace various action steps to the correct user.<br>SynMed® software allows for detailed tracing of replenishment and container stats (user, drug, lot, expiry date, etc.) and for generating corresponding reports. But precise user identification is essential for accurate reporting purposes. |
| | Ensure that a back-up copy of the SynMed® software is automatically transferred to a USB stick and kept in a secure location, away from pharmacy premises, in case of fire. | It is strongly advised to have two USB sticks and alternate their use, and always remove one of them from the premises, and not forget to bring one back every two days and exchange it with the other. If only one USB stick is used, it must |

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| | | remain in the computer port at all times. This backs up data, but does not provide protection in case of fire. |
| | All procedures put in place must be applied by all staff, in order to standardize work methods, minimize risk of error, ensure efficiencies and track all activities. | Standardizing work processes and methods greatly allows for optimum quality control of tasks performed. |
| **11** | **PREVENTING LOSS OR THEFT OF DRUGS** | |
| | Simple and effective measures are in place to avoid the theft or loss of drugs from blister packs produced weekly in the SynMed® system. Always...<br>- have a powerful antivirus program compatible with SynMed® software and installed by Synergy Medical; this will ensure integral data storage and protection;<br>- lock the premises where the robot is located if possible;<br>- assign each staff member authorized to operate the SynMed® system a personal username and password;<br>- program access levels for each user according to the tasks they are authorized to perform;<br>- bar access to the system to all dispensarytechnicians (do not allow them at any time to handle drugs in SynMed® containers.) | It is advisable to follow these safety guidelines. |

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## 2.2 SUMMARY OF SYNMED® SAFETY PRECAUTIONS

**IMPORTANT**: These procedures are mandatory to ensure safe, error-free production of blister packs.

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| 1 | **REPLENISHING THE ROBOT** |
| | 1.1. Only sealed drug jars can be used for replenishing the robot.<br>1.2. When an original jar cannot be emptied into a SynMed® container, it must be immediately resealed.<br>1.3. Each jar must be validated by a barcode scanner during the replenishment cycle. This must also be done for pills available in 28/30 format blister packs.<br>1.4. To ensure proper inventory turnover, new pills can be placed UNDER old ones.<br>1.5. When new drugs are being added to containers with drugs from another lot, pay close attention to the expiry date of the existing lot. Make sure you are familiar with procedures for KEEPING, ADDING or REPLACING lots. When in doubt, consult a supervisor. |
| 2 | **MANUAL INSERTION OF EXTERNAL DRUGS** |
| | 2.1. Before preparing the tray, gather all required drugs.<br>2.2. Returning drug units to their jars is allowed for this procedure unlike the one for replenishing the robot. |
| 3 | **PROPER POSITIONING OF BLISTER CARDS WITH THE HELP OF BARCODE TECHNOLOGY** |
| | 3.1. Barcode scanning must be used to ensure proper positioning of blister pack labels.<br>3.2. Blister pack labels must be affixed to the blisters as soon as blister card validation is completed. |
| 4 | **POST-PRODUCTION CELL COUNT** |
| | Proceed with cell count validation of all blister packs in order to identify jumpers, duplicates, breakages and other anomalies. |
| 5 | **PLACING DRUG CONTAINERS IN THE ROBOT** |
| | All drug containers must be placed in the robot with the help of barcode technology to ensure their proper positioning. |
| 6 | **RETRIEVING DRUGS FROM CLIENTS** |
| | Owing to the elevated risk of a security breach associated with this practice, retrieving customer orders must be done on an exceptional basis. Strict procedures must be put into place by the SynMed® Pharmacist Manager to handle these exceptions. |