STEM CELL LABORATORY (STCL)

DOCUMENT NUMBER: STCL-GEN-002

DOCUMENT TITLE:

STCL Supply Management Procedure

DOCUMENT NOTES:

Document Information

Revision: 10	**Vault:** STCL-General-rel
Status: Release	**Document Type:** STCL

Date Information

Creation Date: 18 Apr 2025	**Release Date:** 08 May 2025
Effective Date: 08 May 2025	**Expiration Date:**

Control Information

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Previous Number: STCL-GEN-002 Rev 09	**Change Number:** STCL-CCR-564

STCL-GEN-002
STCL SUPPLY MANAGEMENT PROCEDURE

1 PURPOSE

1.1 To describe the steps used by trained personnel to order, receive, inspect, document and store supplies used in the Stem Cell Laboratory (STCL).

2 INTRODUCTION

2.1 As part of a quality program for the production of cellular products, the STCL must ensure that supplies and services used by the laboratory consistently meet specified requirements. This is accomplished by the continuous monitoring of supplies received. This procedure defines the process for assuring and monitoring the quality of supplies, from time of receipt to time of use.

2.2 STCL personnel will document receipt of supplies to provide an accurate record of the stock on hand. This record will include stock identification, lot numbers, and expiration dates for laboratory supplies.

2.3 A current manufacturer's Package Insert and Certificate of Analysis (COA) and/ or Certificate of Conformance (COC) are reviewed upon receipt and kept on file, as well as other quality documentation required, when applicable. The required supporting documentation for each supply will be specified in its MSPEC.

3 SCOPE AND RESPONSIBILITIES

3.1 STCL laboratory personnel are responsible for:

3.1.1 Evaluating inventory and ordering necessary supplies.

3.1.2 Creating a Material Specification Form (MSPEC) for each supply, to specify requirements for acceptance and release. The Supply Coordinator will be responsible for the creation of MSPECs, involving SMEs and final users as needed. Keeping a folder with current copies of released MSPECs in the lab, to be used for reference in the supply release process.

3.1.3 Accurately documenting the receipt and inspection of supplies (completing supply receipt log (*STCL-GEN-002 FRM2 STCL Supply Receipt Log*), placing the supplies in the quarantine cage, together with the required documentation (*CoA, Package Insert, Package Insert Review, and MSPEC, as applicable*). If supplies cannot be accommodated in the quarantine cage, they will be identified unequivocally to avoid accidental use or release.

3.1.4 Requesting critical component verification for supplies requiring additional qualification.

3.1.5 Checking to confirm CQP release of the supplies, then storing supplies used in the laboratory.

3.1.6 Alerting the laboratory manager or designee of any discrepancies discovered during this process.

3.1.7 Maintaining current copies of package inserts and Certificates of Analysis (C of As) and/or Certificates of Conformance (C of Cs) when required.

3.1.8 Retaining outdated copies of these documents and alerting the laboratory manager or designee of new versions of these documents.

3.1.9 Releasing supplies into the STCL for use following QA review and release has been completed.

3.2 Laboratory manager or designated STCL staff is responsible for:

3.2.1 Resolving discrepancies that are discovered when supplies are checked in.

3.2.2 Reviewing revised package inserts, alerting personnel of any changes that affect the use of the supply, or initiating revisions to procedures and/or training staff.

3.2.3 Approving MSPECs and its revisions.

3.2.4 Facilitating the receipt of required Certificates of Analysis and/or Certificates of Conformance and ensuring that certificates are on file.

3.2.5 Making sure that these certificates and product inserts are maintained.

3.3 Clinical Quality Program (CQP) / QA Designee (STCL Manager) is responsible for:

3.3.1 Reviewing and inspecting and approving or rejecting all incoming supplies/materials against their MSPECs. Document this on the *STCL-GEN-002 FRM2 STCL Receipt Log.*

3.3.2 Approving new MSPECs and its revisions. As part of that review, CQP will confirm that the vendors and suppliers are qualified, per *COMM-QA-002 Supplier Qualifications*, as applicable.

3.3.3 Reviewing all package insert review logs and document this revision on the *STCL-GEN-002 FRM4 STCL Package Insert Review.*

4 DEFINITIONS/ACRONYMS

4.1	COA	Certificate of Analysis
4.2	COC	Certificate of Conformance
4.3	CQP	Clinical Quality Program
4.4	FDA	Food and Drug Administration
4.5	MSPEC	Material Specification Form
4.6	N/A	Not Applicable
4.7	QA	Quality Assurance

4.8 SAP Duke Electronic Supply Purchasing Program

4.9 STCL Stem Cell Laboratory

4.10 Supply Coordinator Refers to designated STCL staff

5 MATERIALS

5.1 Supply Ordering and Receipt Notebooks

5.2 Colored Lot Dots

5.3 Box cutter (*if needed*)

5.4 Quarantine/Do not use Labels

6 EQUIPMENT

6.1 Date gun

6.2 Computer with SAP access

7 SAFETY

7.1 Use any/all appropriate personal protective equipment when working with incoming supplies that could leak (*i.e., chlorox, etc.*) including, but not limited to, gloves, lab coats, etc.

8 PROCEDURE

8.1 Ordering

8.1.1 Complete a *STCL-GEN-002 FRM1 Supply Ordering Log* to initiate the order of a required supply. Orders should be initiated when any of the following situations occur.

8.1.1.1 Inventory suggests additional supplies will be needed.

8.1.1.2 An increase in the use of a supply is anticipated.

8.1.1.3 A new product is needed for new or existing procedures (*may require a quote*).

8.1.1.4 Product available is approaching the expiration date.

8.1.1.5 PO is needed for payment of maintenance (*requires quote*).

8.1.1.6 Purchase of Capital Equipment (*requires quote*).

8.1.2 The ordering staff will check the ordering log daily and order supplies requested.

8.1.2.1 Requests for expedited ordering should be communicated to the ordering staff through an email request, in addition to completing the order supply form.

8.1.2.2 Items in which order information is not available should be requested through email or verbally with supporting documentation concerning the item(s).

8.1.3 Orders placed in the R/3 SAP system

8.1.3.1 Request a green ticket from the **Authentic Login** site allowing access to SAP.

8.1.3.2 Click on the SAP icon and select the **Procurement** option to log on.

8.1.3.3 Click on **Purchasing** to begin the supply ordering process.

8.1.3.4 From the Create Requisition screen, select a requested delivery date and enter the purchasing group information in all required fields. Indicate for Goods Receipt by typing "R" in the account assignment box.

8.1.3.5 Request a delivery date (*choose 1 week from order date unless expedite is required*).

8.1.3.6 Choose **LABC** for "Plant", **M80** for "Purchasing Group" and **260** for "Material Group".

8.1.3.7 Press **ENTER** and make sure the delivery date is within 7 days from the order date.

8.1.3.8 From the **Create Purchase Requisition**; **Item Overview** screen, enter the first item number in the **Material** box (*if a **Material Master** number is available*), or type the item description in the **Short Text** box when no Material Master number is available.

8.1.3.9 An SAP material number search may be initiated by clicking in the **Material** box, clicking on the drop down menu and following instructions for search options.

8.1.3.10 Items with a number assigned on the SAP Material Master

8.1.3.10.1 Enter the Material Master item number in the **Material** box.

8.1.3.10.2 Enter the quantity and press ENTER.

8.1.3.10.3 Vendor material and price are automatically referenced in the system.

8.1.3.10.4 Proceed to 8.1.3.12.

8.1.3.11 Items without a number assigned on the SAP Material Master

8.1.3.11.1 Enter material name and description in the **Short Text** box.

8.1.3.11.2 Enter the quantity and unit of measure (*i.e., ea, bx, cs, etc.*).

8.1.3.11.3 A new screen will appear requesting vendor ID, price and vendor's material number.

8.1.3.12 A new window will open requesting the account assignment for the item.

8.1.3.12.1 In the **G/L** account field, type 64500 (*for general lab supplies*) if no number is displayed.

8.1.3.12.2 In the cost center box, enter the STCL cost code **266090213** (*for STCL USE **ONLY***).

8.1.3.12.3 Tab over to **Unloading Point** and type **North Pavilion 2400 Pratt Street**.

8.1.3.12.4 Enter **Goods Recipient's** name (*the name of the ordering person*).

8.1.3.12.5 If additional items are to be requested, click on **Repeat Acc. Ass. ON** to skip this screen.

8.1.3.12.6 Each line item has a value limit up to **$4999** any item **over $5000 is blocked** and has to be **released by Clinical Labs finance team via email request.**

8.1.3.13 A new **Delivery Address for Item** screen will open.

8.1.3.13.1 At the address prompt, type **1002026076** and press **ENTER**.

8.1.3.13.2 The name field will display **Duke University Medical Center/Stem Cell Laboratory**.

8.1.3.13.3 The street address box will display **2400 Pratt Street, Durham NC, 27705**. Click next line to add suite 1300.

8.1.3.14 Click on the **Repeat Address ON** box. Confirm that the delivery address is to be held by clicking on the green check. Click on **ADOPT** to accept the data.

8.1.3.15 The program returns to the **Create Purchase Requisition: Item Overview** screen. Additional items any vendor may be added to the request.

8.1.3.16 Upon completion of the ordering process, click on the disk icon on the upper left-hand corner of the screen to generate a purchase requisition number.

8.1.3.17 Record this number on the *STCL-GEN-002 FRM1 Supply Ordering Log* or print a copy of the requisition.

8.1.3.18 Within one day from the date the purchase requisition was generated, check R/3 SAP to ensure that a purchase order number has been assigned.

8.1.3.19 If no PO# has been assigned, contact the procurement office for assistance at 681-5900.

8.1.4 Items that are not entered into the R/3 SAP system.

8.1.4.1 Office supply items ordered from Staples via the Staples corporate website (www.staples.com).

8.1.4.1.1 No requisition number of PO# is generated.

8.1.4.1.2 Order confirmation is received via e-mail.

8.1.4.1.3 Print this e-mail and file with the packing slip upon receipt of the order.

8.1.4.2 Items from the Duke Tissue Culture Facility.

8.1.4.2.1 Order through the website (*www.cancer.duke.edu/ccf/*)

8.1.4.2.2 Send e-mail to:ccfduke@mc.duke.edu.

8.1.4.2.3 Arrangements must be made to have items picked up (*no delivery*).

8.1.4.3 Items from Duke Pharmacy

8.1.4.3.1 Orders faxed on Interdepartmental Request form to the pharmacy.

8.1.4.3.2 Arrangements must be made to have items picked up (*no delivery*).

8.1.4.3.3 Standing orders must be submitted on purchase requisition forms (*i.e., Immucor, Sysmex, etc.*) and sent to procurement so PO# can be generated.

8.2 Receipt of Supplies

The **STCL Supply Coordinator** will perform the following tasks:

8.2.1 **NOTE**: It is imperative that STCL personnel accepting delivery of packages (*the Supply Coordinator or designee*) promptly evaluate the shipment to determine if refrigeration or freezing is required. If required, these products should be handled immediately and stored in the appropriate conditions as detailed on the applicable MSPEC (see section 8.2.8.3).

8.2.2 Compare the supplies received with both the order placed in the ordering notebook and the packing slip for correctness and completion of order. Initial and date the packing slip to be filed.

8.2.3 Visual Inspection

8.2.3.1 Inspect the boxes/cartons/bottles for damage, contamination or leakage, abnormal color and/or cloudiness that may compromise the contents. Ensure that all labels are intact.

8.2.3.2 If no obvious damage or contamination is seen, proceed to step 8.2.4.

8.2.3.3 If damage is apparent, notify the staff in charge of ordering or the STCL manager. Initiate an *Unacceptable Supply/Product Recall Corrective Action Log* STCL-GEN-002 FRM3.

8.2.3.4 Place the item in the quarantine supply cart (cage) in the STCL until the vendor is contacted and the problem is resolved (*i.e., product replaced, credit issued, etc.*). For temperature sensitive items, see section 8.5.4.

8.2.4 Complete STCL-GEN-002 FRM2 *STCL Supply Receipt Log.*

Once the packing slip and items have been reconciled by the STCL Supply Coordinator, the supplies should be placed in the Quarantine Cage together with their STCL-GEN-002 FRM2 *Supply Receipt Log*, the STCL-GEN-002 FRM5 *STCL Material Specification* Form (*if already created*) and supporting documentation (*CoA, Package Insert, qualification results, etc.*) for CQP review of the documentation and release of the supply (signed off approving usage).

8.2.4.1 Document the Receipt Date, Lot Number and Expiration Date on the *Supply Receipt Log* STCL-GEN-002 FRM2.

8.2.4.2 Verify that the expiration date (*if applicable*) has not been exceeded or it is not considered too short. If NO expiration date is assigned to a product, the STCL Supply Coordinator will assign an internal expiration date that is "two (2) years from the date of receipt" of that item.

8.2.4.3 If a correct product is received, but the quantity is incomplete (i.e., part of the order is on backorder), note this in the comment section of the form.

8.2.4.4 If there is a problem with the order and resolution cannot be accomplished, refer the issue to the laboratory manager or QA designee.

8.2.5 Verify receipt of a package insert and/or COA/COC (*if applicable*)

8.2.5.1 The supply coordinator will obtain package inserts for all FDA licensed reagents.

8.2.5.2 COA will be obtained from the manufacturer on products incorporated into the final unit or on non-licensed reagents. Consult STCL-GEN-002 JA1 *COA List (JA1)* to know if a COA should be located for the received item.

8.2.5.3 Document if Package insert and/or COA/COC is required on the STCL-GEN-002 FRM2 *Supply Receipt Log*, according to MSPEC (if available).

8.2.6 Package Insert review:

8.2.6.1 Document the receipt and revision of the package insert on the *STCL-GEN-002 FRM4 Package Insert Review Log*.

8.2.6.2 If there is no insert on file, write the date received on the insert, sign and date. Place a copy of the package insert, together with the *STCL-GEN-002 FRM4 Package Insert Review Log*, in the laboratory manager's mailbox for review.

8.2.6.3 If there is an insert on file, verify that the revision date of the new package insert is the same as the package insert on file in the logbook. If so, document accordingly in *STCL-GEN-002 FRM4 Package Insert Review Log* and place it in the cage together with FRM4. Discard the insert after CQP release.

8.2.6.4 If the new insert is a new revision, write the date received on the insert, sign and date, and place the insert and the *STCL-GEN-002 FRM4 Package Insert Review Log*, in the laboratory manager's mailbox for review.

8.2.6.5 The Lab manager will review all new package inserts and every new version, to verify if procedural changes or additional training is required.

8.2.7 Certificate of Analysis or Conformance review

8.2.7.1 If no COA/COC is included and one is required, obtain the COA/COC. Consult the COA list (JA1) for instructions to obtain the certificate.

8.2.7.2 If a COA/COC is included, check the certificate to ensure that the lot number corresponds to the supply received; sign and date the certificate.

8.2.7.3 Leave the COA/COC together with the *STCL-GEN-002 FRM2 Supply Receipt Log*

8.2.7.4 Certificates will be maintained in the designated file.

8.2.8 Critical Component Qualification Verification (Qualification of Supplies)

If critical supplies coming in direct contact with cellular therapy products during processing, storage, and/or administration are not the appropriate grade for intended use, those supplies must undergo further qualification to ensure they are of the appropriate grade for the intended use. Those test results will be reviewed by CQP for release of the supply into the lab.

8.2.8.1 Each new lot of the current Stemsol **DMSO** product (*or equivalent*) that is used to cryopreserve cellular therapy products is currently being sent to an outside agency (*i.e., BioTools, Inc. or equivalent*) for qualitative ID for DMSO and quantitative determination of the concentration of DMSO before the new lot can be implemented for use in the STCL. Sterility (**14 days**) of each new lot of DMSO is tested in the STCL before it is released for use. Place the

results of the testing together with the supply, log receipt and other supporting documentation in the quarantine cage for CQP release.

8.2.8.2 Although **culture bottles** are sterile upon receipt, we internally qualify new lot #s in the STCL by testing sterility of a set of culture bottles for **14 days** before we start using the new lot #. Place the results of the testing together with the supply, log receipt and other supporting documentation in the quarantine cage for CQP release.

8.2.8.3 If other critical supplies are identified in the future and not found to be of the appropriate grade, additional qualification testing will have to be performed on those supplies as well.

8.2.9 Supplies that have NOT been released by CQP must remain in the quarantine cage and CANNOT be used. If voluminous supplies cannot be accommodated in the quarantine cage or require refrigeration, they will be unequivocally identified with a QUARANTINE label to avoid their accidental use or release.

8.2.10 Once CQP has signed off and released the supplies, the supply coordinator will confirm the CQP release documented on *STCL-GEN-002 FRM4 Package Insert Review Log*, affix a dated FIFO label to the supply, and place the supply on the supply cart so they can be distributed and used throughout the laboratory. For supplies out of the quarantine cage, the supply coordinator will remove the QUARANTINE label and affix a dated FIFO label to the supply prior to distribution to the laboratory.

The **CQP** will perform the following tasks:

8.2.11 CQP will come to the STCL for supply release on a daily basis, Monday-Friday. If items are temperature sensitive, or urgent CQP staff will come on demand.

8.2.12 CQP will perform a review of the supply and its quality supporting documentation, placed together in the quarantine cage, and document that review completing its dedicated section on STCL-GEN-002 FRM2 Receipt Log.

8.2.13 CQP will perform a visual inspection of the supply to confirm it is in acceptable condition, verify the lot number, expiration date, quantity, and compliance with GDP in the completion of the form.

8.2.14 CQP will verify against the MSPEC the requirement for Package Insert, CoA/CoC and Critical Component Verification for the supply. CQP will verify critical component verification/qualification requirements, when required per MSPEC.

8.2.15 CQP will review all package inserts and sign the *STCL-GEN-002 FRM4 Package Insert Review Log* for all supplies requiring package insert, and will QA review all new versions of package inserts.

8.2.16 CQP will verify the lot number and expiration date of the supply in the CoA/CoC, confirming that the supply meets the requirements, and will sign and date the CoA/CoC.

8.3 Labeling Chemical Materials

8.3.1 **All chemical materials must be labeled appropriately.** Affixing the appropriate label to these materials will be the responsibility of the STCL Safety Deputy.

8.3.2 **NOTE**: Clorox is assigned a "one year" expiration date from the Julian date reflected on the container. The top line has a letter followed by a 7 digit code. The letter and first number are producing plant identification; the next 4 digits are a Julian production code, and correspond to the year and the day number. (*For example a code A8**8095**07 was manufactured on the day 95 of 2008, which is April 4th. Expiration date for this bottle will be 04/04/2009*).

8.3.3 Biological materials should be handled with universal precautions.

8.4 Preparation for Storage

8.4.1 Use the date gun to label all received supplies and reagents with the received date.

8.4.2 For supplies monitored with colored lot dots, affix the appropriately colored lot dot to each supply or reagent. Follow the colored lot dot sequence of Red, Orange, Yellow, Green and Blue (**ROYGB**).

8.4.3 Notify the ordering area that the ordered item(s) are ready for storage.

8.5 Storage

8.5.1 When storing reagents (*and dated disposables*), be sure to rotate the stock. Always use the earliest outdating supplies first; first IN, first OUT (referred to as **FIFO**). Follow the colored lot dot sequence of Red, Orange, Yellow, Green and Blue (**ROYGB**).

8.5.2 Due to storage space limitations within the STCL, supply carts are used to store a variety of supply items (*organized to ensure that supplies with the shortest outdate are used first (**FIFO**) in an effort to minimize waste*). There are also other designated storage options for supplies in respective work areas throughout the lab so supplies are readily available when needed. See *STCL-GEN-002 JA2 Storage of Supplies in Designated Areas of the STCL* for more details. Lot number worksheets are also used and available to item description, reflect supplier, lot #, expiration date, quantities used, etc.

8.5.3 Store reagents as indicated by the manufacturer's instructions, maintaining receive date and colored lot dot designation on all items.

8.5.4 Pay special attention to ensure that supplies that need to be refrigerated or frozen are stored as quickly as possible upon receipt. If a supply item must be placed outside of the quarantine cage (*i.e.. in the refrigerator or freezer*) while awaiting CQP release, label the supply item(s) with an

orange **QUARANTINE** label to prevent usage until it has been released by the CQP team. The supply coordinator will confirm that the supply is signed by CQP for release, and then remove the quarantine label from the supply and affix a dated FIFO label before releasing it to the lab.

8.5.5 Complete the Supply Receipt Log, provide all necessary supporting documentation, and request immediate review/release of supply items by the CQP team for urgent "temperature sensitive" supply items to ensure supplies are not compromised.

8.5.6 Appropriately dispose of all outdated supplies. If reagents are being used for "research purposes", be sure supplies are stored accordingly.

NOTE: Notify the lab manager if there is a high volume of supplies being discarded due to expiration dates; since it is the responsibility of all staff to minimize waste, discarding supplies should not occur frequently.

8.6 Recalls

8.6.1 If there is notification of a recalled item, check the supply management documentation to see if the affected items, lot #s, etc., have been ordered and/or used in the STCL.

8.6.2 Notify the lab manager (*or designee*), CQP, and applicable lab staff so an investigation can be initiated. A deviation will need to be submitted in MasterControl if it is determined that there is any negative impact on cellular products that may have come in direct contact with patients.

8.6.3 Complete *STCL-GEN-002 FRM3 Unacceptable Supply/Product Recall Corrective Action Log*.

8.6.4 Since recall notifications are generated through the hospital system as well, it may be necessary to communicate accordingly through the hospital system as per the institutional policies and procedures regarding recall of supplies, equipment, etc. See *DUH Recall Procedure* and/or *DUH Medical Recall Policy*.

9 RELATED FORMS/DOCUMENTS

9.1 STCL-GEN-002 FRM1 Supply Ordering Log

9.2 STCL-GEN-002 FRM2 STCL Supply Receipt Log

9.3 STCL-GEN-002 FRM3 Unacceptable Supply/Product Recall Corrective Action Log

9.4 STCL-GEN-002 FRM4 Package Insert Review Log

9.5 STCL-GEN-002 FRM5 STCL Material Specification Form

9.6 STCL-GEN-002 JA1 Certificates of Analysis and/or Certificates of Conformance

9.7 Purchase Requisition Form, Form DA-29A

9.8 STCL-GEN-002 JA2 Storage of Supplies in Designated Areas of the STCL

9.9 COMM-QA-002 Supplier Qualifications

10 REFERENCES

10.1 AABB Standards for Hematopoietic Progenitor Cell Services, Current Edition.

10.2 FDA: Code of Federal Regulations, Title 21

10.3 FACT Standards for Hematopoietic Progenitor Cell Collection, Processing and Transplantation. (Update ref with revision, etc.)

10.4 SAP R/3 Procedure

11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
10	M. Ritt	- Removed reference to Quality Systems Unit (QSU) throughout the document and replaced with Clinical Quality Program (CQP)

Signature Manifest

Document Number: STCL-GEN-002 **Revision:** 10
Title: STCL Supply Management Procedure
Effective Date: 08 May 2025

All dates and times are in Eastern Time.

STCL-GEN-002 STCL Supply Management Procedure

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Document Release

Name/Signature	Title	Date	Meaning/Reason
Amy McKoy (ACM93)	Document Control Specialist	24 Apr 2025, 09:54:56 AM	Approved