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1.0 Purpose

This procedure describes the policy and process by which Biopharmaceutical Quality Assurance (BQA) has the authority and responsibility to place materials on hold that may possibly compromise the safety, identity, strength (potency), quality, purity, or CGMP compliance of a product.

2.0 Scope

This procedure applies to GMP/GLP raw materials, in-process product, and products used or manufactured by the Biopharmaceutical Development Program (BDP), or for the BDP by contract manufacturers. The procedure also applies to any materials that may have been mislabeled, adulterated, or possibly have had its safety, identity, strength (potency), quality, purity compromised or have a concern with the CGMP compliance of a product. This procedure does not replace the incoming raw material receipt and inspection procedures; refer to ***SOP 20302, Receipt and Inspection of Materials***.

3.0 Policy

It is the policy of the BDP that any material or product that may be compromised in its ability to serve its function or meet regulatory requirements be placed on hold or withheld from release until an investigation demonstrates that any product-related concerns are resolved. It is the responsibility of every BDP employee to bring to the attention of management and BQA any information that indicates a product may have been compromised. Requests for hold/quarantine may also come from other procedures/systems (OOS, calibration, deviations, stability program and from equipment process and facilities failures). The procedures used to place processes, equipment, utilities, or facilities on hold/quarantine are addressed in ***SOP 21526, Engineering Event Management and Status Placarding***, which may be used in conjunction with this SOP.

4.0 Authority and Responsibility

4.1 BDP employees are responsible for notifying their supervisor and/or BQA if they believe a BDP material or product has possibly been compromised. After discussion with the Supervisor, either the Supervisor, or designee, is responsible for filling out the Quarantine/Hold Investigation Notification (**Form 21704-01**).

4.2 BQA Management personnel have the authority and responsibility to quarantine or place on hold any BDP raw material, in-process product, or products that may have been mislabeled, adulterated, possibly have had its safety, identity, strength (potency), quality, purity compromised, or has a concern with the CGMP compliance of a product.

4.3 BQA has the responsibility for:

- Reviewing notifications from BDP employees of known or potential material quality issues.
- Initiating Form 21704-01 after receiving notification of issue / concern (if requested)
- Notifying Department Heads and BDP Management of potential issues under investigation and the final resolution of those issues.
- Quarantine or place On Hold materials with known or potential quality issues.
- Dispositioning materials as a result of a review of the issues or an investigation into the concerns or an MRB action. BQA is also responsible for product release as per ***SOP 21002, Product Release***.

4.4 The BQA Director, or designee, has the authority to remove a hold/quarantine designation.

4.5 BQA is responsible for quality oversight of this procedure.

5.0 Procedure

5.1 Any employee that believes a BDP material or product may have been compromised must report this finding to his/her supervisor and/or BQA. After discussion with the supervisor, either the supervisor or designee is responsible for filling out the top portion of the Quarantine/Hold Investigation Notification, **Form 21704-01**) and submitting the form to BQA management. BQA may initiate **Form 21704-01** on its own when notified either verbally or via email of issue /concern. If anonymous notification is necessary, BQA may be notified directly.

5.2 Upon receipt of Quarantine/Hold Investigation Notification, BQA will assign a unique tracking number to **Form 21704-01**. Tracking numbers are assigned using the coding below: Year (4 digits); Month (2 digits) and sequential number (2 digits).

For Example - **QH: 2020-08-01**would be the first notification issued in August in the year 2020.

5.3 BQA will review forms to make a determination of whether the quality of a raw material, in-process material, or product may be adversely affected, filling in the second half of the Notification, **Form 21704-01**.

5.4 BQA may place the material or product on hold or in quarantine, prior to, during, or after an investigation, depending on the severity of the risk associated with its use. BQA can also place

previously released products back into quarantine if they believe its quality may have been affected. BQA will determine whether the item will be placed on hold or in quarantine and whether MRB review is necessary.

5.4.1 An item that is placed on QA hold can be used in processing or further processed, but the final product is placed on hold when completed until the material or product in question is released from hold.

5.4.2 An item that is placed in QA Quarantine is segregated by having MMIC place the item into the appropriate quarantine area, if possible (follow procedures in ***SOP 20302, Receipt and Inspection Material)***. Items not able to be physically isolated will be placarded with their status. Items placed into QA Quarantine may not be used or further processed until BQA, with assistance from department management and the Project Scientist, as appropriate, releases it from quarantine.

5.5 BQA identifies an item to be placed on hold or in quarantine with a label or placard indicating whether it is on “BQA HOLD" or in “BQA QUARANTINE” with a date, and the person’s initials that filled out the label/placard.

5.6 BQA will then conduct or facilitate a review of the issue or conduct an investigation and document its findings and conclusions. BQA's investigation documentation will be attached to the Quarantine/Hold Investigation Notification, **Form 21704-01**, or will reference an investigation number as appropriate.

5.6.1 Completed **Form 21704-01** and associated documentation becomes part of the project files maintained in BQA Documentation. A copy of the completed form will be placed in the Batch Production Record package (for product-associated Holds/Quarantines).

5.7 The item remains in Quarantine or on Hold until BQA Management determines the final disposition of the item.

5.8 If BQA determines that the item is acceptable for use, the Quarantine or Hold labeling/placards will be removed by BQA personnel and documented as part of the investigation paperwork.

5.9 If it is determined that an item is not acceptable for use:

5.9.1 Materials, in-process product, and final products are moved to quarantine, if not already there, to await destruction or other final removal from the regulated system.

5.10 The change in status from Hold or Quarantine is communicated to users and management by e-mail notification and by sending a copy of the completed and approved **Form 21704-01** to MMIC or the person(s) responsible for the item that had been placed on Hold / Quarantine.

6.0 Definitions

6.1 **MRB –** Material Review Board

6.2 **BQA Product Hold –** A material or product that is placed on BQA Hold, can be used in further processing, but the final product may not be released (or shipped if already released) until the issue associated with the hold is resolved.

6.3 **BQA Quarantine –** A material or product that is placed in quarantine may not be used or further processed until BQA releases it from quarantine.

7.0 References and Related Documents

SOP 20302 *Receipt and Inspection of Materials*

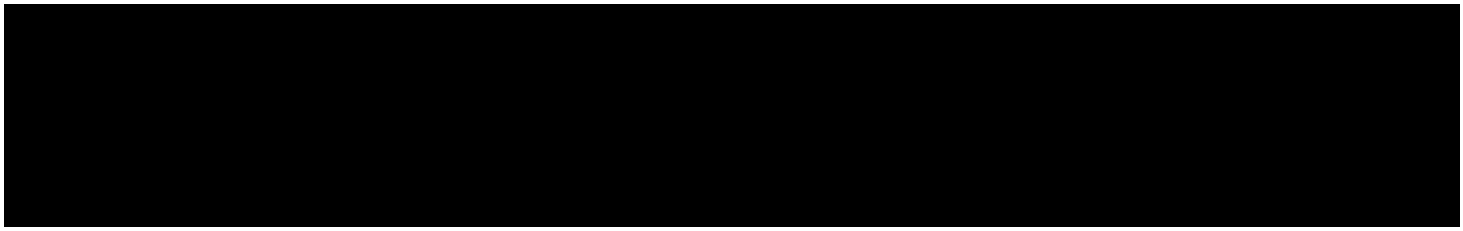
SOP 21002 *Product Release*

SOP 21526 *Engineering Event Management and Status Placarding*

Form 21704-01 Quarantine/Hold Investigation Notification

8.0 Attachments

8.1 **Attachment 1** Example of Quarantine Placard



Attachment 1

BQA
QUARANTINE

Project Name

Project Number: XXXX

Part Number: XXXX Lot Number: L0XXXXXX

Description of Material
DOM: XX/XX/XX

Quarantine By: XXXXXXXXXXXXX

Date Performed: XX/XX/XX

Number Quarantine: _____ **Units:** _____

Do Not Remove Material from this lot without authorization from BQA