Pediatric Blood and Marrow Transplant
Adult Blood and Marrow Transplant
Stem Cell Laboratory

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Approaches to Validation

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COMM-PAS-016
Approaches to Validation

1 PURPOSE

1.1 To establish documented evidence providing a high degree of assurance that a specific system (e.g., manufacturing equipment, instruments, calibration, test equipment, computer related systems, analytical equipment or methods, processes, test method, facilities) will consistently perform to specified requirements under a predetermined range of conditions.

2 INTRODUCTION

2.1 A validation shows that the procedure or process is effective, e.g., that you have established by objective evidence that a process consistently produces a result or a product meets its predetermined specifications.

2.2 Validation studies may be conducted by the department (internal), external service providers, or by experts in the field (manufacturer's representative).

2.3 There shall be written procedures prepared, validated, and followed for prevention of infectious disease contamination or cross-contamination by tissue during processing. 21CFR 1270.31(d).

2.4 Process validations are an essential step in the manufacture of quality products.

2.5 Validation protocols are created to define the validation approach, requirements, activities, and responsibilities for each specific system.

2.5.1 The rigor of the validation activities and the level of validation testing are commensurate with the system's potential impact on product safety, quality and efficacy, and/or the potential impact on data integrity and authenticity.

2.6 Prospective validations, prior to the use of the system, will be performed; however, legacy systems that have been placed in operation prior to validation may be validated using an appropriate method, including concurrent or retrospective validation.

3 SCOPE AND RESPONSIBILITIES

3.1 This procedure describes the process for preparing validation protocols and final reports and applies to all validations completed by personnel and its associated programs. Validation protocols associated with this procedure (COMM-PAS-016 FRM1 *Instrument Equipment Validation Protocol,* COMM-PAS-016 FRM2 *Analytical Validation Protocol, and* COMM-PAS-016 FRM3 *Process Validation Protocol*) should be utilized as a template when developing validation protocols.

3.1.1 Validation protocols for Instrument/Equipment FRM1, Analytical FRM2, and Process FRM3 provide format and details of content to be included in a validation protocol. Applicable contents from these forms can be imported into an MS Word document to create the validation protocol and final report.

3.2 The Medical Director, Supervisor/Manager, APBMT Clinical Quality Program (CQP), and personnel involved in the validation process are responsible for following this procedure. It is the responsibility of supervisor/manager to ensure compliance with this procedure and to train employees responsible for performing this procedure.

3.3 Validation Personnel

3.3.1 Contact CQP to obtain a validation number.

3.3.2 Provide the completed validation protocol to CQP, Medical Director, and additional personnel (i.e. program management, etc.), as necessary, for review and approval prior to initiating the validation.

3.3.2.1 In rare time sensitive situations, the Medical Director may sign off, indicating approval of the protocol and its attachments, remotely via email. In these rare scenarios, the Medical Director will physically sign the associated protocol documentation when available onsite.

3.3.3 Provide the completed validation report to CQP, Medical Director, and additional personnel (i.e. program management, etc.), as necessary, for review and approval.

3.3.4 Manage the validation effort.

3.3.4.1 Assist with developing appropriate validation protocol requirements.

3.3.4.2 Specify within the validation protocol any pre-execution requirements.

3.3.4.3 Complete any pre-execution requirements detailed in the validation protocol and document completion of them in the report.

3.3.4.4 Prepare and execute validation protocols.

3.3.4.5 Complete any post-validation execution requirements (i.e. initiate change controls, SOP updates as applicable)

3.3.4.6 Prepare and submit final reports.

3.3.5 For validation protocols and reports completed by external vendors, validation personnel will ensure that the minimum requirements detailed within this SOP are met.

3.3.6 Ensure appropriate change control procedures are followed for any modifications to applicable systems and that an assessment is made to determine potential impact associated with the change.

3.4 Program Management

3.4.1 Establish the specifications that define the general criteria and key technical requirements for the system, process, or method to be validated. For simple off-the-shelf systems, the specifications may be

based on the manufacturer's design specifications and defined in the validation protocol.

3.4.2 Assist with evaluating the appropriateness of validation protocol requirements.

3.4.3 Review and approve validation protocols and final reports for technical content.

3.4.4 Notify CQP to obtain validation number for validations performed by external sources.

3.5 Facilities

3.5.1 Assist with evaluating appropriateness of validation protocol requirements, as necessary.

3.5.2 Document applicable equipment and utility user requirements or specifications.

3.6 Medical Director

3.6.1 Provide guidance on validation protocols and reports.

3.6.2 Review and approve validation protocols and reports.

3.7 APBMT Clinical Quality Program (CQP)

3.7.1 Issue validation tracking numbers and maintain the validation database including, who the validation tracking number was assigned to, validation tracking number, validation title, status, completion date, and scanned copy of protocol/report or location of validation documents.

3.7.1.1 To enhance traceability of protocol/report documentation, CQP may assign validation tracking numbers to protocols and reports that are not specific to equipment, analytical, or process validations. These may include, but are not limited to, stability protocols/reports, process development protocols/reports, and, research and development protocols/reports.

3.7.2 Review supporting validation documentation to ensure compliance with regulatory requirements, policies, and procedures.

3.7.3 Review and approve validation protocols prior to initiation of validations and review and approve final validation reports.

3.7.3.1 For validation protocols and reports completed by external vendors, CQP will document review and approval on provided forms. Other signatures will be required based on the vendor documentation.

3.7.4 During review and approval of validation reports, verify all post execution requirements are met (i.e. applicable change controls launched and referenced, deviations are appropriately documented and investigated).

3.7.4.1 For validation protocols and reports completed by external vendors, CQP will verify that the minimum requirements detailed within this SOP are met.

4 DEFINITIONS/ACRONYMS

4.1 **Calibration Only –** Conducted for systems that perform very limited and simplistic functions which possess read-only software, no configuration, or pre-set operating range parameters and can be fully verified through calibration testing alone.

4.2 **Certification –** Process to verify that a system performs per manufacturer specification under controlled predetermined conditions.

4.3 **Combined Installation/Operational Qualification (IOQ) –** Qualification process used for systems that do not have the complexity to warrant documentation of IQ and OQ as two separate activities.

4.4 **Commissioning –** start-up and verification that a system performs as specified and is suitable for the initiation of validation activities. Commissioning is a planned, documented, and managed approach to the inspection, start-up and turnover of facilities, utilities, and equipment to the user demonstrating that established codes, design specifications and functional expectations have been met. Commissioning testing is generally a good engineering practice and is an opportunity to maximize the potential for a successful IQ/PQ.

4.5 **Computerized System –** A system that includes software, hardware, application software, operating system software, (for example, automated laboratory equipment, control systems, or manufacturing, clinical, and laboratory database systems)

4.6 **Contract Manufacturer –** A company that provides outsourced process development, manufacturing and packaging services for a fee.

4.7 **Critical Equipment/Instruments –** Equipment or instrument used to manufacture, test or store product and/or whose function has an impact on the quality of these materials.

4.8 **CQP –** APBMT Clinical Quality Program

4.9 **Like for Like –** Equivalent substitution of same part/product code

4.10 **Installation Qualification (IQ) –** Documented verification that an equipment or system installation, in a selected user environment, adheres to approved design requirements and manufacturer's technical specifications.

4.11 **Non-Critical Equipment/Instruments –** Equipment or instrument used for research purposes and whose function does not have impact on product quality or patient sample quality.

4.12 **Operational Qualification (OQ) –** Documented verification that equipment or systems, in a selected user environment, operate per design criteria over defined operating ranges.

4.13 **Performance Qualification (PQ) –** Documented verification that equipment or systems, in a selected user environment, can perform their intended function consistently and effectively within specified, predefined parameters, over a designated time frame, under normal and worst case conditions.

4.14 **Validation –** A process that establishes documented evidence that provides a high degree of assurance that a specific process, equipment, system, or analytical method will consistently produce a product or data, meeting its predetermined specifications and quality attributes. "Validation" refers to any system that needs to be validated or qualified.

4.15 **Validation Deviation –**Deviating from stated/approved validation protocol verification/test procedures.

4.16 **Validation Summary Report –** A documented summary of the validation test results, findings, deviations, and conclusions.

5 MATERIALS

5.1 Validation Protocols – Refer to COMM-PAS-016 FRM1 *Instrument Equipment Validation Protocol*, COMM-PAS-016 FRM2 *Analytical Validation Protocol*, and COMM-PAS-016 FRM3 *Process Validation Protocol*.

5.2 Manufacturer's Validation Protocol, including all associated documentation (process flowcharts, equipment diagrams, test results, data printouts) as applicable.

5.3 Additional equipment and materials requirements shall be determined as directed by the procedure protocol, specific to the operation.

6 EQUIPMENT

6.1 N/A

7 SAFETY

7.1 Appropriate personal protective apparel and equipment is required when performing validations.

8 PROCEDURE

8.1 The Medical Director, Supervisor/Manager, or CQP determines when a validation protocol is required and contacts CQP for a validation number.

8.1.1 CQP maintains the assigned validation numbers for tracking purposes.

8.2 The Supervisor/Manager or designee is responsible for writing and submitting the validation protocol (to include manufacturer's recommendations, regulations, and accreditation standards) to the Medical Director and CQP for review and any other affected department managers for approval.

8.2.1 Prospective GMP validation protocols will be reviewed and approved by the Medical Director and CQP. Additionally, validation protocol approvals may include operations management, applicable SMEs, applicable sponsor representatives (as required by associated CQP

agreements), and facilities management, as required. A signed validation protocol is not required for activities to be performed if the protocol is pre-defined in equipment or facility specific SOPs such as stability protocols or media fills.

8.2.2 If the initial validation protocol is not approved, the Supervisor/Manager or designee must rewrite the protocol and submit for review and approval. A new validation number is not required if initial validation protocol is not approved, the validation protocol owner may use the same protocol number.

8.3 Trained, designated staff will perform and document the validation process.

8.4 Equipment and Utility Qualification

8.4.1 The approach to equipment and utility qualification consists of conducting an Installation Qualification (IQ), and Operational Qualification (OQ), and when deemed appropriate, a Performance Qualification (PQ) for equipment and utilities will be completed, as required, in the associated change control. Large systems that consist of multiple pieces of equipment, such as air systems supplying classified areas, will be commissioned prior to performing any validation testing.

NOTE: Equipment such as Biosafety Cabinets, Laminar flow hoods, and stand-alone instruments will be certified and/or calibrated regularly, which may be conducted in place of qualification testing.

8.4.2 Refer to COMM-PAS-016 FRM1 Instrument/Equipment Validation for guidance.

8.4.3 Equipment qualification will be performed in the following order: 1) Installation Qualification (IQ), 2) Operational Qualification (OQ), 3) Performance Qualification (PQ) (if applicable). Before proceeding to the next qualification step, the preceding step must be complete and/or evaluated to ensure that any open items will not adversely affect the execution of the next step.

NOTE: If the IQ/OQ is performed by the vendor, a separate protocol and/or summary report may not be necessary. However, a protocol number should still be assigned and report/summary approved, as applicable.

8.4.3.1 **Installation Qualification (IQ)** - IQ testing is conducted to provide documented evidence that the system has been installed in a manner suitable for its intended use and according to all applicable specifications.

8.4.3.1.1 Minimally, the following are required to be qualified at installation:

- Equipment used in collection of cellular products
- Equipment used in the processing of cellular products

- Equipment used in the transporting of cellular products
- Equipment used in the labeling of cellular products
- Equipment used in the storage of cellular products

8.4.3.2 The manufacturer's representative, and/or designated staff, may perform IQ and initial calibration and maintenance.

8.4.3.2.1 If IQ is not approved, the Supervisor/Manager will direct further action.

8.4.3.3 **Operational Qualification (OQ) –** OQ testing provides documented evidence that the system being tested operates according to all applicable specifications. Systems are evaluated such that the system response to normal and abnormal operating condition is commensurate with the anticipated response.

8.4.3.3.1 The manufacturer's representative and/or designated staff may perform OQ.

8.4.3.3.2 Depending on the extent and complexity of testing required for each piece of equipment, it is acceptable to combine an IQ and OQ into one IQ/OQ test document. If extensive IQ testing/documentation is required, the IQ and OQ can be written and approved separately.

8.4.3.3.3 Interim approval is allowed for OQ once it is ensured that all critical exceptions (any exception that would prevent execution of PQ in its entirety) have been satisfactorily addressed and closed prior to the start of PQ.

8.4.3.3.4 Interim approval prior to initiating PQ does not include process validation. Process validation may not proceed until all pre-requisite qualifications have been completed.

8.4.3.4 **Performance Qualification (PQ) -** PQ testing incorporates "process" material (or simulated "process" material) to demonstrate that a system/equipment will perform its intended function consistently and effectively, and within pre-determined parameters during normal and "worst-case" use. If PQ is not required, the rationale will be documented in the associated validation report and/or applicable change control. If a PQ is deemed unnecessary, rationale for this decision should be provided within the associated IQ/OQ reports.

8.4.3.4.1 Designated staff will perform PQ, however, a manufacturer's representative, may also perform PQ.

8.4.3.4.2 PQ will include testing the anticipated process parameters simulating actual production with both media and process related components.

8.4.3.5 **Re-qualification –** The Supervisor/Manager will perform a periodic review of equipment, processes, and systems to verify that they continue to operate in a qualified or validated state. Where review of information suggests that a significant change has been made to the qualification or validation status, a re-qualification or re-validation will be performed. The evaluations may include assessment of the prior qualification documentation, review of basic operational or functional testing, and review of the equipment performance history, including review of any deviations or changes (such as an equipment move or repair) that have been made to the equipment.

8.4.3.5.1 Re-qualification will be completed if determined to be necessary. Section(s)/verification(s) may be included or removed based on their applicability to the re-qualification, and documentation must include the rationale for the scope of the new, necessary testing.

8.4.3.5.2 Changes or modifications to computer systems will be evaluated through change control procedures (COMM-PAS-004 *Change Control*), as applicable, and may be captured with all supporting documentation and assessments located in the associated Change Control Request forms, that will evaluate the changes or modifications.

8.4.3.5.3 Changes or modifications to any qualified equipment or utility must be evaluated through change control procedures (COMM-PAS-004 *Change Control*) to determine if the validated state will be impacted by the change, and if additional qualification testing or re-qualification is warranted.

8.4.3.5.4 Equipment should be re-qualified if any changes are made which significantly alter the validated state of the equipment

8.4.3.5.5 Re-qualification may be warranted following any significant equipment repair or

replacement of major components, relocation, changes in software code, or observation of drifts in performance trends.

8.4.3.5.6 If equipment parts are being replaced per a standard, SOP driven process (like for preventive maintenance) and are "like for like", re-qualification may not be warranted.

8.4.3.5.7 Utilizing the specifications (for example, user requirements specifications, design specifications, functional requirements specifications) and the prior executed and approved protocol (and report) as a reference, the impact of the change(s) or modification(s) on the state of the equipment or utility will be evaluated.

8.4.3.5.8 Documentation must include the rationale for the scope of the re-qualification testing and should include the applicable change control number that triggered the testing (such as an equipment move or repair), as appropriate. Please refer to COMM-PAS-004 *Change Control* to ensure the proper procedure is followed for initiating and evaluating any change.

8.4.3.5.9 Summary reports must be drafted for any re-qualification work completed. In addition to assessing the equipment itself, an assessment should be performed in relation to any processes or testing that the equipment supports.

8.4.3.6 **Calibration Only –** Calibration only testing will be conducted for systems which possess read-only software, no configuration, or pre-set operating range parameters that can be fully verified through calibration testing alone. However, IQ/PQ will be performed on systems that possess functions or controls that cannot be tested through calibration (e.g., operating and extended testing) and could affect results.

8.4.3.6.1 For applicable systems, calibration paperwork/process will fulfill the regulatory expectation of qualification and provides documented evidence that the system does what it purports to do.

8.4.4 Once a system or piece of equipment has met all of its qualification testing requirements, it is deemed to be validated to the specific level to which it has been qualified (IQ, OQ, PQ).

8.4.5 Standard operating procedures (SOPs), preventive maintenance and calibration, training, change control, and re-validation are utilized to maintain the validated state.

8.4.5.1 **Preventive Maintenance and Calibration –** Provides a mechanism for detection of instrument deficiencies and the means to provide objective evidence of accuracy conformance in the form of records.

8.4.5.1.1 Applicable to all instruments or equipment that require calibration or preventive maintenance.

8.4.6 A critical equipment list will be maintained by the Supervisor/Manager and may include qualification activities.

8.5 Process Validation

8.5.1 Manufacturing processes will undergo prospective validations to establish documented evidence, which provides a high degree of assurance, that each process will consistently produce a product meeting pre-defined critical quality attributes.

8.5.2 The manufacturing process will be validated and documented independently, subsequent to all facility, equipment, and support system commissioning and completion of all required equipment IQs, OQs, and PQs.

8.5.2.1 The validation will assess specified unit operation within the entire process. The demonstration of consistency of each unit processed, coupled with consistent in-process monitoring, is ultimately consolidated to depict a validated process for manufacture of a product.

8.5.2.2 Tests and acceptance criteria will be evaluated for appropriateness. The validation study will represent the same manufacturing process and environmental conditions to be implemented during routine manufacturing.

8.5.3 Once the system has been validated, the validated systems will be maintained through implementation of standard operating procedures, preventive maintenance programs, calibration programs, and change control procedures. Any change to the validated processes will be evaluated through change control procedures (COMM-PAS-004 *Change Control*) to determine if the validated state will be compromised, and if additional validation testing or re-validation is warranted.

8.5.4 Refer to COMM-PAS-016 FRM3 *Process Validation Protocol* for guidance.

8.6 Analytical Method Validation

8.6.1 As appropriate based on the stage of product development, test methods will be validated according to predetermined procedures and acceptance specifications. Qualification of analytical methods may be appropriate

or acceptable in earlier stages of manufacturing. Final reports will be in place and approved prior to the use of any of these methods in evaluating products.

8.6.2 Data must be available to establish that the analytical procedures used in testing meet proper standards of accuracy, sensitivity, specificity, and reproducibility (as applicable) and are suitable for their intended purpose.

8.6.3 When switching to a new method, a comparability study should be considered to verify that the new method performs comparably or better than the previously validated method. Every effort should be made to ensure that any outside sources of variation between methods are minimized. When making changes to a validated method, an assessment should be made to determine if re-validation is needed. This may include comparability of one or more parameters, as applicable.

8.6.4 Any change to the validated analytical method will be evaluated through change control procedures (COMM-PAS-004 *Change Control*) to determine if the validated state will be compromised, and if additional validation testing or re-validation is warranted.

8.6.5 Refer to COMM-PAS-016 FRM2 *Analytical Validation Protocol* and Guidance for Industry: Analytical Procedures and Methods Validation for Drugs and Biologics (July 2015) for guidance.

8.7 Cleaning Validation

8.7.1 Cleaning validation is the process of establishing documented evidence that a particular cleaning procedure will consistently reduce surface residuals to a predetermined acceptable level.

8.7.2 There will be established documented evidence that the cleaning procedures employed will consistently reduce, with a high degree of assurance, potential contaminating residual(s) to predetermined acceptable levels.

8.7.2.1 Validation of such cleaning procedures may include, but is not limited to, review of environmental monitoring data, certification reports, visual inspections, direct surface testing, and rinse water sampling.

8.7.2.2 Specific methods, testing requirements, and acceptance criteria will be outlined in protocol(s) or procedures.

8.8 Validation Protocols and Supporting Documentation

8.8.1 The validation protocol is a descriptive document which formally states the intent, background, design, and acceptance criteria for the validation study. Validation protocols may include draft versions of SOPs, Forms, or Job Aides, that will be utilized during the associated validation. Draft documents created for executions in a validation activity will be approved as a controlled document and made effective in MasterControl prior to use for GMP processing.

8.8.2 The validation protocol will include a prospective assessment of any prerequisites that are required before execution of the validation protocol (ex. prior equipment qualifications, completion of SOP updates, and validation of other systems/methods).

8.8.3 Validation testing must include verification and testing of critical parameters which reflect established manufacturer, user, and "end product" specifications. The acceptance criteria for the validation testing must be based on those established critical parameters. In order for the validation testing to pass, the test data generated during the validation studies must meet the requirements (e.g., acceptance criteria) set forth in the corresponding test section. The executed protocol and data generated will be reviewed and approved by the Medical Director and CQP.

8.8.4 In situations where validation protocols and/or reports are completed by external vendors, validation protocols and reports generated by the external vendor shall be approved by internal personnel to ensure that the minimum requirements of this SOP are met. This may including approving the protocol and/or report on documentation provided by the external vendor.

8.8.5 Any test result that does not meet the stated acceptance criteria during validation protocol execution is considered a failed validation. Supervisor/Manager, Medical Director, and/or CQP may be consulted to evaluate the situation and determine the most appropriate course of action.

8.8.6 A validation amendment is required when a change from the stated protocol test procedures is deemed necessary after initial review and approval of the protocol.

8.8.6.1 The amended protocol must have a validation number reflecting the revision (e.g. 2018-001-A: first amendment titled 2018-001.1-A, second amendment titled 2018-001.2-A, etc.).

8.8.6.2 The amended protocol must include a revision history section detailing the amendment change and justification for the change.

8.8.6.3 The amended protocol must be rerouted for approval by Supervisor/Manager, Medical Director, and CQP before updated protocol is performed.

8.8.7 A validation deviation is defined as any deviation from stated validation protocol verification test procedures. Any deviation that is found during the execution of a validation protocol must be documented.

8.8.7.1 The deviation, investigation, impact, proposed corrective action (or justification for no corrective action) must be documented, and then reviewed and approved by

Supervisor/Manager and CQP. All deviation documentation should be included in the appropriate qualification report.

8.8.7.2 In situations where, during the execution of the associated validation protocol, a deviation from the validation protocol occurs, the associated investigation and impact assessment will be completed and documented within the corresponding validation summary report.

8.8.7.3 If, during the execution of a validation protocol, there is a deviation from an existing, effective version of an SOP in MasterControl, a formal deviation and investigation report, per COMM-PAS-013 *Deviations and Investigations*, will be launched and referenced within the validation summary report. All events associated with the execution of a validation protocol must be closed before signoff of the associated validation summary report.

8.8.8 A summary report will be developed and approved for each validation/qualification protocol that is executed. The summary report will summarize the following:

8.8.8.1 Conclusion stating whether the instrument/method/process being validated is suitable for its intended use.

8.8.8.2 Testing that met all requirements and acceptance criteria.

8.8.8.3 Testing that did not meet protocol requirements or acceptance criteria.

8.8.8.4 Deviations to changes from the approved protocol that occurred during testing.

8.8.8.5 A description and reference, including the corresponding MasterControl task number, to any associated Deviations that were launched in MasterControl during execution/as a result of the protocol.

8.8.8.6 Description of deviation resolutions, where applicable.

8.8.8.7 A description of any changes that will be required as a result of the completed validation. Included within this description, is a reference to any associated Change Controls, per COMM-PAS-004 *Change Control*, that are launched as a result of the completed validation (ex. SOP updates due to validation/qualification).

8.8.8.8 In situations where a validation protocol has been amended after initial review and approval, a summary report for each amended version of the validation protocol is not required. Minimally however, one summary report that details the requirements outlined in 8.8.8 for the executed validation protocol is required.

8.8.8.9 In situations where validation protocols and/or reports are completed by external vendors, validation reports generated by the external vendor shall be approved by internal personnel to ensure that the minimum requirements of this SOP are met. This may including approving the report on documentation provided by the external vendor.

8.8.9 Summary reports must be approved by the Supervisor/Manager, Medical Director and CQP. Additionally, validation summary report approvals may include operations management, applicable SMEs, applicable sponsor representatives (as required by associated Quality agreements), and facilities management, as required.

8.8.10 The Supervisor/Manager will implement the validated system after approval.

8.8.11 Once validation has been completed, the validation protocol will no longer be updated and will be closed. All subsequent modifications to the validated system will be performed under Change Control procedures (COMM-PAS-004 *Change Control*), unless re-validation is deemed necessary.

8.8.12 Validation documents will be maintained by CQP or may be maintained in the associated department, e.g., equipment qualifications will be maintained within the laboratory.

9 RELATED DOCUMENTS/FORMS

9.1 COMM-PAS-016 FRM1 Instrument Equipment Validation Protocol

9.2 COMM-PAS-016 FRM2 Analytical Validation Protocol

9.3 COMM-PAS-016 FRM3 Process Validation Protocol

9.4 COMM-PAS-004 Change Control

9.5 COMM-PAS-013 Deviations and Investigations

10 REFERENCES

10.1 American Association of Blood Banks. Standards for Hematopoietic Progenitor Cells. Current edition.

10.2 Foundation for the Accreditation of Hematopoietic Cell Therapy (FACT). Standards for Hematopoietic Progenitor Cell Collection, Processing and Transplantation. Current edition.

10.3 Laboratory Instrument Evaluation, Verification and Maintenance Manual, 4th Ed, 1989. College of American Pathologists.

10.4 Module VIII: Validation in: Nevalainen DE, Callery MF. Quality Systems in the Blood Bank and Laboratory Environment. American Association of Blood Banks, 1994.

10.5 21CFR211, Subpart C – Buildings and Facilities

10.6 21CFR 211, Subpart D – Equipment

10.7 FDA Guidance Process Validation 2010, http://www.gmp-publishing.com/media/files/leitartikel_2010/Logfile-8-FDA-PV-Guidance-2010.pdf

10.8 Guidance for Industry Process Validation: General Principles and Practices; January 2011 Current Good Manufacturing Practices (CGMP), Revision 1 http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070336.pdf

10.9 Guidance for Industry: Validation of Procedures for Processing of Human Tissues Intended for Transplantation; http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/ucm073429.htm

10.10 Guidance for Industry: Analytical Procedures and Methods Validation for Drugs and Biologics (July 2015) http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM386366.pdf

11 REVISION HISTORY

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