

Comparison of Quality Management

The tables are populated with data from the FACT-JACIE (4th ed.), Netcord-FACT (4th ed.), WMDA and AABB (4th ed.)

Definitions	Abbreviation
WMDA 2008	W
FACT-JACIE 4 th Ed	F-J
Netcord-FACT 4 th Ed	NC-F
AABB 4 th Ed	AA
Not applicable	NA

	W	F-J	F-N	AA
Quality management system – General Policies				
Quality policy for achieving and maintaining quality; quality policy to describe objectives and commitment	X	Quality manual	X	X
All policies, processes and/or procedures to be captured in writing or electronically and to be followed	X	X	X	X
Defined organizational structure (chart)	X	X	X	X
Emergency operational plans	X	X Disaster Plan	X Disaster Plan	X
Defined qualifications for critical job functions	X	X	X	X
Personnel identification records to include names, signatures, initials or identification codes, and inclusive dates of employment		X Part D	X	X
Ongoing training and competence	X	X	X	X
Defined qualifications for trainers	X	X	X	X
Requirements for continuing education	X	X	X	X
Control of equipment (see more on Computer Processing Units (CPU) systems below)	X	X	X	X
Define equipment specifications before purchase, qualify all equipment for intended use, and identify by assignment of a unique identifier (ID)	NA	X (ID not stated in C standard but in Guide)	X	X
Calibration and accuracy of equipment to include identification of equipment maintained in calibrated state; determination of measurements and accuracy/precision required; defined calibration process; ensure calibration before initial use, after repair, and at intervals; safeguard	NA	X (safeguard from adjustment not)	X (safeguard from adjustment not)	X

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equipment from adjustments that would invalidate calibration		specifically mentioned)	specifically mentioned)	
Assess validity of previous inspection/test results when equipment found to be out of calibration	NA	X		X
Monitoring and maintenance to include cleaning/sanitization, monitoring environmental conditions, defined process to inform personnel when out of service/malfunctioning	NA	X	X Defined process to inform personnel not mentioned	X
Equipment traceability	NA	X	X	X
Agreements with suppliers and customers	X	X	X	X
Agreement review to ensure customer's requirements are defined, differences are resolved, and that facility can meet requirements	X	X	X	X
Define how changes to agreements are made and communicated		Not specified	Not specified	X
Policies, processes, and procedures to ensure that purchased, donated, or acquired materials/services meet specified requirements	X	X (less detail, audit required)	X (less detail, audit required)	X
Evaluation of suppliers (monitor performance, report to management with contracting authority of failures to meet requirements)	X	X	X (Vendor qualification required)	X
Process to ensure quality of HCT/P procurement when performed by a supplier	X	Clinical program to ensure collections in accord with FACT standards	Agreements required Cord Blood Bank (CBB) Med Director Responsible for collection site	X
Qualify facilities providing tests or services	X	X	X	X
Control of work performed (see process control below)	X	X	X	X
Document and Record control system (see more below)	X	X	X	X
Control, evaluation, and reporting of deviations	X	X	X	X
Internal quality assessments	Not specified	X (timetable required)	X	X
Processes for managing results of internal quality assessments	Not specified	X	X	X
Personnel performing internal assessments to be independent of those having direct responsibility for activity being assessed	Not specified	X	X	X
Results of assessment results to be: reviewed by personnel having responsibility for area assessed, evaluated to determine need for corrective and preventive action; communicated to appropriate staff; reported to executive management	Not specified	X	X	X

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Corrective and preventive actions (see more below)	X	X	X	X
Process improvement through tracking and trending	X	X	X	X
Facility (includes safety)	X	X	X	X
Individual responsibilities				
Designated individual in charge of Quality Management Systems (QMS)	X	X	X	X
Quality representative to report quarterly on QMS to executive management	X	X	X	X
Quality representative to provide annual written report to executive management	X	X	X	X
Medical oversight	X	X	X	X
Medical or laboratory director responsibility for all policies, processes, and procedures	X	X	X	X
Technical/laboratory oversight	NA	X	X	X
Quality Audits/Reviews/Oversight				
Executive management (Exec Mgt) responsible for oversight of quality system and facility's operations, for appointing a quality representative	Not specified	X does not specify Exec Mgt	X CBB Director must approve quality supervisor	X
Executive management to review quality system periodically	Not specified	X	X	X
Annual reports from quality representative to be used for management review and improvement of quality system	Not specified	X	X	X
Executive management to ensure quality policy is understood, implemented, and followed at all levels of organization	Not specified	X	X	X
Policies, processes and procedures for corrective and preventive action plans to address root cause of deviations	X	X	X	X
Management to review information on corrective and preventive actions taken	Not specified	X	X	X
Corrective or preventive actions taken to be proportional to magnitude of problems and risks	Not specified	Not specified	Not specified	X
Process for corrective action to include investigation of root cause, investigation of customer complaints, determination of corrective action needed, and ensuring that corrective action is effective	X	X	X	X
Process for preventive action to include analysis of quality indicator data to detect, analyze, eliminate potential causes of nonconformances; initiation of preventive action and application of controls to ensure that p.a. is effective	X	X	X	X
Policies and procedures to manage cellular therapy products with positive microbial culture results to include: labeling, product release, physician, facility and patient notification, reporting to regulatory agencies.	NA	X	X	X

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Computer Systems				
Implementation and modification of CPU system to include:				
System versions, inclusive dates of use	X	X	X	X
Validation/verification of software, hardware, databases, user-defined tables	X	X	X	X
Fulfillment of life-cycle requirements for internally developed software	X			X
Processes for system operation and maintenance	X	X	X	X
Authorizing and documenting modifications to system	X	X	X	X
System security to prevent unauthorized access	X	X	X	X
Documentation understandable to user	X	Written user SOP required all SOPs need to be understandable	Written user SOP required all SOPs need to be understandable	X
Functionality to allow display and verification of data before final acceptance	X	X	X	X
Monitoring data integrity for critical elements	X	X	X	X
Alternative systems to ensure access to critical information and continuous operation when electronic data and computer-assisted functions not available	X	X	X	X
Alternative system must be tested periodically	X	X	X	X
Control of electronic data and information; access, authorization, release of data	X	X	X	X
Individuals authorized to enter, change, release results to be identified	X	X	X	X
Data integrity monitoring	X	X	X	X
Retrievability of data	X	X	X	X
Storage media to be protected from damage of unintended destruction	X			X
Routine back-up of critical data	X	X	X	X
Back-up data stored in off-site location, protected from unauthorized access, loss or modification	X	Does not specify off-site	Does not specify off-site	X
Periodic testing of ability to retrieve data from back-up system	X	Testing of alternative system but does not specify testing back-up retrieval	Testing of alternative system but does not specify testing back-up retrieval	X
Materials Management				

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A materials management system required for supplies and reagents used for processing, testing, cryopreservation, and storage. Must include:	NA	X		X
Examination for damage or evidence of contamination at receipt and prior to approval for use	NA	X	partially	X
Records at receipt of supply or reagent type, quantity, manufacturer, lot number, receipt date, acceptability, and as applicable, the expiration date	NA	X		X
Storage under appropriate environmental conditions in a secure, sanitary, and orderly manner to prevent mix up or unintended use	NA	X		X
Ensure supplies and reagents contacting the cellular therapy product are sterile and of the appropriate grade for the intended use	NA	X		X
Use in a manner consistent with manufacturer's instructions	NA	X		X
Process to prevent use beyond assigned expiration date	NA	X		X
A materials management inventory control system shall be used to ensure the availability and identity of critical reagents and supplies. The system shall:	NA	X		X
Uniquely identify and track critical reagents and supplies used for processing	NA	X		X
A system to identify products processed with a given reagent or supply	NA	X		X
Non-disposable supplies or instruments must be cleaned and sterilized using a method verified to remove infectious agents	NA	X		X
Process Control				
Identify, design, modify, and validate policies, processes, and procedures that affect quality of HCT/Ps	X	X	X	X
Policies, processes, procedures to be carried out under controlled conditions designed to prevent contamination of products, maintain function and integrity, and prevent transmission of infectious disease	X	X	X	X
Policies, processes and procedures to be approved and followed	X	X	X	X
Defined criteria for acceptable in-process test results and final product characteristics	X	X	X	X
Monitoring and control of process parameters and product characteristics	X	X	X	X
Identify need for statistical techniques for controlling and verifying process capability and product characteristics	Not specified	Not specified	Not specified	X
Monitoring clinical outcome data and information on patient adverse events as part of QMS	X	X	X	X

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Control development of new or change to existing policies, processes, and procedures	X	X	X	X
Process planning: Evaluate requirements, review current literature, evaluate risk, identify stakeholders, identify performance measures, evaluate resources, impact of new or changed process, need to create new document(s), review and approve outputs, evaluation extent of validation	Not specified	X (less detail)	X (less detail)	X
Change control mechanism to ensure new or changed products, services, procedures meet QMS requirements	X	X	X	X
Validation of new or changed processes or procedures prior to implementation	X	X	X	X
Controlled implementation of new or changed processes or procedures		X	X	X
Post-implementation review of performance of new or changed processes or procedures		X	X	X
Quality control to ensure that materials (including reagents), equipment, and analytical procedures function as specified	NA	X	X	X
Operational controls (e.g., movement of materials/workflow; segregation; cleaning/setup between runs)	NA	X (Policies to prevent cross-contamination)	X (Policies to prevent cross-contamination)	X
Documents and Records				
Policies, processes, and procedures to control all documents related to Standards	X	Critical documents	X	X
Documents and records to be protected from accidental or unauthorized modification	X	X	X	X
Use of standardized formats for policies, processes, and procedures	X	X	X	X
Review and approval of all documents before use	X	X	X	X
Documents to be identified with current version	X	X	X	X
Documents to be available at all locations where operations are performed	X	X	X	X
Identification of archived or obsolete documents as such to prevent inadvertent use	X	X	X	X
Changes to documents to be reviewed and approved	X	X	X	X
Complete lists of all active policies, processes, and procedures (including labels and forms)	X	X	X	X
Annual review of each policy, processes, or procedure	Not specified	Every 2 years	Every 2 years	X
Copies of archived policies, processes, and procedures to be retained	X	X	X	X
Records to be identified, indexed, filed, storage, maintained, and disposed of	X	X	X	X
Records to be legible	X	X	X	X
Record storage in a suitable environment and in a manner that prevents mix-ups, damage, deterioration, loss	X	X	X	X
Defined processes for changing records; date and identification of person making change to be recorded; changes shall not obscure previously recorded information	X	X	X	X

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Actual result of each action performed to be recorded immediately, and final interpretation to be recorded upon completion of testing	Not specified	X	X	X
Records to be created concurrently with performance of each critical activity, identifying work performed, individual performing, and when performed	Not specified	X	X	X
Copies of records to be verified as containing original content before destruction of original	Not specified	Not specified	Not specified	X
Policies for confidentiality of donor, patient records,	X	X	X	X
Traceability	X	X	X	
Confidentiality of records and data	X	X	X	