Comparison of Quality Management

The tables are populated with data from the standards, manuals and policies from FACT-JACIE, Netcord-FACT, AABB, WMDA, and EFI. Consult the current versions. The crosswalks are intended to point out similarities or general principles of the standards and do not necessarily list specific requirements.

Definitions	Abbreviation
WMDA International Standards for Unrelated Hematopoietic Stem Cell Donor Registries Version 2017	**W**
FACT-JACIE International Standards for Cellular Therapy Product Collection, Processing and Administration 5th Edition	**F-J**
Netcord-FACT International Standards for Cord Blood Collection, Banking and Release for Administration 5th Edition	**NC-F**
AABB Standards for Cellular Therapy Services 6th Edition	**AA**
European Federation for Immunogenetics	**EFI**
Requirement is addressed	**X**
Requirement is not addressed	**-**
Not Applicable	**NA**

	W	F-J	NC-F	AA	EFI
Quality management system – General Policies					
Quality unit with reporting structure independent of processing required	-	-	X	X	-
Quality policy for achieving and maintaining quality; quality policy to describe objectives and commitment	X	Quality Plan (also known as Manual or Handbook)	Quality Plan	X	X
All policies, processes and/or procedures to be captured in writing or electronically and to be followed	X	X	X	X	X
Defined organizational structure (chart)	X	X	X	X	X
Emergency operational plans	X Disaster plan	X Disaster Plan	X Disaster Plan	X	-
Complaint management process	X	X	X	X	X
Adequate staffing, materials, equipment and facility infrastructure	X	X	X	X	X
Defined qualifications for critical job functions	X	X	X	X	X

	W	F-J	NC-F	AA	EFI
Personnel identification records to include names, signatures, initials or identification codes, and inclusive dates of employment	X	X	X	X	X
Identification of minimal staff for facility function	X	X		X	
Ongoing training and competence and action taken when competence is not demonstrated	X	X for competency / - for action in case of no competency	X	X	X
Defined qualifications for trainers	X	X	X	X	(Technical Supervisor)
Requirements for continuing education	X	X	X	X	X
Control of equipment (see more on Computer Processing Units (CPU) systems below) including operational, performance and installation qualification	X	X	X	X	X
Define equipment specifications before purchase, qualify all equipment for intended use, and identify by assignment of a unique identifier (ID)	-	X /- Define equipment specifications before purchase	X	X	Must be validated before use- not covered specifically
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 equipment from adjustments that would invalidate calibration	-	X (safeguard from adjustment not specifically mentioned)	X (safeguard from adjustment not specifically mentioned)	X	X
Assess validity of previous inspection/test results when equipment found to be out of calibration	-	X	Applies to unit processing	X	X
Monitoring and maintenance to include cleaning/sanitization, monitoring environmental conditions, defined process to inform personnel when out of service/malfunctioning	-	X Not specified how to inform personnel when out of service	X Requires records be displayed on or near equipment	X	X

	W	F-J	NC-F	AA	EFI
Equipment traceability	-	X	X	X	-
Agreements with suppliers and customers	X	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	-	X	Requires be dated and reviewed regularly	X	-
Policies, processes, and procedures to ensure that purchased, donated, or acquired materials/services meet specified requirements	X	X	X (materials management system for all acquired goods required to specify requirements)	X	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	X (HCT/P suppliers not specified)	Agreements required Cord Blood Bank (CBB) Med Director responsible for collection site	X	-
Qualify facilities providing tests or services	X	X	X (must audit)	X	X
Control of work performed (see process control below)	X	X	X	X	X
Document and Record control system (see more below)	X	X	X	X	X
Identification, control, evaluation, and reporting of deviations and non-conforming products or services	X	X	X	X	X
Processes to detect, report, evaluate, and manage adverse events	X	X	X	X	-
Internal and external quality assessments	X	X	X	X	X

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Processes for managing results of internal quality assessments	-	X	X	X	X
Personnel performing internal assessments to be independent of those having direct responsibility for activity being assessed	-	X	X	X	X
Results of assessment 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	-	X	X	X	X
Corrective and preventive actions (see more below)	X	X	X	X	X
Process improvement through tracking and trending	X	X	X	X	X
Facility (includes safety)	X	X	X	X	X
Individual responsibilities					
Designated individual in charge of Quality Management Systems (QMS)	X	X	X	X	X
Designated individual must not be supervised by same management as CBB or Processing Facility	-	-	X	-	-
Report quarterly	-	X	X	X	X
Provide annual written report on the functioning of the QMS	-	X	X	X	X
Medical oversight	X	X	X	X	X (Director)
Medical Director or Director shall participate with Quality Unit Supervisor to establish and maintain Quality Plan	-	X	X	X	-
Designated individual responsible for all policies, processes, and procedures	X	X	X	X	X
Technical/laboratory oversight	-	X	X	X	X
Quality Audits/Reviews/Oversight					
Designated individual responsible for oversight of quality system and facility's operations, for appointing a quality representative	-	X	X Quality Supervisor must be different individual	X	X

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			from CBB Director		
Designated individual to do periodic QMS review	-	X	X	X	X
Designated individual to ensure quality policy is understood, implemented, and followed at all levels of organization (Identify the designated individual)	X	X Director	X Quality Unit Supervisor	X	X Quality Manager
Policies, processes and procedures for corrective and preventive action plans to address root cause of deviations	X	X	X	X	X
Review information on corrective and preventive actions taken	X	X	X	X	X
Corrective or preventive actions taken to be proportional to magnitude of problems and risks	X	-	Not specified	X	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	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	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.	-	X	X	X	-
Computer Systems					
Implementation and modification of CPU system to include:					
System versions, inclusive dates of use	X	X	X	X	X
Validation/verification of software, hardware, databases, user-defined tables	X	X	X	X	X
Fulfillment of life-cycle requirements for internally developed software	X	-	-	X	-

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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	X	Written user SOP required all SOPs need to be understand able	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 D12.1.2	-	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 Guidance says “in a site other than the point of primary entry”	Does not specify off-site	X	-

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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	-
Interruption of Operations at Established Sites					
Standards specify requirements for resumption of activities if facility activity is interrupted or ceases	-	X	X	-	-
Materials Management					
A materials management system required for supplies and reagents used for processing, testing, cryopreservation, and storage. Must include:	-	X	X	X	X
Examination for damage or evidence of contamination at receipt and prior to approval for use	-	X	For bags, not specified for all materials	X	X
Records at receipt of supply or reagent type, quantity, manufacturer, lot number, receipt date, acceptability, and as applicable, the expiration date	-	X	-	X	X
Storage under appropriate environmental conditions in a secure, sanitary, and orderly manner to prevent mix up or unintended use	-	X	-	X	X
Ensure supplies and reagents contacting the cellular therapy product are sterile and of the appropriate grade for the intended use	-	X	X	X	-
Use in a manner consistent with manufacturer's instructions	-	X	X	X	X
Process to prevent use beyond assigned expiration date	-	X	-	X	X (or revalidate)

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A materials management inventory control system shall be used to ensure the availability and identity of critical reagents and supplies. The system shall:	-	X	X	X	-
Uniquely identify and track critical reagents and supplies used for processing	-	X	X	X	-
A system to identify products processed with a given reagent or supply	-	X	X	X	-
Non-disposable supplies or instruments must be cleaned and sterilized using a method verified to remove infectious agents	-	X	Sterility required	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	X
Policies, processes and procedures to be approved and followed	X	X	X	X	X
Defined criteria for acceptable in-process test results and final product characteristics	X	X	X	X	X
Monitoring and control of process parameters and product characteristics	X	X	X	X	X
Identify need for statistical techniques for controlling and verifying process capability and product characteristics	-	X	Not specified	X	-
Monitoring clinical outcome data and information on patient adverse events as part of QMS	X	X	X	X	-
Assessment of standard of care of recipients	-	X			
Control development of new or change to existing policies, processes, and procedures	X	X	X	X	X
Process planning: Evaluate requirements, review current literature, evaluate risk, identify stakeholders, identify	-	X (less detail)	X (less detail)	X	X (less detail)

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performance measures, evaluate resources, impact of new or changed process, need to create new document(s), review and approve outputs, evaluation extent of validation					
Change control mechanism to ensure new or changed products, services, procedures meet QMS requirements	X	X	X	X	X
Adherence to good maufacuring practices (GMP)	-	X			
Validation of new or changed processes or procedures prior to implementation	X	X	X	X	X
Controlled implementation of new or changed processes or procedures	-	X	X	X	X
Post-implementation review of performance of new or changed processes or procedures	-	X	X	X	X
Quality control to ensure that materials (including reagents), equipment, and analytical procedures function as specified	-	X	X	X	X
Operational controls (e.g., movement of materials/workflow; segregation; cleaning/setup between runs)	-	X (Policies to prevent cross-contamination)	X (Policies to prevent cross-contamination)	X	X (contamination checks)
Documents and Records					
Policies, processes, and procedures to control all documents related to Standards	X	Critical documents	X	X	X
Documents and records to be protected from accidental or unauthorized access, destruction, or 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	X
Documents to be identified with current version	X	X	X	X	-
Documents to be available at locations where operations are performed	X	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	X

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Complete lists of all active policies, processes, and procedures (including labels and forms)	X	X	X	X	-
ISBT 128 Coding and Labeling Technologies	-	X		X	
Frequency of review of each policy, processes, or procedure	-	Every 2 years	Every 2 years	Every 2 years	X
Copies of archived policies, processes, and procedures to be retained	X	X	X	X	X (Local regulations)
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 and allows retrieval	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	-
Actual result of each action performed to be recorded immediately, and final interpretation to be recorded upon completion of testing	-	X	X	X	-
Records to be created concurrently with performance of each critical activity, identifying work performed, individual performing, and when performed	-	X	X	X	-
Copies of records to be verified as containing original content before destruction of original	-	-	-	X	-
Policies for confidentiality of donor, employee, and patient records	X	X	X	X	-
Regular review of records for accuracy, completeness and compliance	X	X	X	X	-
Traceability	X	X	X	X	-