Turning DC/AC/CC Audit Findings into Quality Gold

Moderators:
Stephanie Thompson, NMDP/Be The Match

Speakers:
John Carpenter, Duke University

Hope Guidry-Groves & Karen Wooten-Miller
Gulf Coast Regional Blood Center

Disclosures

The following faculty and planning committee staff have no financial disclosures:

Name	Institution
John Carpenter, MS, CQA (ASQ)	Duke University
Hope Guidry-Groves, BS	Gulf Coast Regional Blood Center
Karen Wooten-Miller, BS, CQA (ASQ)	Gulf Coast Regional Blood Center
Kuchen Hale	NMDP/Be The Match
Stephanie Thompson	NMDP/Be The Match
Matt Zander	NMDP/Be The Match

Learning objectives

At the conclusion of this session, attendees will be able to:

- Implement changes in their quality system based on audit findings
- Explain how quality and operations contribute to a robust quality system
- Identify areas for improvement and share best practices

Turning DC/AC/CC Audit Findings into Quality Gold at Duke University

John Carpenter, MS, CQA (ASQ)
Quality Assurance Manager
Quality Systems Unit
Duke University Bone Marrow Transplant/Cell Therapy

Quality System Unit History

- New group was needed due to regulations, more complex standards, and interest in new research/therapies.
- Group would need to have skill sets that were not generally found within a hospital setting.
- Group would have an independent reporting structure and would work with varying functional groups.

Quality System Unit History-cont'd

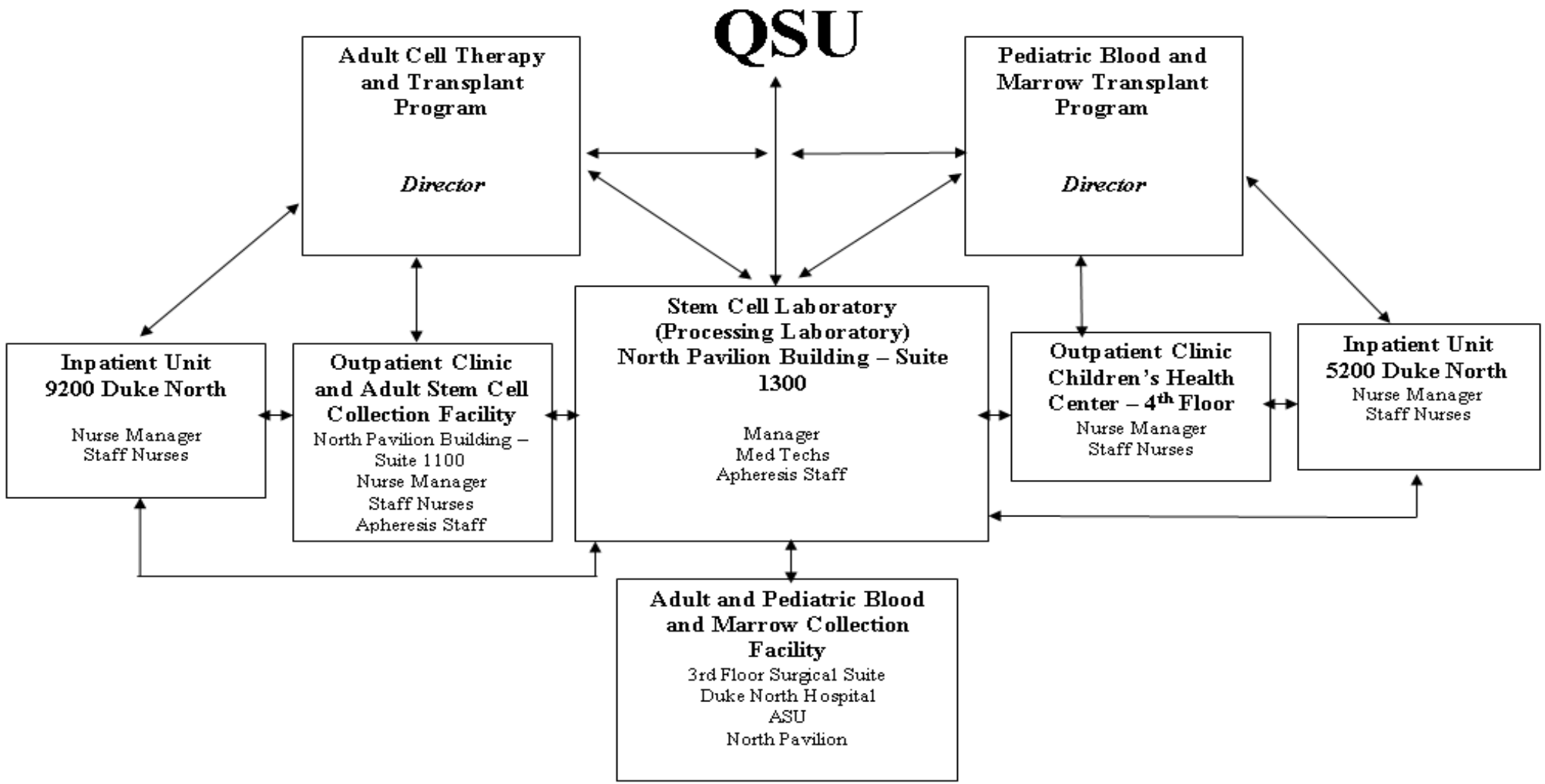
- 2012 the Quality Systems Unit (QSU) was formed. Members came from a variety of backgrounds:
  - Regulatory Affairs
  - Blood and Cellular Therapy Collection
  - Big Pharma
  - Document Control
  - Auditing for cGXP Standards

Quality Systems Unit Oversight

- QSU would be responsible for:
  - Monitoring clinical outcomes, deviations, non-conforming products, adverse events
  - Implementing quality systems that ensure the quality of manufactured products meet applicable regulatory and accreditation requirements
  - Staying abreast of changes and modifying the quality systems as needed
  - Educating staff about the importance to the quality systems
  - Ensuring compliance to the in place quality systems

Quality Systems Unit Integration

Flow Chart of the Adult and Pediatric Blood and Marrow Transplant Programs



Analysis of the Internal Audit Quality System

- Analysis of the internal audit quality system was performed and revealed that the following:
  - Lack of evaluation about the program's performance related to the scope of the audit.
  - Formal responses were not documented.
  - No evaluation of the corrective proposals with follow up.
  - Internal audits were not conducted on a routine schedule.

- The internal auditing quality system was not compliant with the in place regulatory and accreditation standards.

Implementing the Revised Internal Audit Quality System

- QSU educated the program directors and clinical management about the identified deficiencies and the potential ramifications regarding the program's growth.
  - Example: External organizations would not consider partnering with the program.

- Once a remediation approach was agreed upon, procedures were revised and approved, launched to staff for training, and made effective.

Implementing the Revised Internal Audit Quality System-cont'd

Some of the enhancements were:

- Revised procedure to include an audit score and scoring matrix.
- Required a 2 business day acknowledgment upon report receipt and 30 day response timeframe.
- Corrections/proposed actions are now documented.
- Yearly internal audit schedule is now generated.
- Documented education/experience to conduct audit.

Implementation Challenges

- Staff was unaccustomed to being audited by a different department with a different background.
- Based upon previous audits, staff assumed that audits were used to merely check a box.
- Individuals took audit results personally.
- Training staff to look for the root cause of an issue and not just fix the apparent deficiency.

Internal Audit Finding Examples

Training inconsistencies were found when two disinfection techniques were described/demonstrated to the auditor. In one instance the technician placed an alcohol swab on top of the DMSO bottle and punched through the swab with the syringe into the bottle. Other personnel, using the same type of DMSO bottle, were found to be swabbing the top of the bottle, removing the swab, and then piercing the top of the bottle with the syringe.

- Subsequent observations, as a result of this citation, revealed that there was a deficiency in the Personnel/Training quality system regarding aseptic technique training not being performed uniformly throughout the laboratory. As a result, a formal aseptic technique training and assessment program is being developed with program management.

Internal Audit Finding Examples

Jars on the laboratory counter containing alcohol for disinfecting equipment has documented alcohol change dates written on them. There is no procedure that clarifies the frequency at which the alcohol should be changed.

- This citation demonstrated a gap in the Equipment Management quality system. The laboratory procedures for equipment maintenance were assessed to determine the full extent of this type of deficiency. As a result, procedures were updated to reflect the correct way to calculate expiration and change dates for opened items and items transferred to secondary containers.

Internal Audit Finding Examples

Observation of an apheresis procedure revealed that staff did not label the cellular product bag or plasma bag prior to beginning the procedure. This is out of compliance with procedure ABMT-COLL-001 step 8.4.8.

- This citation demonstrated that although the apheresis staff was verifying the identify of the patient/donor, it was not occurring according to procedure. The procedure was deemed to be sufficient regarding the provided instructions. As a result staff was retrained on this procedure and observations were made for a period of time to verify compliance.

Internal Audit Finding Examples

The apheresis area is not documenting the weight set number and expiry date on the ABMT-EQUIP-001 FRM3 Scale Quality Control Record. As a result the scale has been calibrated using an expired weight set.

- Although the apheresis area had a copy of the weight set calibration certificate, this document was filed in a binder in a drawer away from the equipment. Staff was not referencing this document or the associated calibration equipment sticker on the weight set, when recording entries, since this information was not required. By revising this form to include the weight set serial number and expiry date, the form now has a built in quality check to prevent this type of error from recurring.

Using Audit Report Findings

- Corrective actions to audit citations from one department routinely become program wide goals that are used to enhance compliance.

- When documented appropriately (i.e. quarterly reports), audit findings can be used to show continual process improvement to outside auditors.

- Using previous audit findings can guide future audits to verify that the implemented corrective measures are performing appropriately.

Turning DC/AC/CC Audit Findings into Quality Gold

NMDP Council Meeting 2017

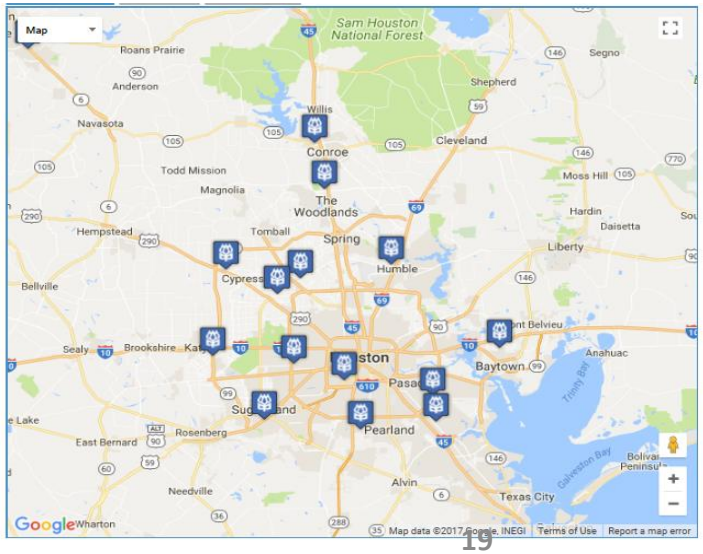
Hope Guidry-Groves – Cellular, Apheresis and Transfusion Services Director
Karen Wooten-Miller – Quality Assurance Compliance Manager

Commit for Life.

Gulf Coast Regional Blood Center

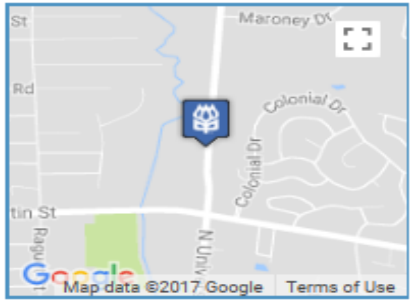
Headquarters

Neighborhood Donor Centers



The Blood Center – Brazos Valley

The Blood Center – East Texas



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Gulf Coast Marrow Donor Program

- In 1991, GCRBC established the Gulf Coast Marrow Donor Program (GCMDP)
- GCMDP is an accredited donor center and recruitment center for the National Marrow Donor Program which operates the Be The Match® Registry (DC 091 and R 091)
- Recruited over **300,000** donors from the Texas Gulf Coast Region and Louisiana
- Managed facilitation of **1,358** lifesaving marrow and stem cell donor collections
- Maintained average donor file of **220,000** potential donors

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Apheresis Collection Center 9793

- We have a multi-bed medical apheresis suite at our Headquarters, with dedicated and experienced staff to facilitate our HPC and medical apheresis procedures for a variety of clients
- **December 2014** - began operations as a NMDP Apheresis Collection Center (AC 9793)
- Collect for 5 Contracted Donor Centers and DC 001 Operated Centers throughout the US
- Collected over **280** stem cell donations to date
- **May 2017** - Accredited by AABB for Cellular Therapy Activity – HPC collection
- **July 2017** - AC 9793 is qualified as a contract manufacturing center for National Marrow Donor Program/Be The Match

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Learning the Ropes

- Who are they
- What exactly do they do
- Quality ≠ Customer Service

2012

January

S	M	T	W	T	F	S
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31				

February

S	M	T	W	T	F	S
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29			

March

S	M	T	W	T	F	S
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	31

April

S	M	T	W	T	F	S
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30					

May

S	M	T	W	T	F	S
		1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30	31		

June

S	M	T	W	T	F	S
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30

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LEARNING THE CT ROPES

- **Governing Regulations/Standards**
  - ✓NDMP Standards
  - ✓CFR 1271 series
  - ✓cGTP
  - ✓Gulf Coast SOPs
  - ✓NDMP Manual of Operations
- **How To Apply Them**

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FUNCTIONAL FITNESS

MDP's understanding of Quality Assurance

- QA = RED TAPE!
- QIR = Not a Team Player
- Customer Service = Quality Service
- We really did it = Process Compliance
- Blank spaces = Proper Documentation
- cGMP = Meeting All Standards
- Best Practices = Standard Operating Procedures

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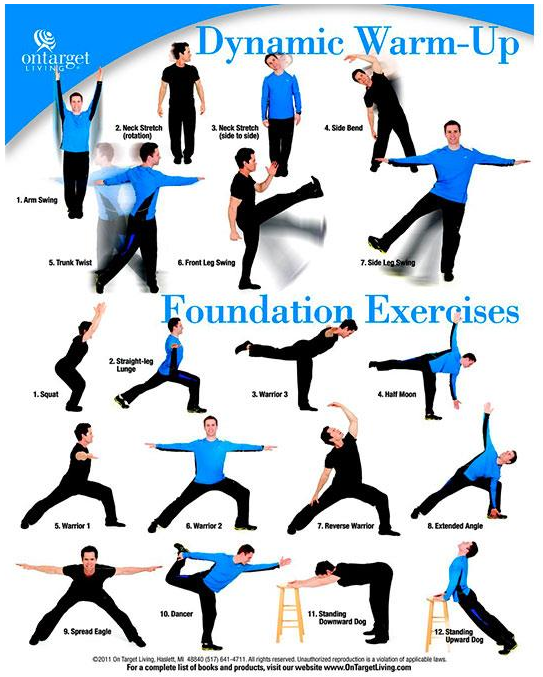
WARM UP EXERCISES

2012 Internal Assessment

- Quality Program
- Contracts
- Personnel/Training/ Competency
- Procedures & Forms/Process Controls
- Facilities
- Records
- Supplies
- Document Control
- Safety



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“Warm Ups” Reaction

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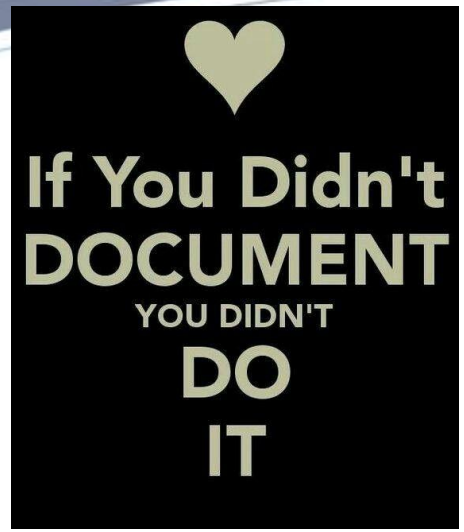
STRENGTH TRAINING



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And then there was NMDP…

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FEELING THE BURN

2012 NMDP Regulatory Audit Results

- **Eligibility**
  - 3 potential Consignee Notifications to TCs
- **Protocol Deviations**
  - Consent
  - Subsequent Donation
- **Operating Procedures**
  - Manufacturing processes/steps not defined in any existing SOPs (11)
  - Uncontrolled documents and job aides
  - Incomplete/Not well-defined processes in existing SOPs
- **Vendor Qualification**
  - Records shall be maintained stating the name, address, and qualifications of any consultants and the type of service they provide
- **Equipment**
  - Blood pressure cuffs not being maintained and calibrated per manufacturer's instructions
  - No documentation of the specific cuff of thermometer used for performing vitals for injections
- **Distribution**
  - Facilities are required to register for all steps of manufacture that they perform
- **Facilities**
  - You must divide a facility used in manufacture of HCT/Ps into separate or defined areas of adequate size for each operation that takes place…to prevent…mix-ups

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BACK TO BASICS BOOT CAMP

Required Regulatory Compliance

21 CFR 211: Good Manufacturing Practice (GMP)

– Set of regulations that outline requirements to ensure the *safety, quality, identity, purity*, and *potency* ("SQuIPP") of biological drug products

21 CFR 1271: Good Tissue Practice (GTP)

– Set of regulations that outline requirements to ensure the *prevention, introduction or transmission of communicable disease* from HCT products intended for transplantation into a human recipient

NMDP Standards

– Patient and donor confidentiality, donor consent

WMDA Standards

– International criteria

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CAPA DRILLS

Differences between correction,
corrective action
and preventive action

Correction
Put fire out
(at the time)

Corrective Action
What caused fire
and how to prevent
recurrence
(after event)

Preventive Action
Stop fire from
happening
(before event)

- Where do we begin
- How do we draft a CAPA plan
- What supporting documentation is required

if you learn from

DEFEAT

then you haven't really lost.

-Zig Ziglar

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AUDIT WORKOUT RECOVERY STRATEGY

- Focus on documentation (SOPs, records, training)
- Think like a blood banker
- Make sure your records reflect what you do
- Evaluate people, process, and product
- Be able to show in word and deed what you do
- Don’t overdo

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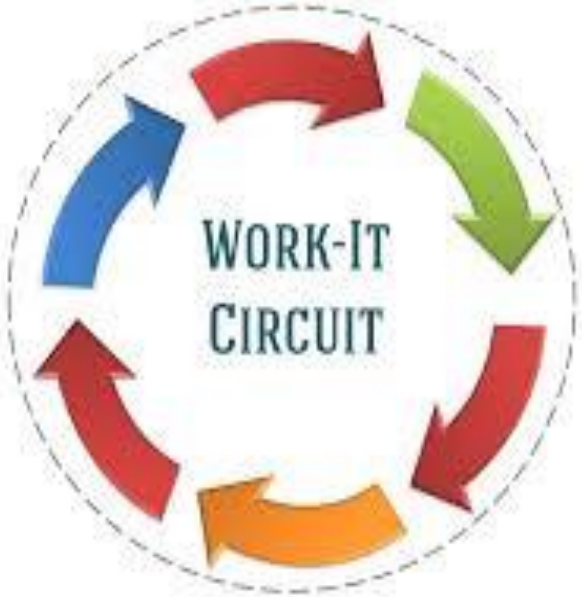
STUDYING THE TAPES

- QA Consultant
- Procedures
- Forms
- Processes
- Policies
- Training



- Documentation
- Incident Management
- CAPAs
- E&T assistance
- CAPA Follow-up

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SCULPTING AND POSITIVE CHANGES

- Created SOPs, updated others and formalized forms
- Added strategic reviews to processes
- Designated space for sample processing and storage
- Initiated annual internal cGTP training
- Updated internal and external training program and documentation
- Enhanced contract specifications
- Removed random desktop versions
- Program QA Coordinator role

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DC LESSONS LEARNED

- We have a quality program, we perform quality work – we need to document it and prove it
- Create a culture of regulatory mindfulness
- Incorporate Quality mindset training sessions
- Standards are your resource
- Self sufficient ≠ Separate/Isolated
- QA is our “Friend” – or at least an “Ally”
- QIR≠ You’re Mean

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OUR QUALITY AUDITING PHILOSOPHY

"Catch our own errors before anyone else does!"

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2014 INTERNAL ASSESSMENT RESULTS

- ❑ Staff are unfamiliar with TBC safety policies
- ❑ Package inserts are not kept on file and reviewed
- ❑ No area for critical supply acceptance review
- ❑ A label control process is needed
- ❑ Donor's HHSQ comments need to be evaluated
- ❑ Clarification is needed for write overs, incomplete data, and documentation discrepancies

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WEIGH IN

- Take your time
- Focus on what drives you
- Look at the entire process as a system
- Make sure your records are well kept and reviewed
- Make sure staff knows what they are doing and why

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ESTABLISHING AN APHERESIS CENTER

- **NMDP Apheresis Center Participation Criteria**
  - Facility Characteristics
  - Personnel and Apheresis Collection Team
  - Support Services
  - Policies and Procedures
  - Administration
- **NMDP 21st Edition Standards**
- **AABB Standards for Cellular Therapy Services**

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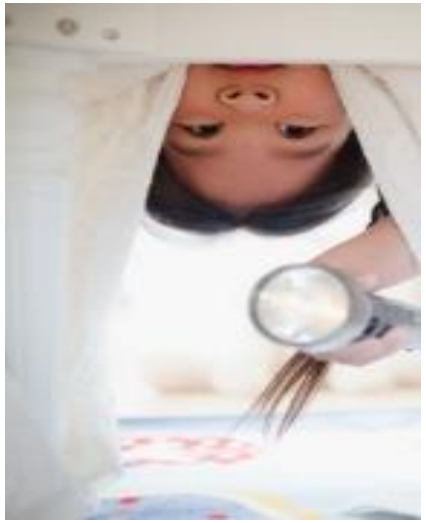
Review of AABB Standards for Cellular Therapy Services, 7th ed., effective 7/1/2015

Part 1. Standards 1.0 – 4.5B			
7th edition	6th edition	Standard Change	TBC Impact
1.1 Structure, Responsibility, and Authority	1.0 Organization	Same wording w/new title	
1.1.1 Executive Management	1.1 Executive Management	Number change only	
1.1.1 NEW	---	Institutional support for CT	
1.1.2 NEW	---	Procurement MD on exec. team; donor eligibility	
1.1.2.1 NEW	---	Procurement MD/licensed/responsibilities/delegation	
1.1.3 Processing Facilities	1.1.2 Procurement &/or Processing	Title change; procurement and processing separated	
1.1.3.1; 1.1.3.2; 1.1.3.3 Laboratory Director	1.1.2.1; 1.1.2.2; 1.1.2.3	Same text; # change only	
1.1.4; 1.1.4.1; 1.1.4.2; 1.1.4.3 Clinical Program	1.1.3; 1.1.3.1; 1.1.3.2; 1.1.3.3	# changes; 1.1.4.1 Clinical Facility rephrased; Clinical Team redefined	

2015/2016 INTERNAL AUDITS



MDP 2015 internal (DC)

(11 findings, 6 observations, 4 recommendations)

CATS 2016 internal (AC/DC)

(11 findings, 4 observations, 4 recommendations)

2015/2016 EXTERNAL AUDITS

- **CIBMTR Pre-audit 2015 (0 findings, 5 observations)**

"During the previous audit, several issues were identified with the donor eligibility forms; all of these occurred on the Health History Questionnaire at Work-up. The current audit identified no errors with any of the donor eligibility forms."

- **NMDP 2015 – DC 091/AC 9793 (2 findings)**

"The Gulf Coast Regional Blood Center has a well developed Quality Plan with defined SOPs addressing Quality Systems. These SOPs were well implemented and integrated into processes and daily operations. There appears to be a good understanding and adherence to Good Tissue Practices (GTPs) and Good Manufacturing Practices (GMPs)."

- **NMDP 2016 DC 091/AC 9793 (2 findings – DC, 0-AC)**

"There were no findings identified during the audit with AC 9793 – Gulf Coast Regional Blood Center conducted on December 6-7, 2016."

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ONGOING BEST PRACTICES

- Comprehensive SOPs
- Filgrastim/Neupogen Tracking Log
- Critical/Essential Supplies Log
- NMDP Announcements Log
- Annual Competency based on new and/or essential processes
- GC1100 – Daily Neupogen (Filgrastim) Assessment Form
- Second reviews
- Quality Essentials Presentations
- Collaborative communication with stakeholders

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NMDP ANNOUNCEMENTS LOG

NMDP Announcement Log

Date Received	Recipient(s) - DC, RG, AC, All	Announcement Content	Impact	Changes	Staff Documentation Required	Status
6/17/2015	DC	New email & web address	SOP 1938.02	Revised; sent to Bo	No	Complete
6/30/2015	DC; sg, vw, cs	Preliminary search question changes	New SOP: 1904.04	Implemented	Yes/complete	Complete
7/2/2015	DC	Process changes in CH. 13 NMDP DM	SOPs 1938.00, 1902.01	Revise SOPs; v9 & v10 comparison	Yes/not sent	Complete
7/2/2015	DC, AC	NMDP consent form in additional language	No SOP impact	None	FYI/sent	Complete
7/8/2015	BM, AC	CAG Nominations	No SOP impact	None	FYI/sent	Complete
7/8/2015	RG	Shipping label changes for consents/swab	Review SOP 1902.00 for chg.	Review SOP1902.00; supplies	Yes/complete	Complete
7/9/2015	Other (HG, BH, LC, PM)	Revised UPOI docs. v14 to v15, eff. 9/1/15	Fill out in September		Yes/complete	Complete
7/14/2015	DC, sg, vw, cs	Updated STAR Link Letter to donors/registry members	No SOP impact	None	FYI/sent	Complete
7/14/2015	BM	H.R. 2820 bill - C. W. Bill Young	No SOP impact	None	FYI/sent by Hope	Complete
7/17/2015	DC	Annual approval of IRB protocols	Needs review	Audit donor charts/complete	Sent with audit results/responses complete	Complete
7/21/2015	DC	Refreshed search materials (You Could Save a Life, etc.)	No SOP impact	None	Yes/FYI only	Complete
7/22/2015	DC	Forms 760/761/763 revised with minor changes	Revise SOP 1915.00 & 1916.00	Change titles and add form 763; Hope revised	Yes/complete	Complete
7/28/2015	DC	LTDFS study enrollment closing with manual & website changes	SOP IMPACT: 1938.01	Leslie to conduct training 8/20/15; Leslie notified AC & CC to use most current form 700 when available; Susan G. trained	Reminder sent 9/29/15	Complete
7/29/2015	DC	Procedure change: DCs to scan & send clearance documentation (Form 700) to CM & NMDP	Revise SOP 1938.03	Revised by Hope and sent to Bo	Staff meeting with Hope/ GC1502 complete	Complete
7/29/2015	DC	Annual approval of Statin/GvHD study to	Appendix B at al expiring 7/29/15	Audit complete/sent to Hope	Yes/sent by Hope/responses	Complete

GC1100 - DAILY NEUPOGEN (FILGRASTIM) ASSESSMENT FORM

Daily Neupogen® (Filgrastim) Assessment Form

DID:	Name:	DOB:	Date:
Day of Assessment: ☐ One ☐ Two ☐ Three ☐ Four ☐ Five ☐ Six			Time:
Blood Pressure: /	Pulse:	Temp: ☐ °F	Weight (Day 1 Only): ☐ lbs ☐ kg
Cuff #:	Cuff Calibration Date:	Thermometer #:	Thermometer Expiration Date:
Vital Signs Taken By: (Circle One): GCRBC Staff / Non-GCRBC Staff / Donor			

Vial Lot #:	Expiration Date:	Vial Size:	Portion Administered:
		☐ 1.0 mL (300 µg) ☐ 1.6 mL (480 µg)	☐ Full vial or ☐ Partial vial Partial dose administered: ________ mL
		☐ 1.0 mL (300 µg) ☐ 1.6 mL (480 µg)	☐ Full vial or ☐ Partial vial Partial dose administered: ________ mL
		☐ 1.0 mL (300 µg) ☐ 1.6 mL (480 µg)	☐ Full vial or ☐ Partial vial Partial dose administered: ________ mL
		☐ 1.0 mL (300 µg) ☐ 1.6 mL (480 µg)	☐ Full vial or ☐ Partial vial Partial dose administered: ________ mL

Was the Neupogen® (Filgrastim) dose reduced? ☐ Yes ☐ No

Specify reason(s) for dose reduction, if applicable: ☐ Bone pain ☐ Donor weight change ☐ Headache ☐ Low platelet count ☐ Local (injection site reaction) ☐ Nausea ☐ Vomiting ☐ Other reason Specify other:

Neupogen® (Filgrastim) Administered by (Print Name): **Sign/Date:**

CONDITIONS PRESENT PRIOR TO ADMINISTRATION OF FILGRASTIM
Grades for all conditions defined on back (*ADL = Activities of Daily Living)

Fever in absence of infections	☐ None	☐ 38–39°C/100–102.2°F	☐ >39–40°C/102.2–104°F	☐ >40°C/104°F,<24 HRS	☐ >40°C/104°F,>24 HRS
Fatigue (lethargy, malaise, asthenia)	☐ None	☐ Grade 1	☐ Grade 2	☐ Grade 3	☐ Grade 4
Rashes on skin	☐ None	☐ Grade 1	☐ Grade 2	☐ Grade 3	☐ Grade 4
Injection Site [Neupogen® (Filgrastim) or IV]:	☐ None	☐ Grade 1	☐ Grade 2	☐ Grade 3	---
Nausea	☐ None	☐ Grade 1	☐ Grade 2	☐ Grade 3	☐ Grade 4
Vomiting	☐ None	☐ Grade 1	☐ Grade 2	☐ Grade 3	☐ Grade 4
Loss of Appetite (anorexia)	☐ None	☐ Grade 1	☐ Grade 2	☐ Grade 3	☐ Grade 4
Inability to Sleep (insomnia)	☐ None	☐ Grade 1	☐ Grade 2	☐ Grade 3	☐ Grade 4
Dizziness, vertigo, or lightheadedness	☐ None	☐ Grade 1	☐ Grade 2	☐ Grade 3	☐ Grade 4
Fainting (syncope)	☐ None	---	---	☐ Grade 3	☐ Grade 4

SITES OF PAIN

Pain Scale: *None:* Grade 0; *Mild:* Pain not interfering with function; *Moderate:* Pain interfering with function but not ADL*; *Severe:* Pain severely interfering with ADL*; *Disabling:* Pain inhibits ADL*; **ADL = Activities of Daily Living*

Back	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Disabling
Bones	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Disabling
Headache	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Disabling
Hip	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Disabling
IV Site	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Disabling
Joints (Excluding Hip)	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Disabling
Limbs (arms, legs, hands, feet)	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Disabling
Muscles	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Disabling
Neck	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Disabling
Throat	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Disabling
Other pain site:	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Disabling

Additional Notes:

Assessed By: (Print Name): **Sign/Date:**

Fever in absence of infections:
- **Grade 0**: None
- **Grade 1**: 38.0–39.0° C / 100.0–102.2° F
- **Grade 2**: Greater than 39.0–40.0° C / 102.2–104.0° F
- **Grade 3**: 40.0° C / 104.0° F for less than 24 hours
- **Grade 4**: 40.0° C / 104.0° F for more than 24 hours

Fatigue (lethargy, malaise, asthenia):
- **Grade 0**: None
- **Grade 1**: Mild fatigue over baseline
- **Grade 2**: Moderate or causing difficulty performing some ADL
- **Grade 3**: Severe fatigue interfering with ADL
- **Grade 4**: Disabling

Rashes on skin:
- **Grade 0**: None
- **Grade 1**: Macular or papular eruption or erythema that is asymptomatic (discrete areas of raised or flat, discolored and/or reddened skin patches, with no other symptoms)
- **Grade 2**: Macular or papular eruption or erythema with pruritus or other associated symptoms (same as above in conjunction with symptoms such as itching and pain)
- **Grade 3**: Severe, generalized erythroderma or macular, papular, or vesicular eruption (same as above with the possible addition of fluid-filled blisters; also the condition is not widely spaced, but instead covers the majority of the body)
- **Grade 4**: Generalized exfoliative dermatitis or ulcerating dermatitis (skin inflammation leading to peeling and/or ulceration)

Injection Site Reaction (Neupogen® (Filgrastim) or IV):
- **Grade 0**: None
- **Grade 1**: Pain; itching; erythema
- **Grade 2**: Pain and swelling with inflammation or phlebitis
- **Grade 3**: Ulceration or necrosis that is severe; operative intervention indicated
- **Grade 4**: N/A

Nausea:
- **Grade 0**: None
- **Grade 1**: Loss of appetite without alteration in eating habits
- **Grade 2**: Oral intake decreased without significant weight loss, dehydration, or malnutrition
- **Grade 3**: Inadequate oral caloric or fluid intake
- **Grade 4**: Life-threatening consequences

Vomiting:
- **Grade 0**: None
- **Grade 1**: 1 episode in 24 hours
- **Grade 2**: 2-5 episodes in 24 hours
- **Grade 3**: 6 or more episodes in 24 hours
- **Grade 4**: Life-threatening

Loss of appetite (anorexia):
- **Grade 0**: None
- **Grade 1**: Loss of appetite without alteration in eating habits
- **Grade 2**: Altered intake without significant weight loss or malnutrition
- **Grade 3**: Significant weight loss or malnutrition
- **Grade 4**: Life-threatening consequences

Inability to Sleep (insomnia):
- **Grade 0**: None
- **Grade 1**: Occasional difficulty sleeping, not interfering with function
- **Grade 2**: Difficulty sleeping, interfering with function but not interfering with ADL
- **Grade 3**: Frequent difficulty sleeping, interfering with ADL
- **Grade 4**: Disabling

Dizziness, vertigo, or lightheadedness:
- **Grade 0**: None
- **Grade 1**: With head movements only; not interfering with function
- **Grade 2**: Interfering with function, but not interfering with ADL
- **Grade 3**: Interfering with ADL
- **Grade 4**: Disabling

Fainting (syncope):
- **Grade 0**: None
- **Grade 1**: N/A
- **Grade 2**: N/A
- **Grade 3**: Present
- **Grade 4**: Life-threatening consequences

AABB ACCREDITATION
Laying the Foundation

"Processes are everything"

- Review website
- Contact AABB
- Accreditation Overview
- Begin project management
- Paperwork, paperwork, paperwork
- Submit Fees
- Initial Accreditation Process Description

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AABB ACCREDITATION

Developing the Workout Plan

- Standards Review 1/26/17
- Self Assessment Submission 3/1/17

▲ C **1.2.3.1** All policies, processes, and procedures shall be in writing or captured electronically and shall be followed.	• *How does the facility ensure that policies, processes, and procedures are followed?*	Medical Services and Cellular Apheresis and Transfusion Services SOPs, series 1800 and 1900
▲ C **1.2.3.2** The procurement medical director shall review and approve all procurement policies, processes, and procedures.	• *How does the facility determine which policies, processes, and procedures are the responsibility of the Laboratory Medical Director? Technical Director? Clinical Program Director?*	Document Systems SOPs specific to SOP and associated document 's generation, validation, and review. 2701.00 – Standard Operating Procedures 2702.00 – Document Validation 2713.00 – Master Control – Approval Route 2706.00 – Document Review
▲ C **1.2.3.3** The laboratory director shall review and approve all medical laboratory policies, processes, and procedures.		Assessment Program Assessment Schedule SOP 276.00 – Internal Assessment Program
▲ C **1.2.3.4** The laboratory director shall review and approve all technical policies, processes, and procedures.		Organizational chart for Chief Medical Officer and Chief Technical Officer SOP 1619.00 CLIA Laboratory Director Responsibilities
▲ C **1.2.3.5** The clinical program director shall review and approve all clinical policies, processes, and procedures related to administration and patient care	• *What is the mechanism for the appropriate medical and / or technical director review?*	1.2.3.5 N/A. We do not have a clinical program

- AABB Review of Self Assessment Completion 3/10/17

  "Congratulations! Your facility has completed the initial accreditation process and is ready to transition to the on-site phase. "
- Self assessment follow-up
- AABB on-site assessment scheduled Q2

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DAILY CONDITIONING

- Focus on Documentation
- Monitor for Trends
- Adhere to SOPs
- Write procedures that anyone can follow
- Document transparently
- Fill in the blanks/Answer the questions
- Learn from your mistakes
- Don’t assume

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QA CONDITIONING CONSIDERATIONS

- Work to cultivate organizational perception of CATS as another manufacturing entity
- Review/revise QA policies and procedures to address NMDP confidentiality requirements
- Include NMDP and AABB CT Standards review in the rotation and add updates to the change process rotation
- Increase QA staff knowledge of CATS processes and educate for auditing
- Continue quality training for new employees

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OLYMPIC QUALITY GOLD

AABB Accreditation

Gulf Coast Regional Blood Center

having been assessed by AABB, has been found to meet the requirements of applicable Standards of this organization and therefore is granted this

CERTIFICATE OF ACCREDITATION

for the following activities:

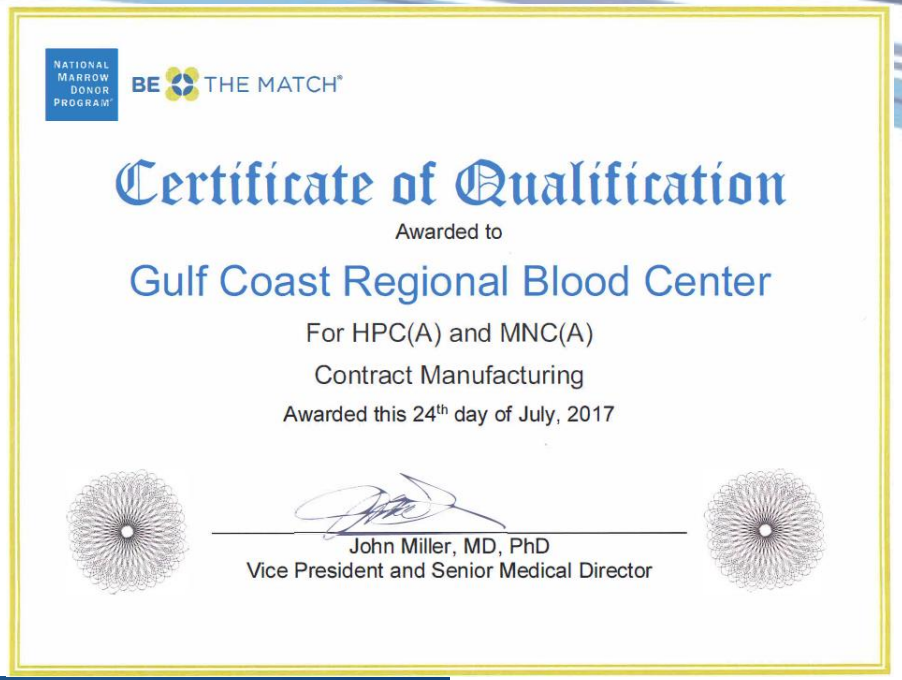
Donor Center Activities
IRL Activities
Transfusion Activities
Cell Therapy Activity: HPC - collection

In Witness whereof the undersigned, being duly authorized, have caused this Certificate to be issued and the AABB Corporate Seal to be affixed.

Effective Dates
July 01, 2017 - June 30, 2019

President, AABB

Chair, Accreditation Program Committee



NATIONAL MARROW DONOR PROGRAM

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Certificate of Qualification

Awarded to

Gulf Coast Regional Blood Center

For HPC(A) and MNC(A)

Contract Manufacturing

Awarded this 24th day of July, 2017

John Miller, MD, PhD
Vice President and Senior Medical Director

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Questions

Evaluation Reminder

Please complete the Council Meeting 2017 evaluation in order to receive continuing education credits and to provide suggestions for future topics.

We appreciate your feedback!