(9340-QE-CT) Beyond See One Do One: Developing a Spiffy Training and Competency Program for the Cellular Therapy Laboratory

October 14, 2013  4:30 PM - 6:00 PM
Event Faculty List

Event Title: 9340-QE-CT Beyond See One Do One: Developing a Spiffy Training and Competency Program for Cell Therapy Laboratory
Event Date: Monday, October 14, 2013
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BEYOND SEE ONE DO ONE: 
DEVELOPING A SPIFFY TRAINING AND 
COMPETENCY PROGRAM FOR A CELL 
THERAPY LABORATORY

Objectives

- Discuss the essential elements and regulatory 
  considerations for developing a training and 
  competency program for a Cell Therapy 
  Laboratory
- Explore innovative training methods and 
  management tools
- Discuss competency strategies for laboratory 
  staff, medical staff and Quality Assurance 
  Unit

Quality Operations Subsection

- AABB’s Cellular Therapies Section has subsections 
  which allow members to participate in groups based on 
  their area of interest
- Today’s session was suggested by Quality Operations 
  Subsection
  - Group “meets” monthly via conference call
    - Third Thursday of the month at 2pm EST
    - Discussions focus on a variety of quality related topics 
      facing cell therapy departments
- Please consider joining our subsection!
<table>
<thead>
<tr>
<th>Presenters</th>
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| **Andrew Patmos**  
  Quality Improvement/Assurance Specialist  
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SCENARIOS

Scenario #1
What would you do if a staff member did not meet the requirements during an annual competency assessment and the next day you were short staffed and lab was over booked?

Scenario #2
A new staff member is hired that has lots of previous experience. Your policy requires her to perform procedures 3 times with supervision before being signed off. After watching her once, she does such a good job that you think you could actually learn a thing or two from her and she even suggests a few ways to improve your procedures. How would you proceed?
Scenario #3

Due to inclement weather only one of your technologists in the lab was able to make it to work. There is a bone marrow transplant scheduled involving removal of incompatible RBCs and the staff person is not signed off as being trained on this process. The transplant must happen today, what do you do?

Scenario #4

You are hiring a new Quality Assurance staff person who has very little experience in QA and you realize that you don’t have an adequate training plan in place. What are some useful training tools or resources for new QA staff?
Training Program Design and The Adult Learner

2013 AABB Annual Meeting
October 14, 2013

Andrew Patmos
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Cell Manipulation Core Facility
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Agenda

- Background on CMCF and Training Program
- Three Components of Training Program
- The Adult Learner and Enemies of Learning

Goal

- Provide you with ways to make your training programs more efficient and more effective

Training vs. Education

- Training
  - Changes behavior
  - Develops skills as a means to an end
- Education
  - Increases knowledge
  - Development is the end itself
Cell Manipulation Core Facility

- Located at Dana-Farber Cancer Institute
- Work closely with Brigham and Women's Hospital and Boston Children’s Hospital
- Approximately 30 full-time employees
  - Quality Control Department
  - Stem Cell Transplant Lab
  - Novel Cell Therapy Lab
- Process over 1000 products annually

CMCF Training and Competency Program

- As CMCF grew in size and jobs became more specialized, increased need for new training program
- Began working on redesigning program in early 2011, implemented in 2012
- Since implementation in February of 2012, 11 new staff members have been hired

Goals For Training Program

- Meet regulatory requirements
- Ease the way new staff are brought on board
- Ensure that new staff all receive proper training and maintain competency
- Design a program that is user friendly, is efficient and sustainable
Building Sustainability

- Anticipate what will happen in the future by looking to the past
- Prepare for the expected and unexpected
- Find ways to save time and increase efficiency
- Develop all aspects of the training program

Three Components of Training Programs

- Orientation Goal - Effectively assimilate new personnel into existing culture
- Training Goal - Develop skills required to correctly perform job functions
- Competency Goal – Ensure that staff maintain skills

Before New Hire Orientation

- Designated person contacts new employee one week prior to start date:
  - Welcome Letter
  - Address parking, dress code, hours, lockers and other common questions
  - Provides contact person
  - Send Training Calendar for first week
  - Prepare all paperwork ahead of time
Company Orientation

- Wide variety of people
- Broad in scope
- Covers:
  - Company policies
  - Time reporting
  - Benefits
  - History of Company
- Often done by HR → Uniform

Department Orientation

- Varies by department/supervisor → Non-Uniform
- Broad overview of the department
  - Learn what their role is
  - Meet and greet with all staff members
  - Show what resources are available
  - Upstream and downstream areas
- Theory and Compliance
  - Good Manufacturing Practices
  - Documentation/SOPs

Real World vs. Theoretical

- Operational Training:
  - Takes place on the floor
  - Hands on
  - Easy to document
  - Floor trainers following SOP → Uniform
- Theory and Compliance Education:
  - Lecture hall or computer
  - Thought based
  - More difficult to document
  - Floor trainers understanding varies → Non-Uniform
EXAMPLE:

- Company has “Math Day” during their basic skills orientation
- Pros:
  - Ensures that everyone is consistent when performing calculations
  - Reduces the number of errors
- Cons:
  - People hate it
  - Enemies of learning

“There can be few intellectual quests that, for educators and trainers of adults, assume so much significance and yet contain so little promise of successful completion as the search for a general theory of adult learning”

~ Stephen Brookfield

Concepts of Adult Learning Theory

- Adults want to know:
  - Why they need to learn something
  - How it relates to them
  - How it will benefit them
  - How soon it will benefit them
Example:
- GMP Training

Concepts of Adult Learning Theory
- Body Learns, Not the Mind
- See One, Do One

Example: Banjos
Concept: Enemies of Learning

- Attitudes, emotions and/or behavior patterns that interfere with our ability to learn

Knowing

- “I already know this”
- “This is just like X, and I already know that”

Inability to Admit We Don’t Know

- Knowledge is highly valued
- Not knowing is undervalued
The Magic Pill / Clarity
- Wanting knowledge/understanding instantly
- Wanting things to be clear all the time

Ego
- We can be our own worst enemies
- Unwillingness to be a beginner
- Making it personal
- Wanting to do it by yourself
- “I can’t learn this”

What to do with this?
- Recognize the enemies of learning when they come up, then set them aside.
- Address enemies of learning up front in training sessions.
- Answer some of the following in trainings:
  - Why do you need to know this?
  - How will this training benefit you?
  - How will you apply this knowledge?
  - How long will this take?
- Look for these not only in your co-workers, but in yourselves as well.
Training Programs

- Fully develop three main components
  - Orientation
  - Training
  - Competency
- Keep goals in mind
- Develop documentation and procedures
- Anticipate the unexpected and the expected
- Use knowledge of how adults learn to advantage

Thank You

- Diane Kadidlo & AABB
- CMCF Staff
- Darlys Schott
- Mary Ann Kelley
- Olive Sturtevant
- Karl Stasko
- Sharon Anderson
- Bethany King
- Steve Brown
- Robson Goulart
- Ruth Muller
- Karen Snow

References


Beyond See One Do One:
Training and Competency
for The Forgotten

Objectives
- Discuss the essential elements and regulatory considerations for
developing a training and competency program for cellular therapy
program
  - Review the intent of the regulations
  - Discuss the differences between training and competency assessment
- Explore innovative training methods and management tools
  - Review different approaches to assessment
- Discuss competency strategies for lab staff, medical staff and quality
  assurance unit
  - Identify who and when to perform assessments
  - Identify key areas for assessment
- Identify ways to measure the success of your training & competency
  assessment program

This presentation will cover
Three different areas
1. Assessment of Lab Personnel performing CLIA (CMS) approved tests
2. Using the 6-methods of assessment for the CT processing lab for QC tests
   - CLIA
   - Processing
3. Using similar tools to assess clinical staff for key areas in cellular therapy
CLIA Definition of Covered Tests

- If you test or examine human specimens and report patient specific results for the diagnosis, prevention or treatment of any disease or impairment, or the assessment of the health of individual patients/human beings, then the test(s) fall under CLIA regulations.

- Test system means the instructions and all of the instrumentation, equipment, reagents, and supplies needed to perform an assay or examination and generate test results.

- Given this definition, QC tests for the quality assessment of Cell Therapy Products are not covered, except:
  - The exception is sterility cultures;
  - If the reporting of a positive find may lead to the treatment of a Donor/patient;
  - PB CD34 for collection;
  - May be different if your CT products are licensed, i.e. Cords.

- This presentation is focused on the CMS document, please note your accrediting agency (AABB, Joint Commission or CAP for CLIA) may have additional/more stringent requirements.

Competency Assessment for the TC (moderate complexity) and TS (high complexity testing)?

- Responsibilities delegated in writing to the TC and TS.
- TC/TS available to provide consultation to the laboratory.
- Selects test methods that are appropriate for the laboratory's patient population.
- Assures that performance specifications are established or verified for necessary tests.
- Enrollment in an approved HHS approved proficiency testing program for each test requiring PT.
- Review of PT results.
- Ensure that a Quality Control (QC) program is in effect and is adequate for the laboratory.
- Resolves technical problems and assures remedial actions are taken.
- Ensures patient test results are not reported until all corrective actions have been taken and the test system is functioning properly.
- Identifies training needs and assures that each individual performing tests receives regular in-service training and education appropriate for the tests they are perform.

Cell Processing QC Lab at DFCI

- Our CLIA certificate is for;
  - Immunology - Peripheral blood CD34 to assess qualification for apheresis.
  - Microbiology - Sterility cultures on products.
  - Results of product sterility cultures are reported to the physicians and positive findings may lead to the treatment of a Donor patient.
  - Hematology - TNC used for a percentage method of CD34 tests.
Competency vs. Proficiency

- **Competency Assessment**
  - Confirms Lab Personnel can adequately perform laboratory duties

- **Proficiency Testing**
  - Assess the lab's ability to perform accurate and reliable testing of unknown samples

Competency Assessment

- Training and personnel evaluation is not the same as competency assessment
- Competency is application of knowledge, skills and behaviors of performance after staff has been trained
  - Six methods must be used
  - Assess testing personnel for all CLIA required lab tests performed
  - Frequency
    1. Semiannually in the first year
    2. Annually thereafter
    3. Any time a method or instrument changes prior to reporting results

6 Methods to Assess Competency (CLIA)

1. Direct observation
2. Monitoring recording and reporting of results
3. Review of intermediate test results
4. Direct observation of instrument maintenance and function checks
5. Assessment of test performance
6. Assessment of problem solving skills
Which Personnel

- Clinical Consultant (CC)*
- Technical Consultant (TC)*
- Technical Supervisor (TS)*
- General Supervisor (GS)*
- Testing personnel
- Lab Director

* In addition to the six required methods for assessments, must also assess for competency based on their federal regulatory responsibilities

Responsible Party for Performing the Assessment

- **Moderate Complexity**
  - Technical Consultant

- **High Complexity**
  - Technical Supervisor
  - Delegate in writing to a General supervisor

- Peer TP cannot be designated to perform competency assessment if they do not qualify as GS, TC, TS
- Lab Director ultimately responsible

CLIA and DFCI-CMCF

Cell Manipulation Core Facility performs high complexity testing:

<table>
<thead>
<tr>
<th>CLIA Licensed</th>
<th>Other Testing</th>
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<tbody>
<tr>
<td>ABO &amp; Rh</td>
<td>CD3+ Counts</td>
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<tr>
<td>CD34+ Counts *</td>
<td>CD35+ Counts</td>
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<tr>
<td>Cell Counts</td>
<td>CFU Assay</td>
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<tr>
<td>Sterility</td>
<td>Endotoxin</td>
</tr>
<tr>
<td></td>
<td>Trypan Viability</td>
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</tbody>
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* Testing that CMCF bills for
CURRENT PROCESS

- Six assessment methods are used annually for each person performing lab tests.
- Competency assessment on key tests.
- All staff assessed at six months and annually thereafter.
- Assessments performed by Supervisor or qualified designee from Quality Assurance or Technical Staff.
  - This has been delegated to qualified staff from the CLIA Lab Director.

How We Track Competency

- Each assessment has its own form, which gets stored in staff members training binder.
- States clear objectives and passing criteria.
- May cover more than one assessment method.
- Staff are rated from A (can train others) to D (needs more training).

How We Track Competency

- Competency Assessment Tracking Documents created each year.
- Lists all required competency assessments.
- Maintained by QA.
- Provides a quick reference to track assessment throughout the year.
On-going Evaluation & Areas for Improvement

- Ensure that all tests on CLIA license are included on annual competency.
  - Use all six assessment methods for each test and method were applicable (CD34 single vs dual platform).

- Delegation Responsibility
  - Document the delegation of responsibility from the Laboratory Director to Technical Supervisor to General Supervisors.
  - All current QC Staff meet the requirement of a GS

- Timetable -
  - Clarify the timing for semi-annual competency assessment during first year of employment.
  - (Within 3-6 months and before end of first year)

References

1. What Do I Need to Do to Assess Personnel Competency?, CMS, November 2012
2. Current CLIA Regulations
3. FDA Searchable web site for test complexity
   http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm

Personnel Regulations

- 21 CFR 1271.170 Personnel.
  (a) General. You must have personnel sufficient to ensure compliance with the requirements of this part.
  (b) Competent performance of functions. You must have personnel with the necessary education, experience, and training to ensure competent performance of their assigned functions. Personnel must perform only those activities for which they are qualified and authorized.
  (c) Training. You must train all personnel, and retain as necessary, to perform their assigned responsibilities adequately.

- 21 CFR 211 Subpart B
- 21 CFR 600 Subpart B
- 21 CFR 820 Subpart B
Definition of Competence

- Technical Competence:
  - Detecting errors
  - Following procedures
  - Troubleshooting
  - Not making mistakes
  - Motor skills

- Productive
  - Professionalism
  - Fiduciary competence
  - Moral and ethical standards

Competency Levels

- Initial Training
  - Learning-dependent
  - Requires direct supervision

- Trained
  - Qualified for specific tasks, processes
  - Can work independently in those areas

- Skilled level assessments
  - Management skills
  - Interaction with external groups
  - Regulatory / Compliance

- Expert level
  - Technical Assessment
  - Management
  - Operational strategies

Competency Evaluation Methods

- Review of
  - Test results or worksheets
  - Quality control records
  - Proficiency testing results
  - Preventive maintenance records
  - Deviations, omissions
  - Poor product outcomes
  - Product release criteria not met

- Direct observation of
  - Instrument set up, use, & PMs
  - Testing
  - Product processing
  - Testing - Blind samples

- Didactic
  - Lecture
  - Written assessments
    - Recall
    - Problem solving skills
Competency Assessment For All

- Lab Personnel including Lab Director
- Nursing or other health care provider
- Physicians
- Contract Personnel
- Volunteers

How Much is Enough?

- How should Competencies be assessed and Skills maintained?
- Are “Skilled” or “Expert” staff members exempt?
  - “They have been doing this since the beginning of time”
- New vs. seasoned employees
  - “See one, do one, teach one”
  - Does this equate competence?
- “I have read and understood the following SOP”
  - Is Knowledge Transfer implied
  - What about actual performance?

Areas for Training

- Technical
- Safety
- Regulatory
- Management
- Customer service
- Diversity
- Computer
- On-going
Areas for Training

- Technical
- Safety
- Regulatory
- Management
- Customer service
- Diversity
- Computer
- On-going

What about assessment for competency?

When to Re-Assess

- Deviation trending
- Frequency of performing the task
- Task complexity level
- New process or protocol

Competency Assessment

- On-going
- Risk and complexity based
- More than a record of attending a training session, reading an SOP, or witnessing process being performed
- Direct observation
- Test runs
- Didactic
Aseptic Processing Skill and Knowledge Assessment

- Aseptic facility design principles
- Proper way to work within an ISO 5 hood
- Personnel training and media fill challenge testing
- Equipment and facility cleaning assessment
- Environmental monitoring findings
- Monitoring product contamination
- Personnel monitoring
- Direct observation
- Use of PPE
- Work practices
- Personnel monitoring

Aseptic Techniques - Media Fills

- Media fills should simulate actual procedures
  - Challenge the process
  - Frequency of assessing
  - Define acceptable results
  - Document assessment
- Simulate open processes such as:
  - Ficolling or cell expansion process
    - Use Soy Casein throughout the process
    - Take three sterile samples at each critical step
    - Incubate samples @ RT for 7 days, then 7 days @ 30 – 35 °C

Mix of Methods to Assess Skills and Knowledge

- Review of Work
- Direct observation
- Unknown samples (PT, blind samples, etc)
- Educational Programs and Testing
  - Quizzes to assess understanding
Subjective Testing and Assessment

- **Flow cytometry**
  - Non-routine markers
  - Reliance on cell lines and cell development stage for positive controls
  - Changing gates could change counts
    Does the product still meet release criteria?

- **Assessment of Cell Cultures**
  - Non-hematopoietic
  - Malignant
Changing the Bead Gate

Physician Order ≥2.0 *10^6 CD34+/Kg

<table>
<thead>
<tr>
<th>Initial Analysis</th>
<th>Corrected Product</th>
</tr>
</thead>
<tbody>
<tr>
<td>CD34 Count</td>
<td>CD34 Count</td>
</tr>
<tr>
<td>Passed Criteria</td>
<td>Need to Recollect Donor</td>
</tr>
<tr>
<td>≥2.0 *10^6 CD34+</td>
<td></td>
</tr>
</tbody>
</table>

Corrected Product CD34 Count

Need to Recollect Donor

CD34+

Neg

Control

Dilution

CD34+/ul

ul/ml to

cells/ml

Product

Volume

Pt wt/Kg

Cal

Factors

1000

50

43

116

1

15

1725

1.73E+06

8.63E+07

2.01E+06

109

1

15

1620

1.62E+06

8.10E+07

1.88E+06

Physician Order

≥2.0 *10^6 CD34+/Kg

Pack As Much As Possible Into Each Assessment

Manual Cell Counts

- Pipetting accuracy
- Proper use of hemocytometer and counting of cells
- Dilutions
- Calculations
- Cell Identification

Areas of Risk

- Pipetting skills are the least controlled process in the laboratory
- Inaccurate pipetting can affect:
  - multiple tests
  - leads to inaccurate data generation
  - incorrect cell counts
  - Expensive QC issues
  - Poor PT performance - CUA status
  - Release of non-conforming products
- Other factors - Environment and Sample Types
- Ergonomics - Risk to employee injuries
- Assessment of what pipette to use
1.1.1 Executive Management

Each facility shall define executive management. Executive management shall have responsibility and authority for the facility's operations, for appointing a quality representative, for performing management reviews, and for compliance with these CT Standards and applicable laws and regulations. Executive management shall have the authority to establish or make changes to the facility's quality and operational policies, processes, and procedures.
“...qualified by training and/or experience and relevant continuing education in activities performed by the facility as required by these CT Standards.”

1.1.2.1 Laboratory Medical Director
1.1.2.2 Laboratory Director
1.1.3.2 Clinical Program Director

... qualified by training and experience to direct the medical / technical / clinical aspects for the provision of cellular therapy products and services.

Review the documentation that these individuals are qualified by training and experience to direct the medical / technical / clinical aspects for the provision of cellular therapy products and services.

Review the documentation of the relevant continuing education of .......

When AABB is the facility’s CLIA provider:

Verify that the Medical Director is the CLIA-qualified laboratory director of record. If not, verify that the CLIA-qualified laboratory director of record meets CLIA requirements for qualifications (42 CFR 493.1251(d)).

* Standards for Cellular Therapy Services, AABB 6th ed

C 2.2.2 Training*

The facility shall establish and maintain policies, processes, and procedures for identifying job-specific or quality-systems-related training needs and providing for the training of all personnel who perform activities that affect product or service quality. The facility shall define the qualifications required for trainers.

Do you have job descriptions for non laboratory staff involved in critical operations of cellular therapy?
What credentials or past training are required?
Are critical and unique requirements defined?
Successful non contaminated BM collections
Working knowledge of 1271 subpart D
Do:
Are all of CRBs in relevant areas required or even addressed?
HIA
Donor assessments
GVHD
Is there an On-Boarding Training program for Clinicians?
How to document in the eMR
How to order chemotherapy?
How to order a CT product
How to report an adverse event?
Is training documented?
How is it competency assessed or reassessed?
How is retraining handled?

C 2.2.3 Competence

2.2.3.1 Action shall be taken when competence has not been demonstrated. NEW*

Evaluations of competence shall be performed before independent performance of assigned activities and annually thereafter for defined tasks and activities* 42 CFR 493.1451(b)(8).

Time points:
- Initial, six months, and annually thereafter
- When initial assessment of competence is repeated (biennial requirement)
- When initial assessment of competence is repeated (unspecified requirement for unlisted tasks)

Six Methods to Assess Competency:
- Direct observation of routine patient test performance (preanalytic, analytic, postanalytic)
- Monitoring the recording and reporting of test results
- Record review
- Review of immunofluorescence test results or worksheets, quality control, proficiency testing, and preventive maintenance
- Direct observation of performance of instrument maintenance and function check
- Calibration
- Assessment of test performance through testing previously analyzed specimens, internal blind testing, samples
- Assessment of problem solving skills conducted?
2.2.3 Competence

2.2.3.1 Action shall be taken when competence has not been demonstrated. NEW

Clinical Assessments:
- Direct observations (Audit)
- Collection
- Assessment of Donor
- Review and Monitoring records for completeness and accuracy
- Donor eligibility
- Notes / documentation in the medical record
- Assessment of understanding:
  - Quiz
  - Direct questions
  - Presentations
  - Data at quality meetings
  - Professional meetings

Refresher training
- One on one review
- Continuing education
- CME on relevant topics
- Peer Meetings (case reviews, presentation, literature review) *
- On-line presentation*
- New or revised procedures / policies*
- *followed by quiz or return of understanding

Bone Marrow Contamination

Contamination Rate by Harvester

Why do this?
- Standards and regulation
- Enhance the quality of the program by increasing the knowledge of staff and helping them integrate requirements, methods, etc. consistently into their practice
- Gain buy-in to the standards / regulations by executive management and clinical staff
- Reduce non-conformances, complaints and BPD
- Enhance staff satisfaction
C 2.2.4 Continuing Education

- Requirements for relevant continuing education in activities performed by the facility as required by these CT Standards shall be defined for and met by all relevant employees.

- Training beyond the Technical Staff in the laboratory:
  - Technical, Clinical, Quality, and Trainers activities
  - Donor medical suitability and eligibility
  - Administration of CT products
  - Non-conforming, Ineligible, Novel

- Assessment and review of outcomes
  - Assessment and review of Adverse Events

- Relevant Employees:
  - Screening personnel (Donor and patient coordinators, RN/PA/NP, lab assistants, etc.)
  - Collection personnel (MT, MD, RN/PA/NP, lab assistants, Phlebotomists,)
  - Laboratory personnel
  - Laboratory supervisors and administrators
  - Clinical personnel (MD (Directors, fellows, house staff), NP, RN, PA)

Conclusions

- Competency assessment of staff can be managed and documented successfully
- Not just for laboratory staff
- Broaden the scope to the clinical staff
- Make assessments part of the CT programs practice
- Wherever possible take advantage of electronic systems and routine audits