
Information System Needs of Hospital Based Cell Processing Facility

Cell Therapy Liaison Meeting
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History of Cell Manipulation Core Facility @ Dana-Farber Cancer Institute

- n 1996 - Established as DFCI Core
 - q Located in DFCI
 - q Consolidated all clinical cell processing into a single facility
 - q Supported DFCI, BWH and Children's Hospital
- n 2000 - Established as Core Facility for Dana-Farber/Harvard Cancer Center
 - q Support clinical research at all DF/HCC clinical sites



Dana-Farber Cancer Institute



Brigham and Women's Hospital



Children's Hospital Boston



Beth Israel Deaconess Medical Center



Massachusetts General Hospital

Research and Academic Key Interactions

- n Joint Program in Transfusion Medicine
 - q DFCI, BWH and Children's Hospital Blood Banks
 - q Transfusion Medicine Training Program includes MGH and BIDMC
 - n Center for Human Cell Therapy
 - q Support for clinical translation and IND applications for Harvard affiliated investigators
 - n Harvard Stem Cell Institute
 - q Supports development of therapeutic applications of stem cells for various diseases and tissue repair
 - n DFCI Cancer Vaccine Center
 - q Supports development and testing of novel immune therapies for cancer
 - q Development of cellular vaccines
 - q Development of adoptive cell therapies
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Process Volume/Product Type

n Volume

- q Currently supports ~25-30 DF/HCC clinical trials
- q Process ~1200 - 1500 products/year

n Product Types

- q Both PHS Act Section 351 and 361 products
 - n Hematopoietic Progenitor Cells
 - q FACT accredited laboratory for adult and pediatric stem cell transplant programs at Children's, BWH and DFCI
 - n Tumor/Dendritic Cell Vaccines
 - n Adoptive Immunotherapy
 - q 50% of clinical trials are conducted under IDE/IND (Phase I)
 - n Investigator initiated
 - n Company sponsored
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Regulatory Environment

- n FDA
 - q Investigational uses of cells and devices
 - q cGMP Regulations as of May 25, 2005
 - n FACT
 - q Accreditation of cell processing for both adult and pediatric stem cell transplant programs
 - n Joint Commission
 - n DF/HCC Institutional Review Board
 - n Department of Public Health
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CMCF IS Challenges

- n Academic hospital based cell manufacture site that
 - q Is a clean room facility (paperless?)
 - q Needs appropriate documentation to comply with multiple regulatory requirements for
 - n Product safety
 - n Patient safety
 - q Produces multiple types of cellular products
 - n Simple and complex
 - n Genetically modified- viral and non-viral
 - q Supports numerous clinical studies with different data capture formats
 - q Provide data for IND annual reports
 - q Interact with multiple off-site clients
 - n Collection
 - n Infusion
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CMCF Current Operations

- n Computer System
 - q MISYS (Sunquest)
 - n Blood Bank Laboratory System
 - n Product Inventory
 - n Cell dose data (hematopoietic progenitor cells-related and cryopreserved)
 - n Disposition
 - n Manual Documentation/MS Excel and Access/Filemaker database
 - q Physician order for processing and infusion
 - q cGTP documentation and checklist
 - q cGMP information
 - n Manufacture (procedure, data, equipment, cleaning)
 - n Material and reagent inventory
 - n Environmental
 - n QC test results
 - q Billing
 - q Scheduling
 - q Deviations
 - q Infusion related adverse events
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Current Interactions with other Information Systems

n Clinical Care

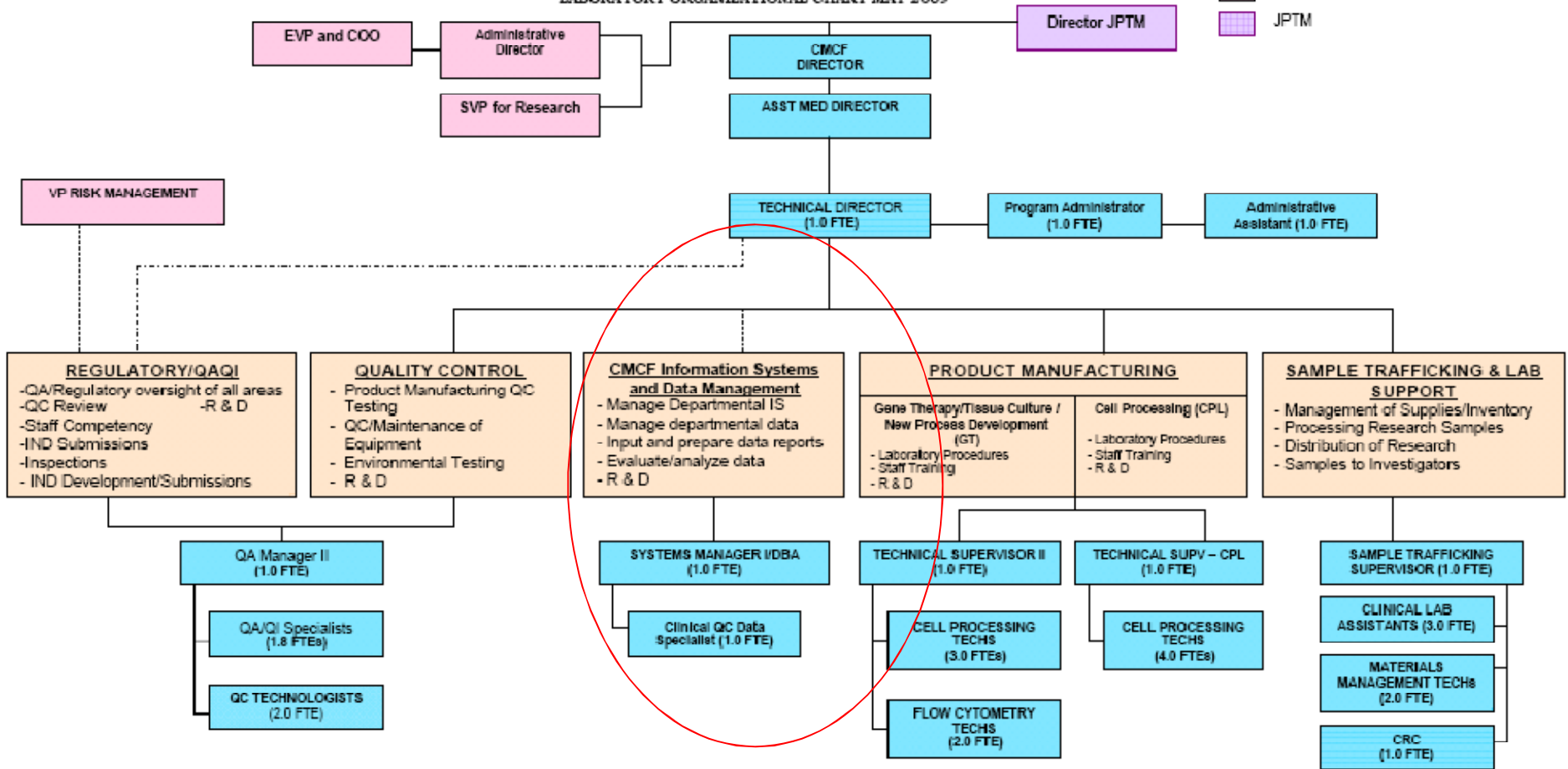
- q Chemotherapy Order Entry (COE)
- q Hospital Long-term Medical Record

n Clinical Research

- q QACT (Quality Assurance for Clinical Trials)
 - n Documentation of patient consent and enrollment to clinical studies
 - q Link to Outcome data
 - n DFCI Electronic Data Capture (eDC)
 - q Allo and Auto BMT treatment plans, IND and non-IND protocols
 - q Provide QA data for transplant service (FACT accreditation)
 - q Provide manufacture data for IND annual reports
 - n CIBMTR
 - q Allo BMT product data
 - n Company sponsored clinical protocols
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CELL MANIPULATION CORE FACILITY
LABORATORY ORGANIZATIONAL CHART MAY 2009

- CMCF LABORATORY STAFF
- DFCI ADMINISTRATION
- JPTM



New CMCF IS Projects

- n Electronic Physician Order
 - q Biotherapy Order Entry (BOE) System
 - n Manufacturing Execution System
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Biotherapy Order Entry - BOE

- n For DFCI/BWH/MGH (Partners) patients only
 - n Partners IS build and maintenance
 - n Replace written physician orders
 - q Cell Collection
 - q Cell Processing
 - q Product release and administration
 - n Link to QACT- Clinical protocol registration
 - n Develop computerized templates for cellular products dispensed from CMCF
 - n Develop templates for all cellular therapy treatment regimens and clinical trials
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Manufacturing Execution System (MES)

- n Build and support by outside vendors
 - n Requirements
 - q Computerized manufacturing record for all cell manufacturing procedures
 - q Computerized inventory with bar-coding of all approved reagents and manufacturing components
 - q Perform calculations
 - q Electronic tracking of reagents, equipments, and products
 - q Link clinical information to products
 - q Interface with laboratory instruments
 - q Interface with other hospital information systems
 - q Web-based ordering system (Outside of Partners)
 - q Meet and integrate ISBT Label requirements
 - q Future 510K licensing
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CMCF MES Project Timeline

- n 2003- Purchased 1st system but unable to validate due to data lost and stability issues
 - n 2005- Initiate new search for MES system
 - q Obtain consultant
 - q Writing systems requirement for Request for Proposal (RFP)
 - q Evaluation of RFP and interview vendors
 - q Contract negotiation
 - n 2007- Selected Vendor/signed contract
 - q MES used in Pharmaceutical industry
 - q System to document “complex” manufacturing procedures
 - n July 2009- System delivered but awaiting “Sandbox” testing
 - q Potential renegotiation
 - q Consider another vendor (based on blood banking IS)
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MES Projects Obstacles

- n Blood Banking based vs. Pharmaceutical manufacture systems
 - q Blood Bank based system
 - n Good product inventory but not source material inventory
 - n Excellent audit history tracking
 - n Limited and rigid template builder
 - n Ready for new ISBT label
 - q Pharmaceutical system
 - n Allow flexible template building
 - n Excellent cGMP documentation for complex cell manufacturing
 - n Difficult to integrate clinical information (considered as customization)
 - q Lacking donor-recipient link/tracking/data field
 - n Batch record reports may not meeting the cell product requirements
 - n Companies are not Interest in 510K licensing
 - n Cost- \$ 1-2 million (include implementation)
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Summary

- n There is an urgent need for computerization in cell processing laboratories to ensure product quality and patient safety.
 - n Integration of necessary clinical information in cell manufacture system is the major obstacle.
 - n Development of cell manufacture Information System is complex and its investment is expensive.
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