DACUM Research Chart for Product Changeover Process

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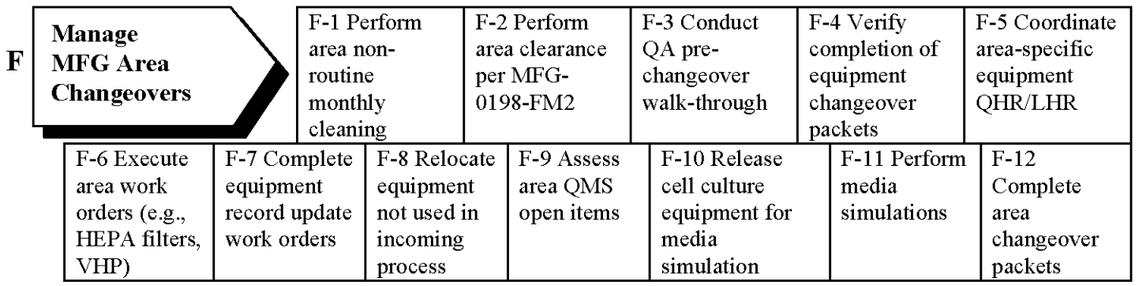
Duties	Tasks											
A Maintain Changeover Process Documents	A-1 Assess MFG-0198 (Area Clearance) for revision	A-2 Assess MFG-0267 (Equipment Changeover) for revision	A-3 Assess QA-0260 (Area Changeover) for revision	A-4 Assess TMS-0017 (Equipment Cleaning) for revision	A-5 Assess TMR-0057 (Environmental Monitoring) for revision	A-6 Assess MFG-0242 (Equipment Return to Service) for revision	A-7 Assess QC-0261 (EM Alert/Action) for revision	A-8 Assess MFG-0100 (Gowning) for revision	A-9 Assess MFG-0101 (Personnel Flow) for revision	A-10 Assess MFG-0102 (Material Flow) for revision	A-11 Assess MFG-0103 (Equipment Flow) for revision	A-12 Assess MFG-0104 (Equipment Status Tags) for revision
	A-13 Assess MFG-0105 (MFG Facility Cleaning) for revision	A-14 Assess QA-0102 (QHR/LHR) for revision	A-15 Assess MFG-0110 (Labeling of In Process MTLS) for revision	A-16 Assess MFG-0270 (Simultaneous Processing) for revision	A-17 Assess FAC-0028 (Maintenance Program) for revision	A-18 Assess FAC-0004 (Calibration Program) for revision	A-19 Assess FAC-0093 (Plant QC Alarms) for revision	A-20 Assess Validation master plan for revision	A-21 Assess MBR's for revision	A-22 Assess campaign limit technical report for revision	A-23 Assess LOG-0006 (SAP Material Master) for revision	A-24 Assess LOG-0007 (SAP Process Orders) for revision
	A-25 Assess QA-0271 (Approved Vendors) for revision	A-26 Assess QC-0209 (EM Program) for revision	A-27 Revise Material Allocation Forms	A-28 Assess Engineering Turnover Packages (ETOPS)								
B Participate in Changeover Training Activities	B-1 Identify content SMEs	B-2 Participate in changeover process analysis workshop	B-3 Prioritize changeover tasks to be analyzed	B-4 Participate in changeover task analysis process	B-5 Participate in changeover training needs analysis	B-6 Develop area-specific changeover training curricula	B-7 Develop area-specific changeover overviews	B-8 Develop changeover training materials (e.g., videos, job aids,	B-9 Develop changeover tests/quizzes	B-10 Develop task-specific changeover OJTs	B-11 Identify SME-Trainers	B-12 Qualify SME-Trainers
	B-13 Complete web-based changeover training (by individuals)	B-14 Provide classroom changeover training	B-15 Complete classroom changeover training (by individuals)	B-16 Provide OJT changeover training	B-17 Complete OJT changeover training (by individuals)	B-18 Develop changeover product process overview presentation						
C Manage Changeover Supply Requirements	C-1 Assess process documents for supply needs	C-2 Evaluate QC sampling load for adequate supplies	C-3 Create list of new supply items (e.g., resins, membranes, consumables)	C-4 Qualify new vendors/ products	C-5 Update approved vendor list	C-6 Update SAP with new items	C-7 Develop bill of materials	C-8 Order product-specific maintainable parts (e.g., hoses, elastomers)	C-9 Order changeover-specific consumable parts (e.g., elastomers, product contact diaphragms)	C-10 Order general use consumables (e.g., pipette tips, conical tubes)	C-11 Order new raw materials	C-12 Conduct inventory of changeover supplies
D Manage Equipment Changeovers	D-1 Assess process documents for equipment needs	D-2 Perform post campaign equipment cleaning	D-3 Collect product clearance rinsate samples	D-4 Collect post visual inspection swab samples	D-5 Establish equipment changeover schedule	D-6 Participate in daily return to service meetings	D-7 Assess all open QMS items (e.g., CAPA, CC WO)	D-8 Perform equipment specific QHR/LHR	D-9 Perform equipment calibrations (e.g., exit, as found, annual)	D-10 Perform annual equipment PM	D-11 Perform PM on COP valves	D-12 Install new equipment
	D-13 Validate new equipment	D-14 Dedicate product specific equipment	D-15 Verify equipment automation	D-16 Perform equipment return to service	D-17 Release equipment from QHR/LHR	D-18 Complete equipment changeover packets						
E Manage Changeover Sampling and QC Testing	E-1 Assess EM sampling plan	E-2 Assess product process sampling plan	E-3 Assess validation sampling protocols	E-4 Assess QC test methods for changes	E-5 Qualify QC test methods	E-6 Revise QC test methods	E-7 Order QC supplies and reagents	E-8 Coordinate staffing needs with sampling plan (e.g., QC, validation,	E-9 Prepare validation sampling packets	E-10 Collect samples (e.g., validation, EM, cleaning verification)	E-11 Process samples (e.g., validation, EM, cleaning verification)	E-12 Provide QC test results for daily return to service

This analysis was completed to document the tasks involved by various stakeholders to the product changeover process. The purpose for doing it was to identify the foundation for the training curricula that will need to be developed to train Alexion employees in the changeover process.



Document Number	Document Title
FAC01-TR05	Campaign Limit Technical Report
FAC-0004	Calibration Program
FAC-0028	Facilities Maintenance Program
FAC-0093	Plant Control System Alarm Response Procedure
LOG-0006	SAP Material Master Maintenance
LOG-0007	SAP Production Process Orders
MFG-0100	Gowning Procedure for Manufacturing Areas
MFG-0101	Personnel Movement
MFG-0102	Material and Waste Movement
MFG-0103	Equipment Flow
MFG-0104	Equipment Status Tags
MFG-0105	Cleaning Procedure for the Manufacturing Facility at ARIMF
MFG-0110	Labeling of In-process Materials
MFG-0198	Area Clearance
MFG-0242	Pre-Campaign Equipment Start-Up and Return to Service Procedure
MFG-0267	Change-Over Procedure for Commercial Manufacturing Process Equipment at ARIMF
MFG-0270	Simultaneous Processing in Commercial Manufacturing
QA-0102	Quarantine / Limited Use, Hold and Release Procedure
QA-0260	Product Change-Over Procedure for Commercial Manufacturing Rooms
QA-0271	Approved Vendor List
QC-0209	Environmental Monitoring Program
QC-0261	Alert and Action Levels for Clean Rooms at ARIMF
TMR-0057	Environmental Monitoring Sampling and Frequency
TMS-0017	Visual Inspection of Cleaned Equipment and Sampling of Equipment for Cleaning Verification
VMP-01	Validation Master Plan for the Rhode Island Manufacturing Facility

Acronyms

LSO Learning Solution (SAP)
MBR Master Batch Record
MFG Manufacturing
OJT On-the-Job-Training
PM Preventative Maintenance
QA Quality Assurance
QC Quality Control
QMS Quality Management System
QHR Quarantine/Hold and Release
SAP Systems Application and Products in Data Processing
SME Subject Matter Expert
VAL Validation
VHP Vaporized Hydrogen Peroxide
WO Work Order

General Knowledge and Skills

Knowledge of:
Instrumentation
Science-based approach
Validated systems
Changeover requirements
GMP fundamentals
GDP fundamentals
Microbial awareness
Safety practices
SAP
Process fundamentals
Root cause analysis

Skills:
Critical thinking
Investigation
Math
Computer
Training
Communication
Analytical
Troubleshooting
Organizational

Work Behaviors

Accountable
Accurate
Active listener
Calm
Complaint
Compliant
Deadline-oriented
Deliberate
Detail-oriented
Ethical
Flexible
Forward thinking
Honest
Multitasking
Open-minded
Organized
Patient
Prepared
Reliable
Responsible
Safety-oriented
Self-motivated
Team player
Technically oriented
Thorough
Willing to learn

Tools/Equipment/Supplies/Materials

PPE
cGMP documents
Software:
- Trackwise
- NextDocs
- MODA
- LSO
- Darwin
- SAP
- HMI
- INFOR

Cleaning supplies
Torque wrenches
Basic hand tools
Sampling supplies
Process monitoring equipment
Clean out of place (COP) equipment
Testing supplies
Gowning supplies
Raw materials
Purification columns
Fixed equipment (bioreactor, Biosafety Cabinet (BSC), Laminar Flow Hood (LFH), skids)
Personal computer
iPad
Labeling supplies
In-process materials
Consumables

Future Trends and Concerns

Changing regulatory expectations
Migrating to single-use equipment
Limited physical plant space
Update of electronic systems
Equipment life cycle
Product inventory
Patient demand
Supply chain constraints
Staff turnover
Tribal knowledge
Employee training
24/7 staffing scheduling
Clean in Place (CIP) capacity
Ineffective communication
Need for OJT trainer qualification program

Acronyms

BSC Biosafety Cabinet
CAPA Corrective Action/Preventative Action
CC Change Control
CGMP Current Good Manufacturing Practices
CIP Clean-in-Place
COP Clean-Out-of-Place
EM Environmental Monitoring
FAC Facilities
FM Form
GDP Good Documentation Practices
HEPA High-Efficiency Particulate Absorption
HMI Human Machine Interface
LFH Laminar Flow Hood
LHR Limited Use/Hold and Release
LOG Logistics