Modular Documentation System for Fermentation and Mammalian Process

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FUJIFILM Diosynth biotechnologies

Introduction

- Fujifilm did not have a single template for most documents
  - Used excel sheets
  - Adjusted documents each time for specific process or formulation
- Caused employees to allot more time to adjust documents needed prior to use
- Needed development of a system which allowed for a testing environment for scale-down of fermentation and cell culture processes
  - Enabled direct tech transfer and installment of new equipment

Goals

- Create a modular documentation system
- Streamline shakedown processing
- Improve current documentation to increase simplicity and functionality
  - Expand application across multiple processes without making fundamental changes to the document components
- Save company time, money, and other resources in process runs due to consistency between documents
- Ensure the compliance regulations are upheld where needed

Impact

- **Company/Economics:**
  - Efficiency with modular documentation and being able to streamline processes save time
  - Creating more generic documents that can be easily adapted to specific processes, results in higher potential to decrease batch runs and perform GMP runs without executing engineering runs to test a new capability of the production system
  - Gaining a competitive advantage will also create a significant impact by being able to implement modern documentation to processes as opposed to other companies in the industry
- **Societal Benefits:**
  - The modular documentation processes facilitate quicker development and production of biopharmaceuticals for patients in need

Deliverables

Section I: Consumable Materials

Instructions: Check the consumables needed to perform the Unit Operation

Adapters

☐ 1/2" TC to Quick Connect Body 6" long, Disposable Adaptors (Sterile)	☐ 1/2" TC to Quick Connect Insert 6" long, Disposable Adaptors (Sterile)	☐ 3/4" TC to Quick Connect Body 6" long, Disposable Adaptors (Sterile)	☐ 3/4" TC to Quick Connect Insert 3' Long, Disposable Adaptors (Sterile)
☐ 3/4" TC to Quick Connect Insert 6" Long, Disposable Adaptors (Sterile)	☐ AQS X Swabable Valve Assembly - Sterile	☐ Female Luer Adapter X, Tri Clamp Adapter; Jumper #47	☐ Female Luer Adapter X, Tri Clamp Adapter; Jumper #47
☐	☐	☐	☐
Name	**Catalog Number**	**Vendor**	**Volume Needed**

- Bags/Culture Bags and Plates
- Bottles
- Equipment
- Filters
- Flasks
- In-line
- Jumper
- Sampling
- Tubing
- Vials/Tubes

Downstream Bill of Materials: Consumables Section

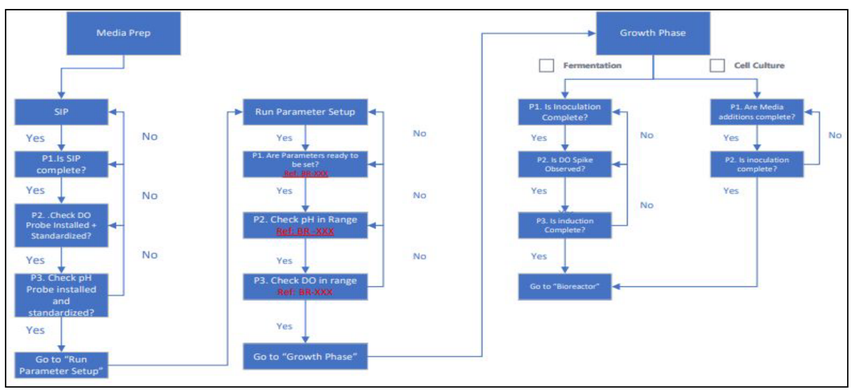
STEP #	OPERATION DESCRIPTION/DATA	PERFORMED BY DATE	VERIFIED BY DATE
4.11	**PURIFICATION**		
	NOTE: Refer to RDD_XXX for purification steps. Specify order of purification. Step 1: ☐Centrifugation ☐Viral Filtration ☐Depth Filtration Step 2: ☐Centrifugation ☐Viral Filtration ☐Depth Filtration Step 3: ☐Centrifugation ☐Viral Filtration ☐N/A Step 4: ☐Centrifugation ☐Viral Filtration ☐N/A Step 5: ☐Centrifugation ☐Viral Filtration ☐N/A		
	CENTRIFUGATION N/A ☐		
4.11.1	Record Centrifuge ID number: _____ Confirm validation of equipment ☐		
4.11.2	Confirm centrifuge has been set up properly according to SOP_XXX.		
4.11.3	Start up centrifuge per SOP_XXX.		
4.11.4	Ensure process conditions are set according to RDD_XXX and/or PFD_XXX.		
4.11.5	Record number of centrifuge cycles run:_____ Record RPMs for centrifuge operation:_____ Record duration _____hr_____minutes		

Mammalian Batch Record: Purification Section

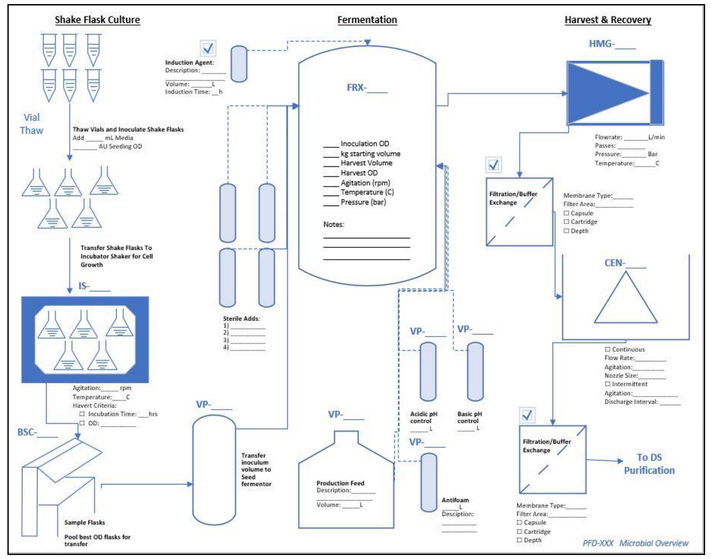
2.0 SAMPLING INSTRUCTIONS

Collection Vessel	5 mL Cryo Vial	
Sampling Procedure	Standard ☐ Reference: SOP-_____	Custom ☐
Sterile Collection ☐ Yes ☐ No		
Custom Procedure ☐ N/A		
Step	**Instruction**	
Ex. 4.1.2	Take 5 additional samples here to track OD	

Sample Plan



Recipe Design Description



Process Flow Diagram

Recommendations

- **Corporate Integration**
  - Validate and integrate these documents into shakedown runs
  - Apply documentation to show vendors site and process capabilities
  - Assess potential commercialization options for modular documentation systems
- **Documentation**
  - Integrate vendor and catalog information to autofill in the BOM

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