

Faster Tech Transfers Through Seamless Digital Transformation

Bob Lenich, PKM Business Director, Emerson Life Sciences



Agenda

The Recipe Specification Management Opportunity

Digitalization in Recipe Parameter Management and Integration

Industry Standard Library

Roche Case Study, Beyond Execution—Data Accessibility

Digitalization in Recipe Parameter Management

General Recipe

- Specifies processing activity & recipe parameters for multiple manufacturing sites
- Excel or Word files
- NOT Part 11, Anex 11, or ALCOA+
- “Paper Document” Approvals

Very Difficult to standardize and re-use previous work



High Effort

Site Recipe

- Specifies processing activity & recipe parameters) for a specific site
- Excel or Word files
- NOT Part 11, Anex 11, or ALCOA+
- “Paper Document” Approvals

Manual Typing
Very Slow



Time Lost

Master Recipe

- MES specifies electronic batch record requirements
- Manual product change process
- ALCOA+, Part 11 and Annex 11 aligned
- Individual system approvals

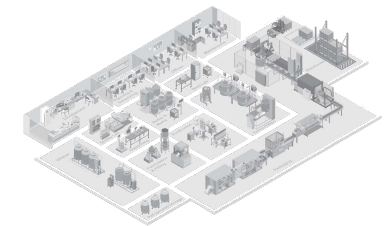
Not Flexible /
Difficult to Change



High Cost

Control Recipe

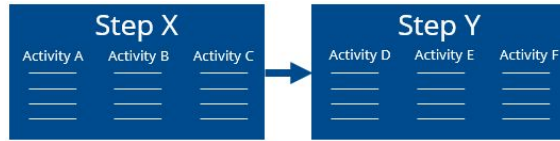
- DCS specifies equipment control requirements
- Manual product change process
- ALCOA+, Part 11 and Annex 11 aligned
- Individual system approvals



Digitalization in Recipe Parameter Management

Traditional Approach

Recipe is created from scratch without reusable components



Isolated work for different groups

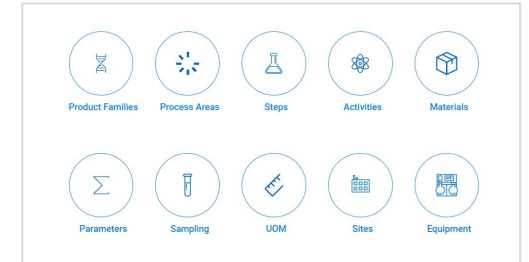


Manual Review/Approval; Physical Meetings

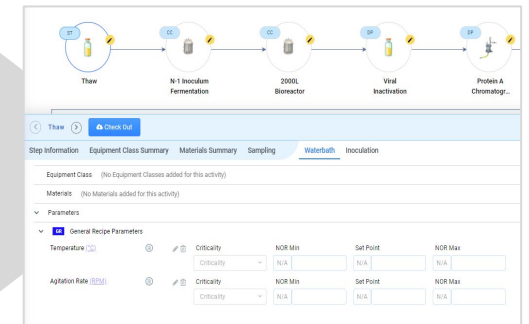


BEST Practice Approach

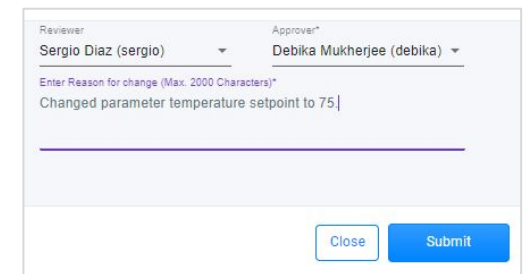
Configuration objects created using reusable components (data model based on S88 standards)



Common Digital Collaboration Platform for multiple personas



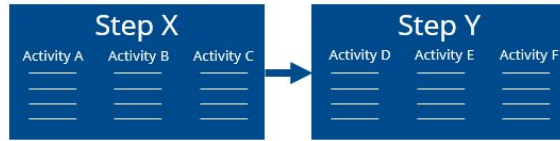
Automated Review & Approval Workflow



Digitalization in Recipe Scale-up and Integration

Traditional Approach

Individual Recipes with no Scale Up option



Separate document management system



Isolated Files / Separate Handling and Transfer



BEST Practice Approach

Scale Up Calculations

Operators

+ - * / π ln e log () If

else else if pow min max sum avg

Valid Calculation

Preview Value: 8.00 Round off: None Decimal places: 2

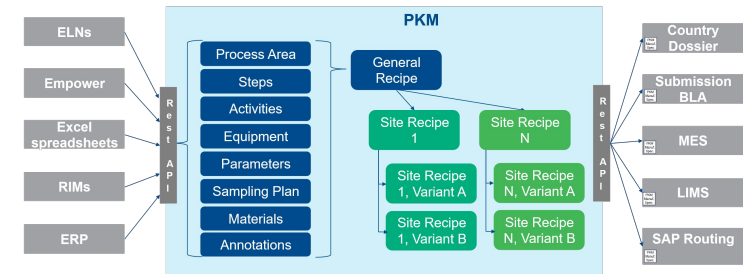
Multiplication Factor: Current UOM: Previous UOM:

1 $[[\text{Thaw.Step Information.Parameter.Moisture content.Min}]]^2$

Electronic Audit Logs & Versioning



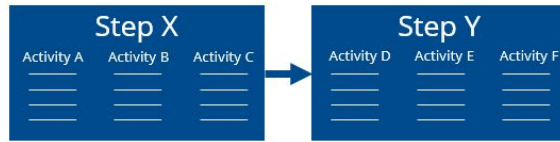
Integration with planning and executions systems



Digitalization in Parameter Risk Assessment

Traditional Approach

Risk study created from scratch without reusable components



Isolated work for different groups



Manual Review/Approval; Physical Meetings



BEST Practice Approach

Parameter Relationships created using linked recipe parameters

Process Parameter	Molecular Weight	% Moisture	Color	Conductivity	Density (g/cc)	Res
Quality Parameter Score (7 Parameter Score)	5	4	3	2	5	12
Temperature (Setpoint) (°C)	5	5	5	5	5	12
Agitation Rate (1/min)	5	5	5	5	5	16
Initial Viable Cell Density (cells/ml)	5	5	5	5	5	14
Agitation Time (min)	5	5	5	5	5	17
Initial Viable Cell Density (cells/ml)	5	5	5	5	5	14
Dissolved Oxygen (% of air saturation)	5	5	5	5	5	17
Antibiotic Addition Rate (mg/ml)	5	5	5	5	5	14
Mixing Duration (min)	5	5	5	5	5	14
Duration (hours)	5	5	5	5	5	17
pH (min)	5	5	5	5	5	14

FMEA Digital Collaboration Platform for multiple personas



Risk Name	Activity Name	Process Parameter	Failure Mode	RPN	Risk
Initial Viable Cell Density	Initial Viable Cell Density	Initial Viable Cell Density	Initial Viable Cell Density	12	12
Agitation Rate	Agitation Rate	Agitation Rate	Agitation Rate	16	16
Initial Viable Cell Density	Initial Viable Cell Density	Initial Viable Cell Density	Initial Viable Cell Density	14	14
Dissolved Oxygen	Dissolved Oxygen	Dissolved Oxygen	Dissolved Oxygen	17	17
Antibiotic Addition Rate	Antibiotic Addition Rate	Antibiotic Addition Rate	Antibiotic Addition Rate	14	14
Mixing Duration	Mixing Duration	Mixing Duration	Mixing Duration	14	14
Duration	Duration	Duration	Duration	17	17
pH	pH	pH	pH	14	14

Automated Review & Approval Workflow

Reviewer: Sergio Diaz (sergio) | Approver: Debika Mukherjee (debika)

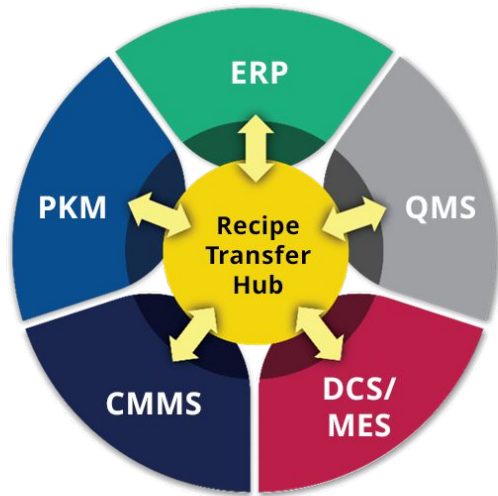
Enter Reason for change (Max. 2000 Characters)*
Changed parameter temperature setpoint to 75

Close Submit

Transfer Hub Platform

A Better Way to Handle Transforming and Connecting Execution Systems

Digital Recipe Lifecycle Management



- Integrated, digital recipe lifecycle management
- Industry standard building blocks, ontology, and integration
- Multi-phase digital deployments (development, clinical, commercial)

“Recipe” One-Click Tech Transfer Leadership

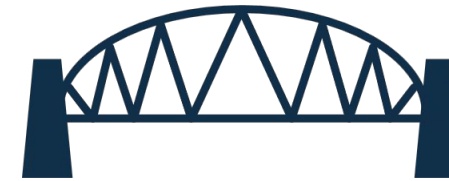


Pharmaceutical companies conduct 20-30 tech transfers per year, a typical tech transfer takes 6-24 Months



Process Science
Drug Substance/
Drug Product Recipe

Single Place for Recipe
Specification Approvals



Transfer Hub

Single Place for Execution
System Parameter
Specification Approvals



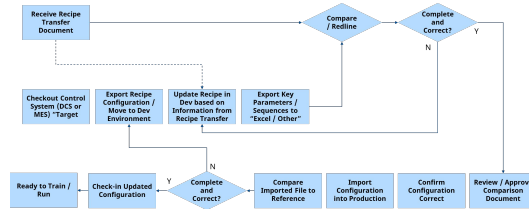
Operations
Manufacturing/
Master Recipes

Single Place for Execution
System Acceptance / Use

Digitalization in Recipe Parameter Integration with Execution Systems

Traditional Approach

Manual comparison of process specification to automation system



Isolated Files / Separate Handling and Transfer

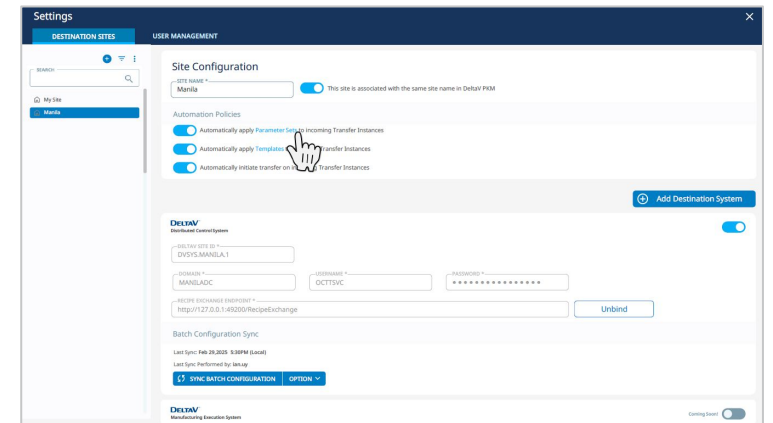


BEST Practice Approach

Digitally compare and map process and automation parameters

PARAMETER	KIND	ATTRIBUTE	VALUE	UOM	DATA TYPE	PJM.ACTIVITY	DESTINATION PATH
Antifoam Addition Flow Rate	Set Point	Criticality	15	sgpm	Single Select	Cell Recovery	
Antifoam Addition Flow Rate	Set Point	NOR Min	10	sgpm	Numeric Input	Cell Recovery	
Antifoam Addition Flow Rate	Set Point	NOR Max	15	sgpm	Numeric Input	Cell Recovery	
Mixing Duration	Set Point	NOR Min	40	rpm	Numeric Input	Cell Recovery	
Mixing Duration	Set Point	NOR Max	60	rpm	Numeric Input	Cell Recovery	
Mixing Duration	Set Point	NOR Max	80	rpm	Numeric Input	Cell Recovery	
Size	Quantity	Volume	5000	L	Numeric Input	N-1 Cell Cultur...	
Glucose	Quantity	Quantity	1	L	Numeric Input	Packing	

Integration to executions systems

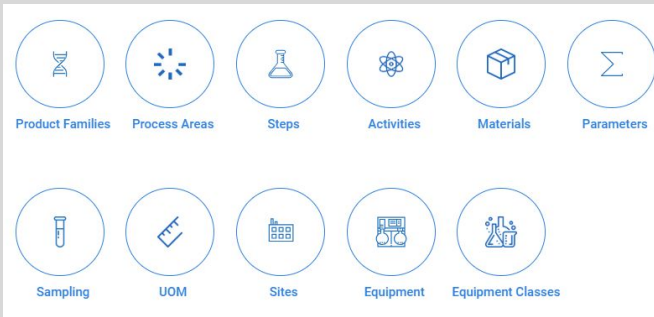


Process Knowledge Management Platform

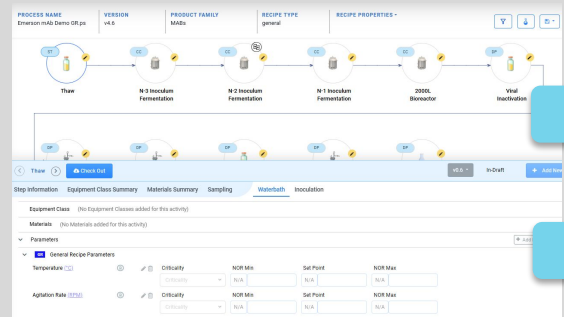
The Right Technology for an Optimized Recipe Parameter Management Work Process

Process Specification Management

Recipe Elements / Template Library



General / Site Recipe Specifications



CPPs

CQAs

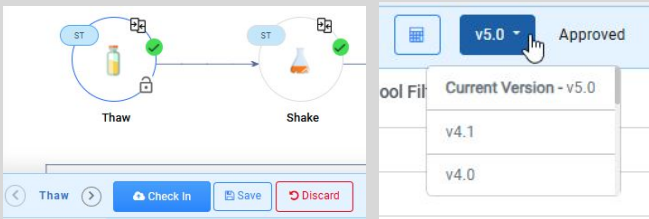
Process Risk Assessment

Cause & Effect Study

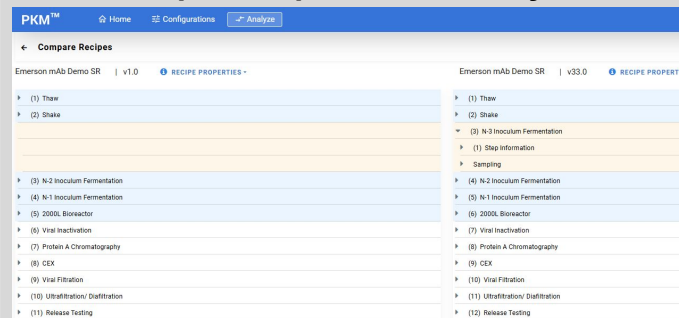
Failure Modes & Effects Study

Control Strategy Capture

Change Mgmt / Propagation / Versions



Recipe Comparison / Facility Fit



Quality Parameters

Operating Parameters

Equipment Characterization

Material ID's / Formulations

LIMS Method Characterization

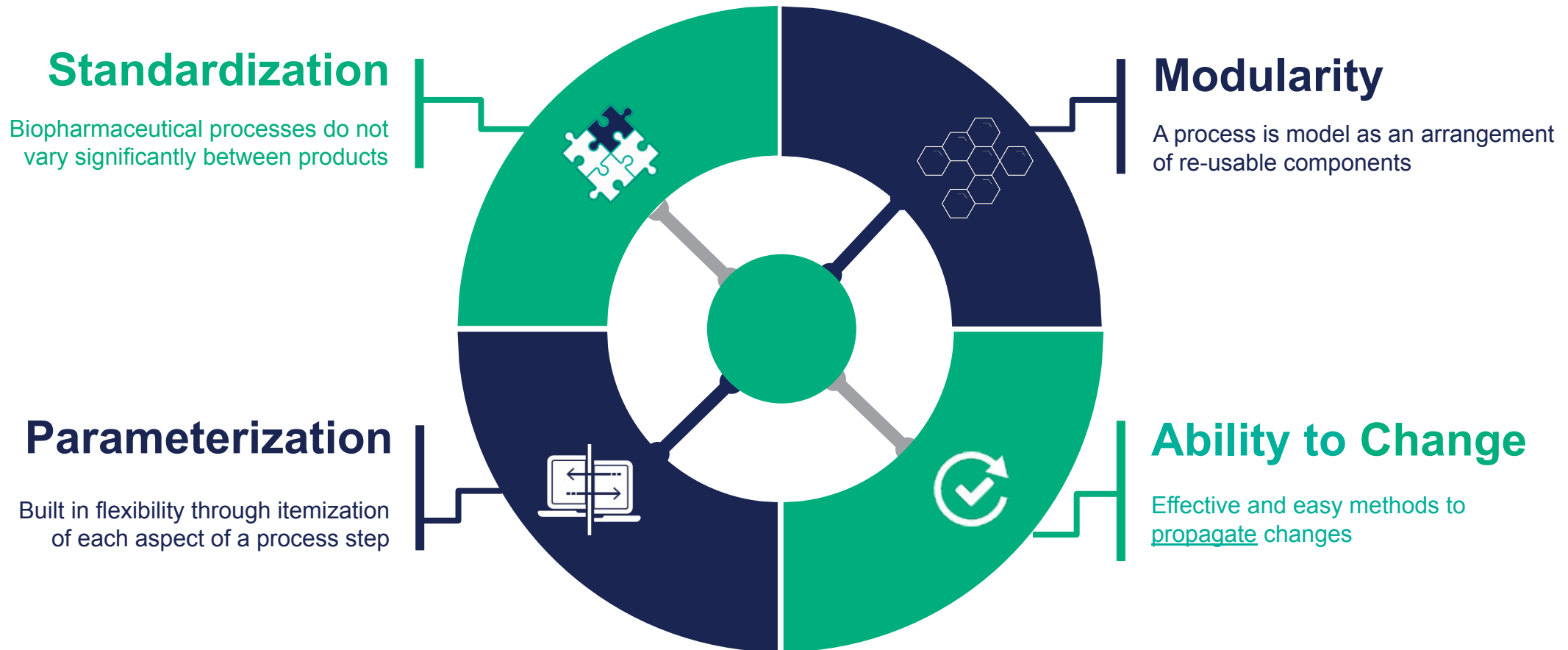
Qualified Risks to Investigate

Control Strategy Focus Areas

Recipe Transfer Management integration

Industry Standardized Library

A Better Way to Time to Value for Making Digital Transfer a Reality



Standardized Naming and Convention

- **Firm on vision, flexible on details:** Senior Leadership endorsed harmonization, technical communities of practice defined and aligned across departments
- **Term Alignment Sources:**
 - Existing international pharmaceutical standards where previously defined
 - Process knowledge and product experience of our network operations communities of practice

SNaC

Standardized Nomenclature and Conventions



~~ProteinA Chromatography~~



~~Capture Chromatography~~



Affinity Chromatography

De-concatenated Terminology Affords Modular Data Constructs

Step + Activity + Parameter + Attribute syntax creates human-readable combination of context and parameter data within the system that structurally creates unique key-values

Examples

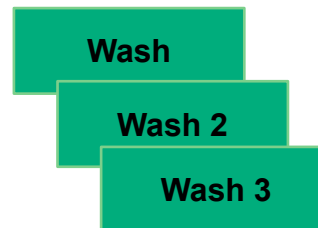


The process parameter would be used in a **Mixing** activity, thus not requiring the prefix



The user would include the Working Volume Parameter instead of the Working Volume

The user would include the Working Volume Parameter instead of the Working Volume



“Affinity Chromatography”

Wash Volume Target

100 Steps / 100 Activities / 1000 Parameters / 100 Attributes

1,000,000,000

Individual Terms without Concatenation

OR

1,300

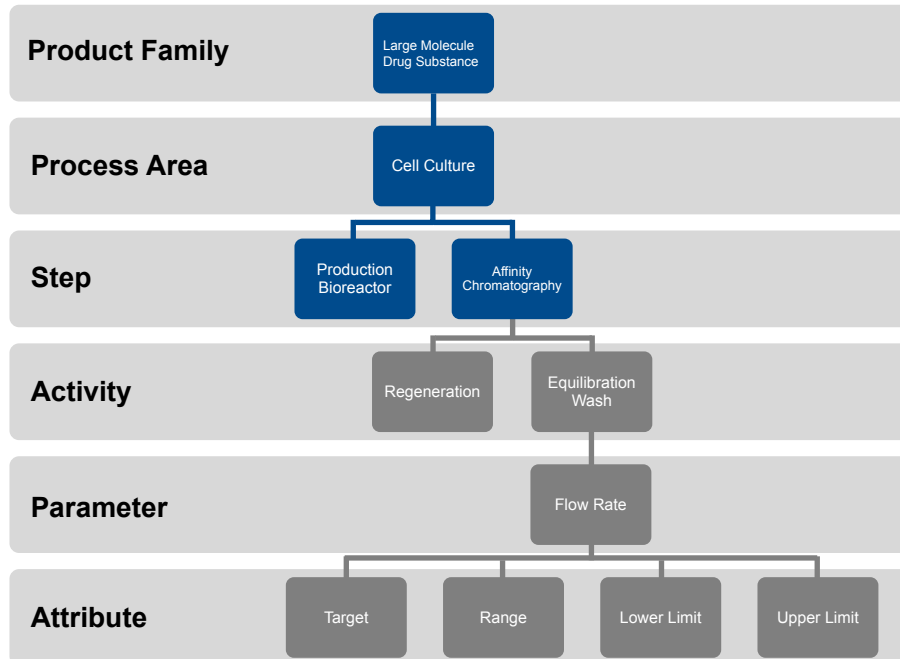
Data Objects with Concatenation

1 Millionfold Reduction in Data Objects!

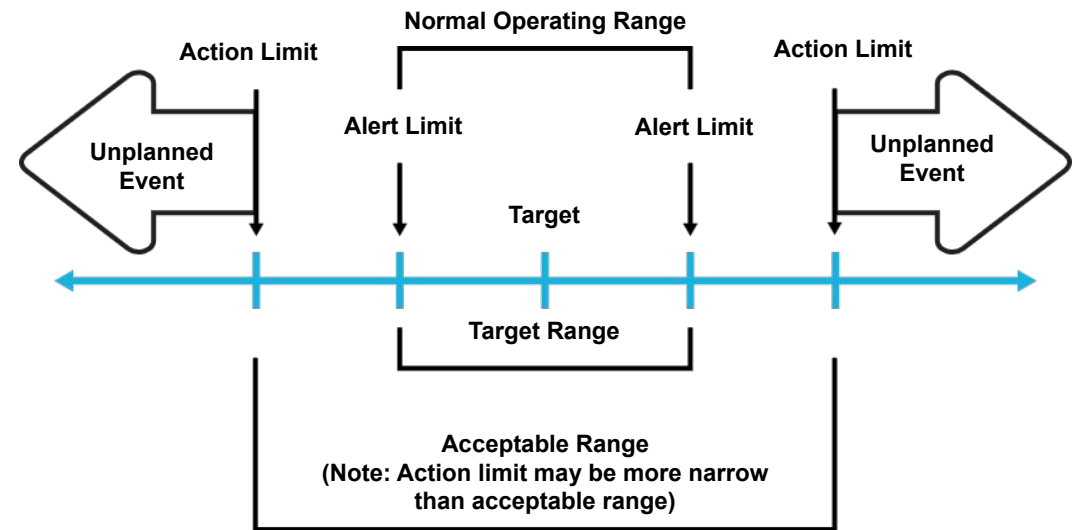
Standardized, Modular Recipe Library: Supports Submission Requirements

Modular Taxonomy Constructs =
Step + Activity + Parameter + Attribute syntax

“Affinity Chromatography Resin Equilibration Wash
Wash Flow Rate Target”



Standard Parameter Set with Attributes =
Target, Limits, Type, Monitoring Method



Parameter Attribute	Use	GR or SR
Setpoint	Setpoints is used when a control setpoint is required (i.e. dO2, temperature, flow setpoint) to achieve a target value.	SR
Target	Used for in-process measurements, for example: pool adjusted pH target, batch feed volume target. This attribute will be used as a control setpoint when it is required (i.e. do2, temperature, and flow setpoint) -in this case, color coding will be utilized to differentiate between process target automation setpoint.	GR/ SR
Limits Low/High	Can describe either a one-sided or two-sided range for a process parameter or material attribute for which operation within this range will produce a material meeting relevant quality criteria.	GR
Parameter Type	Classification of parameter from source documents, such as crucial process parameter, Critical Quality Attribute, or a Key Performance Indicators, etc.	GR/ SR

Standardized, Modular Recipe Library: Supports Submission Requirements

Pre-Defined Phase Appropriate Display

- Early Development
- Pre-Tox
- Tox
- Phase I
- Phase II
- Phase III
- PPQ (Qualification)
- Commercial Manufacturing
- Commercial (Legacy)

Relate Attributes to Phase

Add New Import Export

Search Rows: 10 Count: 9 1 / 1

SNo.	Modify	Phase Name*	Attribute Name*	Modify
1.	Edit	Tox	Acceptable High-(withQualifier), Acceptable Low-(withQualifier), Adjustment Type, Adventitious Agents Removal Method, Bag Freeze Strategy, Bag Scale, Blowdown Gas, Bottle Size, Buffer Alias, Calculated Acceptable High, Calculated Acceptable Low, Calculated Target, Cell Bank Type, Cell Density Control Mode, Cell Density Specification, Cell Density Specification UOM, Centrifuge Type, Constant Selection, Control Strategy, Cultivation Vessel Type, Cycle Begin, Cycle End, DP Dosage Form, DS Container Type, DS Storage Container, Dilution Process, Direction, Elution Type, Excursion High, Excursion Low, Excursion Time, Excursion Time (h), Excursion Type, Filling Method, Filtration Flow Path, Filtration Method, Flag, Flow Path, Foam, Fractionation Criteria, Freeze Strategy, Freeze Type, Hold Vessel Type, Membrane Material, Mfg Control Type, Mixing Method, Mixing Vessel Type, Mode of Operation, On/Off, Parameter Type, Pooling Criteria, Recovery Type, Recycle Tank Scale, Reference Temperature, Sample Target, Scale Up, Setpoint-(withQualifier), Slurry Concentration Determination Method, Storage Conditions, Tank Scale, Target-(withQualifier), Temperature Shift Type, Text, Text Input, Thaw Equipment, Trigger Type, UDF Flow Path, Up/Down, Vessel Designation, Yes/No Selection, dO2 Control Selection, pH Adjustment Strategy	Edit Delete
2.	Edit	Pre-Tox	Acceptable High-(withQualifier), Acceptable Low-(withQualifier), Adjustment Type, Adventitious Agents Removal Method, Bag Freeze Strategy, Bag Scale, Blowdown Gas, Bottle Size, Buffer Alias, Calculated Acceptable High, Calculated Acceptable Low, Calculated Target, Cell Bank Type, Cell Density Control Mode, Cell Density Specification, Cell Density Specification UOM, Centrifuge Type, Constant Selection, Control Strategy, Cultivation Vessel Type, Cycle Begin, Cycle End, DP Dosage Form, DS Container Type, DS Storage Container, Dilution Process, Direction, Elution Type, Excursion High, Excursion Low, Excursion Time, Excursion Time (h), Excursion Type, Filling Method, Filtration Flow Path, Filtration Method, Flag, Flow Path, Foam, Fractionation Criteria, Freeze Strategy, Freeze Type, Hold Vessel Type, Membrane Material, Mfg Control Type, Mixing Method, Mixing Vessel Type, Mode of Operation, On/Off, Parameter Type, Pooling Criteria, Recovery Type, Recycle Tank Scale, Reference Temperature, Sample Target, Scale Up, Setpoint-(withQualifier), Slurry Concentration Determination Method, Storage Conditions, Tank Scale, Target-(withQualifier), Temperature Shift Type, Text, Text Input, Thaw Equipment, Trigger Type, UDF Flow Path, Up/Down, Vessel Designation, Yes/No Selection, dO2 Control Selection, pH Adjustment Strategy	Edit Delete
3.	Edit	Phase III	Acceptable High-(withQualifier), Acceptable Low-(withQualifier), Action High-(withQualifier), Action Low-(withQualifier), Adjustment Type, Adventitious Agents Removal Method, Alert High-(withQualifier), Alert Low-(withQualifier), Bag Freeze Strategy, Bag Scale, Blowdown Gas, Bottle Size, Buffer Alias, Calculated Acceptable High, Calculated Acceptable Low, Calculated Target, Cell Bank Type, Cell Density Control Mode, Cell Density Specification, Cell Density Specification UOM, Centrifuge Type, Constant Selection, Control Strategy, Cultivation Vessel Type, Cycle Begin, Cycle End, DP Dosage Form, DS Container Type, DS Storage Container, Dilution Process, Direction, Elution Type, Excursion High, Excursion Low, Excursion Time, Excursion Time (h), Excursion Type, Filling Method, Filtration Flow Path, Filtration Method, Flag, Flow Path, Foam, Fractionation Criteria, Freeze Strategy, Freeze Type, Hold Vessel Type, Membrane Material, Mfg Control	Edit Delete

Standardized, Modular Recipe Specification Library: Supports Submission Requirements

- Pre-Defined Parameter Descriptions

Bowl Speed

Description :

This is the speed that the centrifuge bowl spins at to separate the solids (e.g. cells and debris) from the cell culture fluid. Drug Substance (LMDS) Gene Therapy Development Center (GTDC)

Close

- Consistency Across the Enterprise

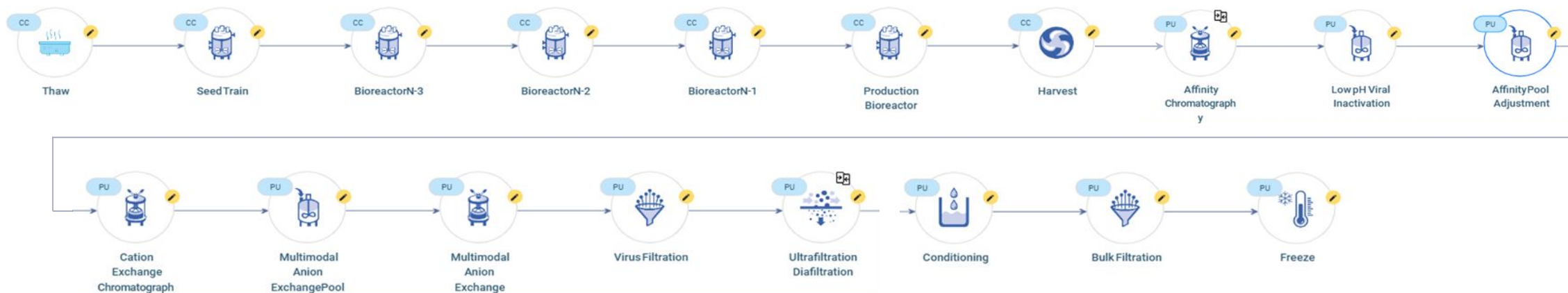
SR Flow Rate

Description :

This is a conversion of the GR flow rate to a site-specific unit of measure (i.e. CV/h or cm/h -> L/h) and is calculated based on the inputs of Flow Rate or Linear Flow Rate and Column Volume. Drug Substance (LMDS) Gene Therapy Development Center (GTDC)

Close

Standardized, Modular Recipe Specification Library: Commonly Used Standardized Building Blocks--Steps



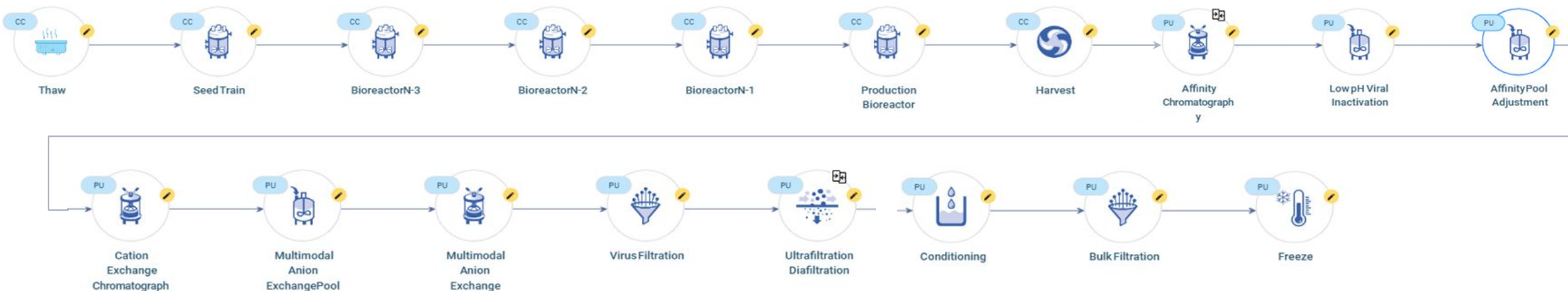
Process Area	Step Name
Media and Buffers	Buffer Preparation
Media and Buffers	Kit Preparation
Media and Buffers	Medium Preparation
Media and Buffers	Solution Preparation
Cell Culture	Bioreactor N-1
Cell Culture	Bioreactor N-2
Cell Culture	Bioreactor N-3
Cell Culture	Bioreactor N-4
Cell Culture	Production Bioreactor
Cell Culture	Harvest
Cell Culture	Seed Train
Cell Culture	Seed Train Expansion Cultures
Cell Culture	Thaw
Purification	Affinity Chromatography
Purification	Affinity Load Adjustment
Purification	Affinity Pool Adjustment
Purification	Anion Exchange Chromatography
Purification	Anion Exchange Load Adjustment
Purification	Anion Exchange Pool Adjustment

Process Area	Step Name
Purification	Assembly
Purification	Assembly Pool Adjustment
Purification	Bulk Filtration
Purification	Bulk Re-Freeze
Purification	Cation Exchange Chromatography
Purification	Cation Exchange Load Adjustment
Purification	Cation Exchange Pool Adjustment
Purification	Column Integrity Test
Purification	Column Packing
Purification	Column Unpacking
Purification	Compounding
Purification	Conditioning
Purification	Conjugation
Purification	Conjugation 2
Purification	Depth Filtration
Purification	Detergent Viral Inactivation
Purification	Freeze
Purification	Hydrophobic Anion Exchange Chromatography
Purification	Hydrophobic Anion Exchange Load Adjustment

Process Area	Step Name
Purification	Hydrophobic Anion Exchange Pool Adjustment
Purification	Hydrophobic Interaction Chromatography
Purification	Hydrophobic Interaction Load Adjustment
Purification	Hydrophobic Interaction Pool Adjustment
Purification	Low pH Viral Inactivation
Purification	Multimodal Anion Exchange Chromatography
Purification	Multimodal Anion Exchange Load Adjustment
Purification	Multimodal Anion Exchange Pool Adjustment
Purification	Multimodal Cation Exchange Chromatography
Purification	Multimodal Cation Exchange Load Adjustment
Purification	Multimodal Cation Exchange Pool Adjustment
Purification	Multimodal Chromatography
Purification	Multimodal Load Adjustment
Purification	Multimodal Pool Adjustment
Purification	New Membrane Preparation
Purification	Pegylation
Purification	Reversed-Phase High-Performance Liquid Chromatography
Purification	Reversed-Phase High-Performance Liquid Load Adjustment
Purification	Reversed-Phase High-Performance Liquid Pool Adjustment

Process Area	Step Name
Purification	Size Exclusion Chromatography
Purification	Size Exclusion Load Adjustment
Purification	Size Exclusion Pool Adjustment
Purification	Ultrafiltration Diafiltration
Purification	Urea Treatment
Purification	Virus Filtration
Purification	Virus Filtration Load Adjustment
Purification	Bag to Bag Refiltration
Purification	Bioburden Reduction Filtration
Cell Banking	Ampoule Fill and Freeze
Cell Banking	Cryobag Fill and Freeze
Cell Banking	Thaw and Expansion
Cell Banking	Harvest, Concentration, and Formulation
Cell Banking	Lyophilization
Drug Product-E	Capping and Closure
Drug Product-E	Dilution
Drug Product-E	Filling and Stoppering
Drug Product-E	Inspection
Drug Product-E	Pooling
Drug Product-E	Sterile Filtration

Standardized, Modular Recipe Specification Library: Commonly Used Standardized Building Blocks--Activities



Process / Step Area	Activity Name	Process / Step Area	Activity Name	Process / Step Area	Activity Name	Process / Step Area	Activity Name	Process / Step Area	Activity Name
Assembly	Filters	Cell Culture	Seed Train Expansion	Purification	Post-Use Regeneration	UFDF	Post-Use Flush	Drug Product	Automated inspection
Assembly	Pool Combination	Cell Culture	TFDF Operation	Purification	Pre-Cycle Elution	UFDF	Post-Use Integrity Test	Drug Product	Bag to Bag Refiltration
Assembly	Reductant Addition	Cell Culture	Thaw	Purification	Pre-Cycle Equilibration	UFDF	Post-Use Normalized Permeability test (NP)	Drug Product	Crimping
Assembly	Single Use Assembly	Cell Culture	Thaw into Seed Train Bioreactor	Purification	Pre-Cycle Regeneration	UFDF	Post-Use Regeneration	Drug Product	Manual Inspection
Media and Buffers	Additions	Cell Culture	Thaw into Spinner or Shake Flask	Purification	Pre-Equilibration	UFDF	Post-Use Regeneration Flush	Drug Product	Mixing
Media and Buffers	Adjustment	Cell Culture	Thaw into Wavebag	Purification	Reagent Addition	UFDF	Post-Use Sanitization	Drug Product	Packing Configuration
Media and Buffers	Adventitious Agents Removal	Cell Culture	Transfer	Purification	Regeneration	UFDF	Post-Use Sanitization Flush	Drug Product	Product Definition
Media and Buffers	Filtration	Harvest	Cell Lysis	Purification	Regeneration Flush	UFDF	Pre-Use Flush	Drug Product	Stoppering
Media and Buffers	pH Adjustment	Harvest	Centrifuge Operation	Purification	Regeneration-Sanitization	UFDF	Pre-Use Integrity Test	Drug Product	Thaw in Bags
Media and Buffers	Weigh & Dispense	Harvest	Depth Filtration	Purification	Sanitization	UFDF	Pre-Use Regeneration	Drug Product	Thaw in Bottles
Cell Culture	Antifoam Addition	Harvest	Detergent Addition	Purification	Sanitization Flush	UFDF	Pre-Use Sanitization	Drug Product	Thaw in Tanks
Cell Culture	Batch Feed	Harvest	Flocculation	Purification	Sanitization-Storage	UFDF	Recovery		
Cell Culture	Concentration	Purification	Chilling	Purification	Storage	UFDF	Recovery Blowdown		
Cell Culture	Glucose Addition	Purification	Column Integrity Test	Purification	Wash	UFDF	Recovery Buffer Displacement		
Cell Culture	Harvest Conditions	Purification	Column Packing	UFDF	Cassett Installation	UFDF	Skid Sanitization and Storage		
Cell Culture	Inoculation	Purification	Column Unpacking	UFDF	Conditioning	UFDF	Steam Sanitization		
Cell Culture	Manipulation Conditions	Purification	Elution	UFDF	Diafiltration	UFDF	Tangential Flow Depth Filtration (TFDF)		
Cell Culture	Passage	Purification	Equilibration	UFDF	Dilution	UFDF	Ultrafiltration		
Cell Culture	Post Batch	Purification	Expansion	UFDF	Integrity Test	Cell Banking	Filling		
Cell Culture	Post-Inoculation Addition	Purification	Flush	UFDF	Low dP Recycle	Cell Banking	Formulation		
Cell Culture	Pre-Harvested Cell Culture Fluid (PHCCF)	Purification	Heated Hold	UFDF	Mini Post	Cell Banking	Freeze		
Cell Culture	Pre-Inoculation Conditions	Purification	Infrequent Sanitization	UFDF	Mini Post Flush	Cell Banking	Freeze in Bags		
Cell Culture	Quench	Purification	Load	UFDF	Normalized Permeability Test (NP)	Cell Banking	Freeze in Bottles		
		Purification	Pooling	UFDF	Pool Storage	Cell Banking	Freeze in Tanks		

Standardized, Modular Recipe Library: Key Step Elements

Step Equipment and Materials

Step Information | Equipment Summary | Equipment Class Summary | Materials Summary | Sampling | Filters | Column Integrity Test | Single Use Assembly

Equipment Class

- GR General Recipe Equipment Classes
 - Chromatography Skid
- SR Site Recipe Equipment Classes

Equipment (No Equipment added for this activity)

Materials

- GR General Recipe Materials
 - GR Resin

Material Name	Material ID	Recipe Name	Recipe Version	Material Role	Storage Temperature Qualifier	Storage Temperature	Storage Temperature Units
- SR Site Recipe Materials
 - SR Resin

Material Name	Material ID	Recipe Name	Recipe Version	Material Role	Quantity	Quantity Units	Material Alternate

Step General and Site Parameters

Parameters

General Recipe Parameters

Bed Height (mm)

Setpoint (withQual...)	Target (withQual...)	Acceptable Low (withQual...)	Acceptable High (withQual...)	Action Low (withQual...)	Action High (withQual...)
N/A	+ 15	N/A 5	N/A 20	N/A	N/A
Alert Low (withQual...)	Alert High (withQual...)	MAR Low (withQual...)	MAR High (withQual...)	PAR Low (withQual...)	PAR High (withQual...)
N/A 10	N/A 18	N/A	N/A	N/A	N/A
Hybrid Low (withQual...)	Hybrid High (withQual...)	Parameter Type	Mfg Control Type		
N/A	N/A				

Temperature (°C)

Setpoint (withQual...)	Target (withQual...)	Acceptable Low (withQual...)	Acceptable High (withQual...)	Action Low (withQual...)	Action High (withQual...)
N/A	N/A 25	N/A 20	N/A 30	N/A	N/A
Alert Low (withQual...)	Alert High (withQual...)	MAR Low (withQual...)	MAR High (withQual...)	PAR Low (withQual...)	PAR High (withQual...)
N/A 22	N/A 28	N/A	N/A	N/A	N/A
Hybrid Low (withQual...)	Hybrid High (withQual...)	Parameter Type	Mfg Control Type		
N/A	N/A				

Differential Pressure (kPa)

Setpoint (withQual...)	Target (withQual...)	Acceptable Low (withQual...)	Acceptable High (withQual...)	Action Low (withQual...)	Action High (withQual...)
N/A	N/A 52.34	N/A 52.00	N/A 53.00	N/A 52.11	N/A 52.50
Alert Low (withQual...)	Alert High (withQual...)	MAR Low (withQual...)	MAR High (withQual...)	PAR Low (withQual...)	PAR High (withQual...)
N/A 52.34	N/A 52.84	N/A	N/A	N/A	N/A
Hybrid Low (withQual...)	Hybrid High (withQual...)	Parameter Type	Mfg Control Type		
N/A	N/A				

Site Recipe Parameters

Column Diameter (mm)

Setpoint (withQual...)	Target (withQual...)	Acceptable Low (withQual...)	Acceptable High (withQual...)	Action Low (withQual...)	Action High (withQual...)
N/A	N/A 53.4	N/A	N/A	N/A	N/A
Alert Low (withQual...)	Alert High (withQual...)	MAR Low (withQual...)	MAR High (withQual...)	PAR Low (withQual...)	PAR High (withQual...)
N/A	N/A	N/A	N/A	N/A	N/A
Hybrid Low (withQual...)	Hybrid High (withQual...)	Parameter Type	Mfg Control Type		
N/A	N/A				

Column Volume (L)

Setpoint (withQual...)	Calculated Target	Calculated Acceptable Low	Calculated Acceptable High	Action Low (withQual...)	Action High (withQual...)
N/A	N/A 5029.67	N/A 1676.55	N/A 8706.23	N/A	N/A
Alert Low (withQual...)	Alert High (withQual...)	MAR Low (withQual...)	MAR High (withQual...)	PAR Low (withQual...)	PAR High (withQual...)
N/A 1	N/A	N/A	N/A	N/A	N/A
Hybrid Low (withQual...)	Hybrid High (withQual...)	Parameter Type	Mfg Control Type		
N/A	N/A				

Scalable calculations based on equipment included

Step Sample Plans

Step Information | Equipment Summary | Equipment Class Summary | Materials Summary | Sampling | Filters | Column Integrity Test | Single Use Assembly

General Recipe Sampling

1 Sample Name Placeholder SR Sampling Plan

Time Period	Activity	Reference Document	Analytical Method	Parameter	Decimal Places	Hold Step	Sampling Process Type	Lower Acceptance Criteria Limit Qualifier	Lower Acceptance Criteria Limit	Upper Acceptance Criteria Limit Qualifier	Upper Acceptance Criteria Limit	Qualitative Acceptance Criteria Limit	Lower Alert Limit Qualifier

Site Recipe Sampling

1 Sample Name Placeholder SR Sampling Plan

Time Period	Activity	Reference Document	Analytical Method	Parameter	Decimal Places	Hold Step	Sampling Process Type	Lower Acceptance Criteria Limit Qualifier	Lower Acceptance Criteria Limit	Upper Acceptance Criteria Limit Qualifier	Upper Acceptance Criteria Limit	Qualitative Acceptance Criteria Limit	Lower Alert Limit Qualifier

Column Integrity Test / Step Information / Column Volume / Calculated Target

Preview Value: 5029.67 | Round off: None | Decimal places: 2

Multiplication Factor: | Current UOM: | Previous UOM: |

1 [(S).Step Information: 141592653589793] * pow((withQualifier) / 2, 2) * 10000

(S).Step Information.Parameter.Column Diameter.Target-

This Calculation contains qualifiers. Be aware.

Cancel



Proposed Solution / Value

- Licensor Process Development Planner
- Licensor Manufacturing Automation Planner

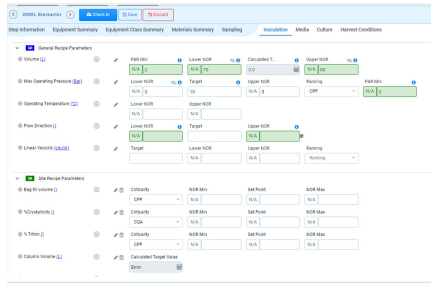
Licensor
Process Specification



1

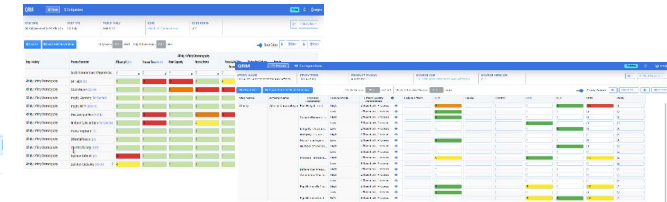
Licensor “Blue-print”
modality recipe

- Modify to product specific “line” recipe



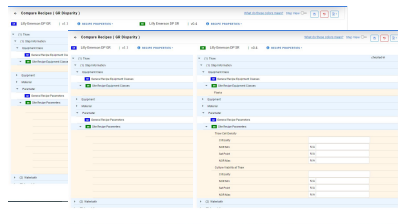
2a

Digitally assess parameter relationships and do FMEA / Control Strategy to manage risk



2b

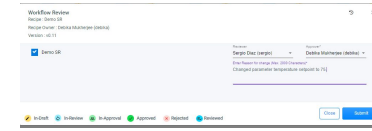
Digitally compare “product line recipe” to Licensor production capabilities for best fit



3

Update targeted Licensor site recipe to address gaps

- Versioning / joint digital reviews
- Audit trail



4

Finalized site recipe on planned Licensor line

- Joint digital reviews
- Versioning

PKM Platform

4.1.4.1.2 Activity Set Up

Parameter	Parameter Value	Unit	Control	Setpoint	Setpoint	Setpoint
OP	Control Filter	Filter	OP	Percent Flow Calc	N/A	N/A
OP	Control Filter	Filter	OP	Percent Flow Calc	N/A	N/A
OP	Control Filter	Filter	OP	Percent Flow Calc	N/A	N/A

Note: Press other **Parameter** button for **category** list of parameters and attributes at **activity** table may not accommodate all attributes.

4.1.4.1.3 Activity Pre-Cleaning

Parameter	Parameter Value	Unit	Control	Setpoint	Setpoint	Setpoint
OP	Control Filter	Filter	OP	Percent Flow Calc	N/A	N/A
OP	Control Filter	Filter	OP	Percent Flow Calc	N/A	N/A
OP	Control Filter	Filter	OP	Percent Flow Calc	N/A	N/A

Note: Press other **Parameter** button for **category** list of parameters and attributes at **activity** table may not accommodate all attributes.

4.1.4.1.4 Activity Pre-Steaming

Parameter	Parameter Value	Unit	Control	Setpoint	Setpoint	Setpoint
OP	Control Filter	Filter	OP	Percent Flow Calc	N/A	N/A
OP	Control Filter	Filter	OP	Percent Flow Calc	N/A	N/A
OP	Control Filter	Filter	OP	Percent Flow Calc	N/A	N/A

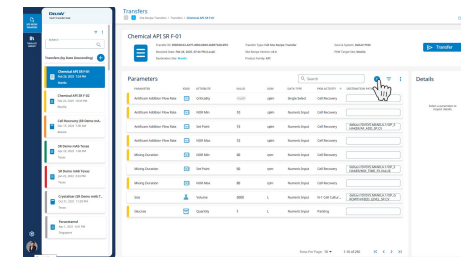
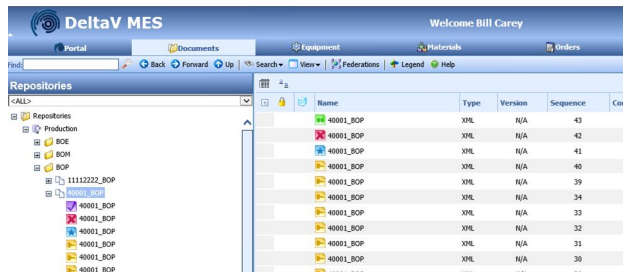
Note: Press other **Parameter** button for **category** list of parameters and attributes at **activity** table may not accommodate all attributes.



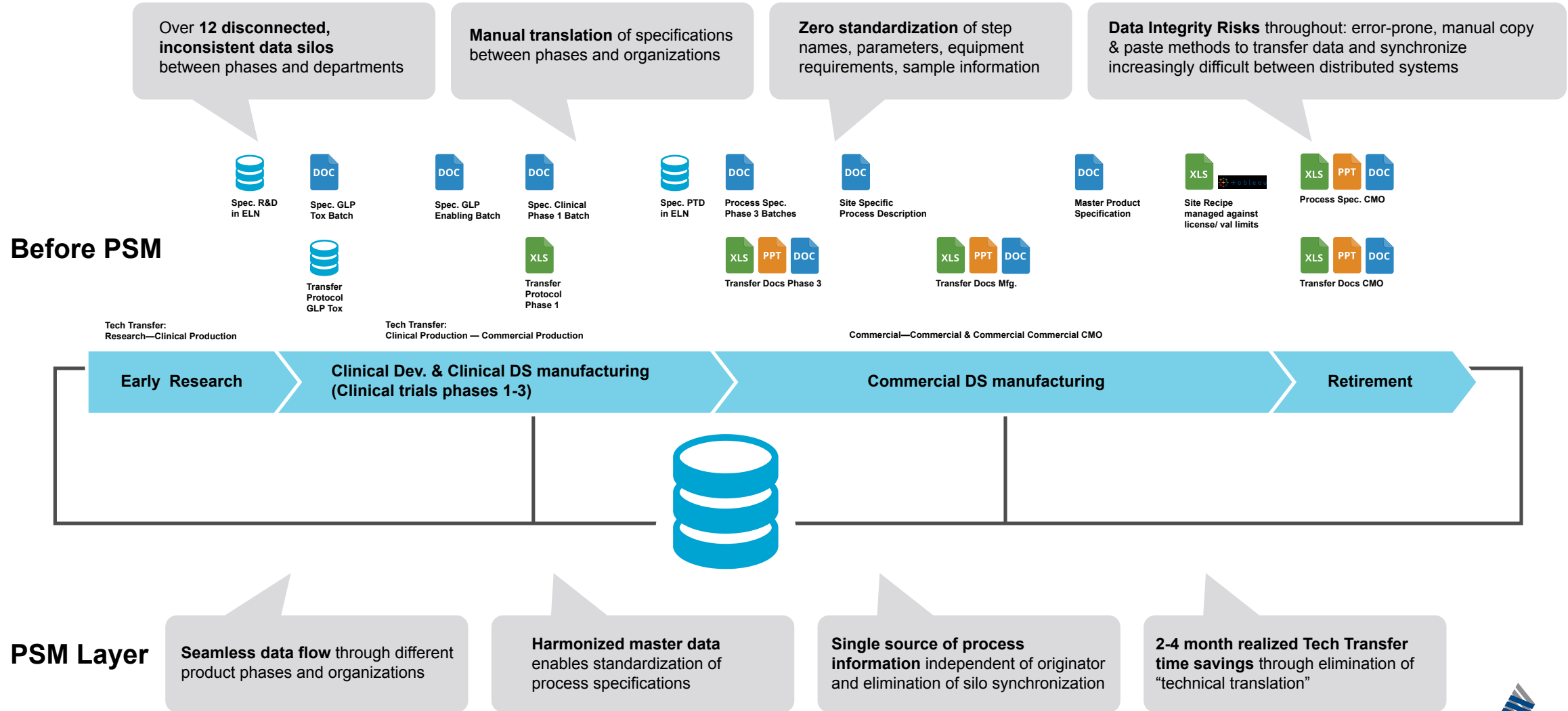
Transfer Hub Integration to Licensor Execution

5

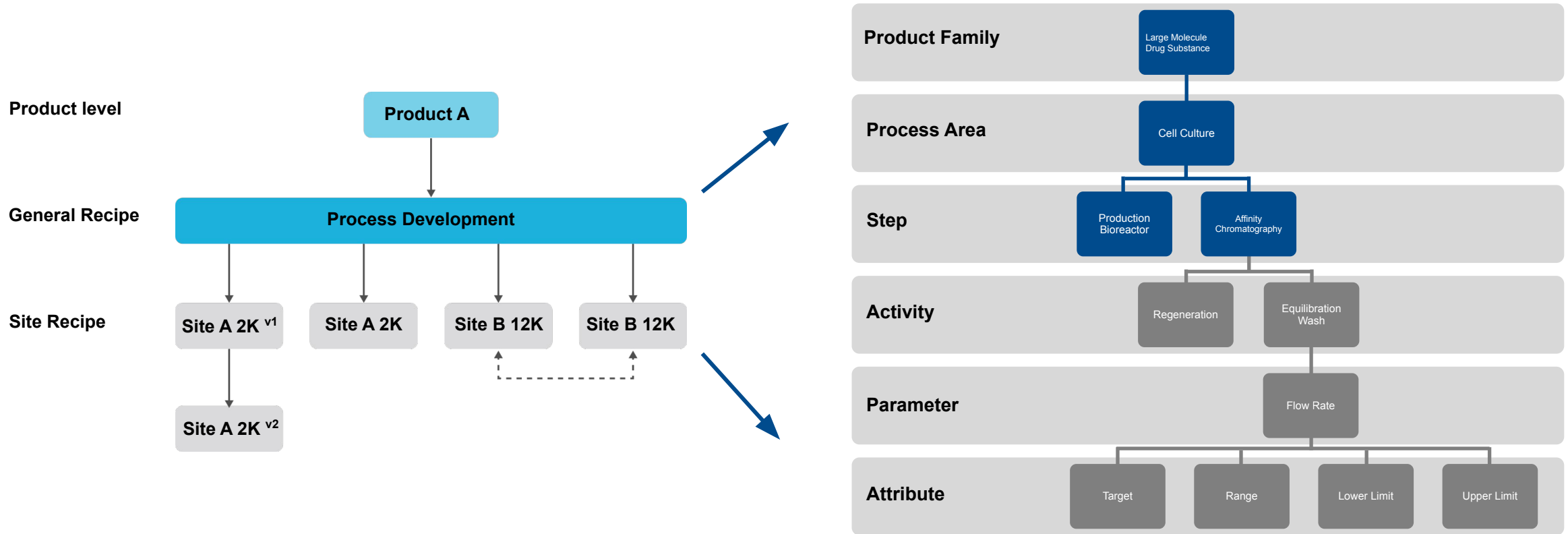
Map of PSM elements to execution system parameters



The Roche Product Specification Management Opportunity: Harmonized, Central Nomenclature across Product Portfolio Lifecycle



Roche Product Data Architecture Philosophy



Roche recognized the need to **establish master data ownership** and consistency across development programs to improve process prior knowledge management, accelerate ML data opportunities, and avoid the growth of unstructured product data siloes

Roche PSM Case Study: Genentech Clinical Supply Center



Production Bioreactor

ProdBio_Add_p_Fee2_Tar

Production Bioreactor Additions Feed 2 Target

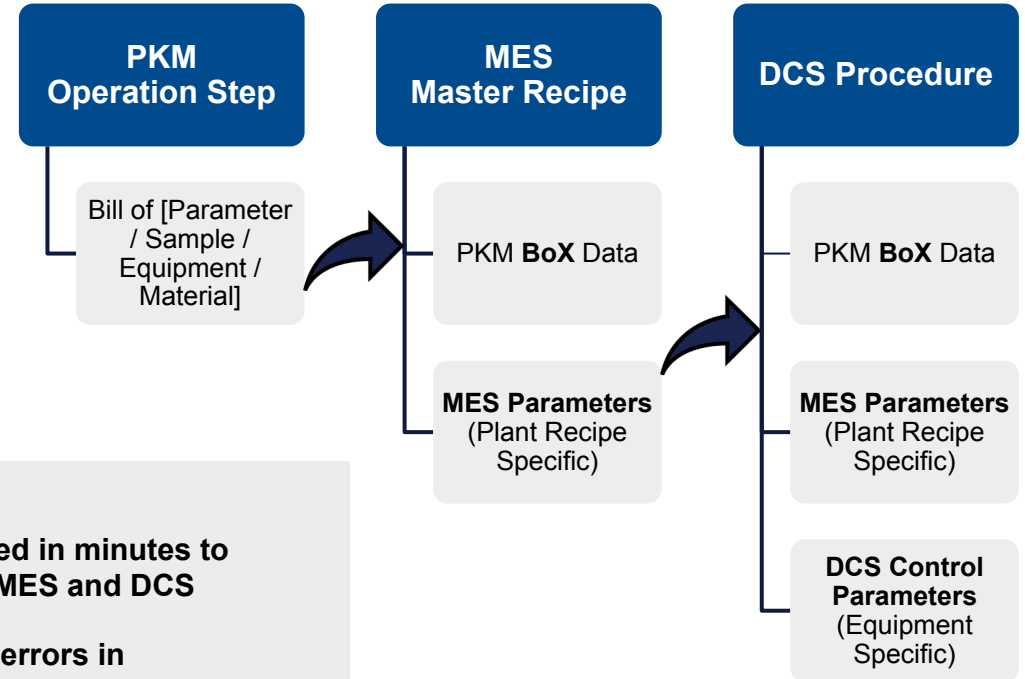


Roche Emerson Exchange presentation 2025 May

Result:

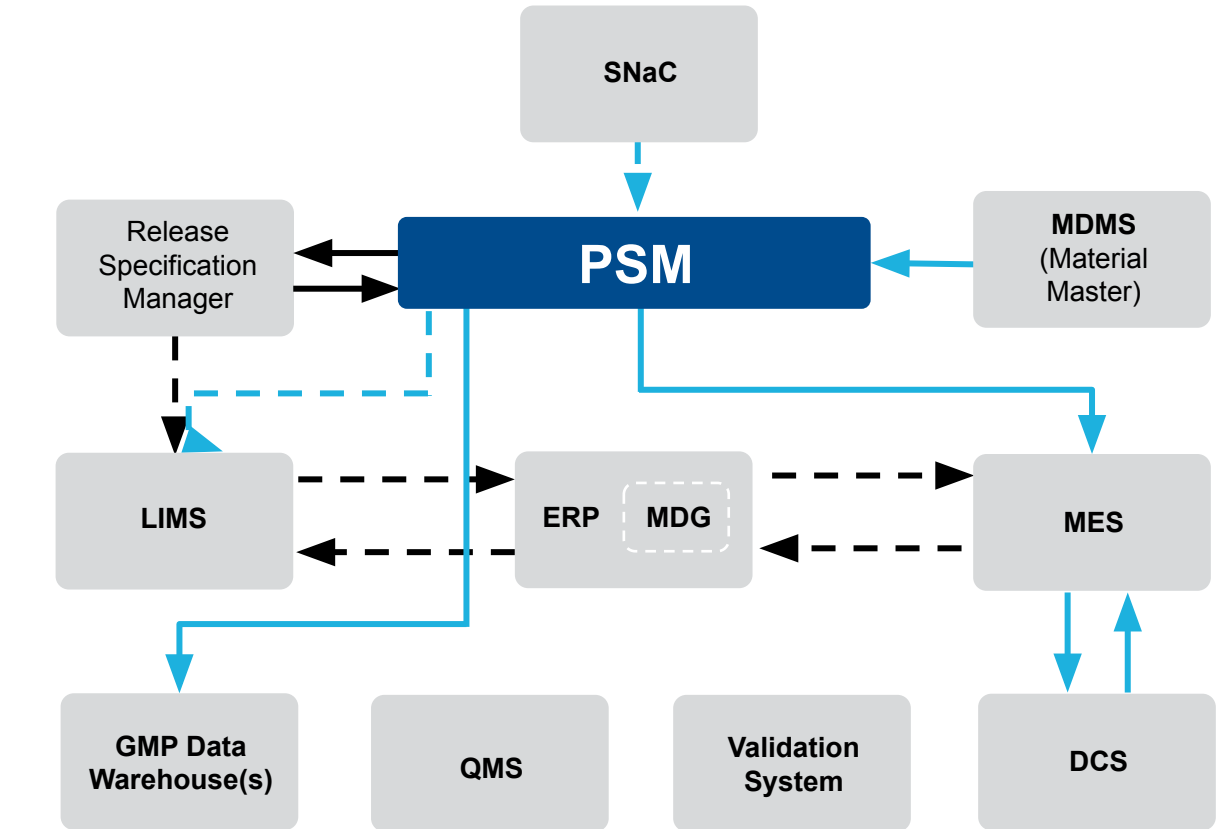
- Thousands of parameters transferred in minutes to auto-approved recipe templates in MES and DCS
- Elimination of human transcription errors in batch creation
- Reduction in 7 FTEs for recipe authoring annually for 10 tech transfer per year

5 Minute Creation of Master Batch Records



PSM Central to Roche IT Landscape

- PSM **receives** standards (from SNaC) and material master data (from MDMS and eventually MDG).
- PSM will **send** product master data to MES, LIMS, data warehouses, and more...
- There are manual workflows incorporating QMS and electronic validation systems with PSM serving as the source of data and change histories.
- Consuming systems can further enrich PSM product data for additional data contextualization, and can greatly enhance external consumer data accessibility.



- Implemented
- Defined process for manual updates
- Planned
- Out of Scope for BC 2.0 scope

Beyond Roche Execution: PSM Data Accessibility

1. Recipe Right First Time Error Checking Bot for Data Entry Standards Enforcement

“N is expected unit of measure for DCS”

GR General Recipe Parameters

Total Impulse Produced by Thruster Firing (lb-f)

Criticality: Category 3

Target-(withQ...: = 4000

Lower Limit: < 3950

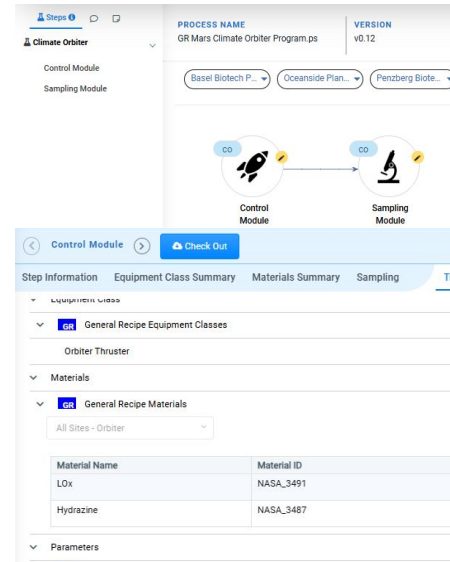
Upper Limit: > 4100

Test on Filters Table when applicable for step:

Units	Filter Flush Volume	Filter Flush Volume Units	Flush Material ID#	Material Role	Where Used	Filter f			
10	30	L	10086	Sterile Filter	Chrom Skid	✓ Passed	✓ Passed	✓ Passed	
11	None	None	None	Vent Filter	Chrom Skid	✓ Passed	✓ Passed	✓ Passed	
12	None	None	None	Vent Filter	Chrom Skid	✓ Passed	✓ Passed	✓ Passed	
13	None	None	None	Vent Filter	Chrom Skid	✓ Passed	✓ Passed	✓ Passed	
14	None	None	None	Vent Filter	Chrom Skid	✓ Passed	✓ Passed	✓ Passed	
15	None	None	None	Vent Filter	Chrom Skid	✓ Passed	✓ Passed	✓ Passed	
16	None	None	None	Vent Filter	Chrom Skid	✓ Passed	✓ Passed	✓ Passed	
17	120	L	10086	Depth Filter	Chrom Skid	✓ Passed	✓ Passed	✓ Passed	
18	30	L	10086	Sterile Filter	Chrom Skid	✓ Passed	✓ Passed	✓ Passed	
19	70	L	None	Viral Pre-Filter	VF System	✗ Failed	✓ Passed	✓ Passed	

Beyond Roche Execution: PSM Data Accessibility

2. Recipe Data Visualization Outside of PSM for Non-PSM User Data Consumers

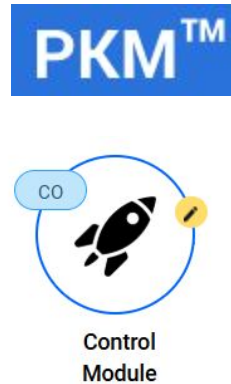


Recipe Name	Most Recent Recipe Version	Recipe Version	Step Name	Activity Name	Component Name	Parameter Type	Field Name
1.0 M NaOH, 1 M NaCl	Yes	v0.5 - 1.0 M NaOH, 1 M Na...	Buffer Preparation	(All)	(All)	N/A	(All)

Recipe Name	Recipe Versio..	Step Name	Step Versio..	Activity Name	Component Ty..	Parameter Ty..	Component Name	UoM	Lower Limit	Upper Limit
1.0 M NaOH, 1 M NaCl	v0.5	Buffer Preparation	v1.0	Step Information	Parameter	N/A			15	30
1.0 M NaOH, 1 M NaCl	v0.5	Buffer Preparation	v1.0	Step Information	Parameter	N/A			12.0	14.0

Beyond Roche Execution: PSM Data Accessibility

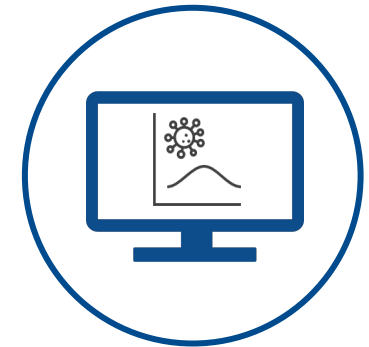
PSM Solution



MES Batch Report



Data Historian



3. Recipe and Execution Data Exposed to Regulatory Information Management for Intelligent Authoring of Filings

S.2.5

KPI	Acceptance Criteria	PPQ Batch 1	PPQ Batch 2
Parameter 1	34.6 – 57.0	40.5	42.4
Parameter 2	95% - 100%	98%	97%
Parameter 3	3 - 8	5	4

Questions / About the Presenter

- Emerson | Life Sciences Business Director
- Wide experience applying technology to solve manufacturing operation problems
 - Driving Emerson's Life Sciences solution strategy
 - Instrumentation through Manufacturing Operations Management
- BS Chemical Engineering Rose-Hulman Institute of Technology
- MBA University of Texas at Austin
- >40 years in the automation industry, mostly in Life Sciences
- Contact info:
 - Emerson | 1100 W. Louis Henna Blvd. | Building 1 | Round Rock | TX | 78681 | USA
 - T +1 512 834 7033 | C +1 512 350 4002
 - bob.lenich@emerson.com
 - www.linkedin.com/in/bob-lenich



Thank you!

