Faster Tech Transfers Through Seamless Digital Transformation

Bob Lenich, PKM Business Director, Emerson Life Sciences

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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

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

Master Recipe

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

Control Recipe

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

Very Difficult to standardize and re-use previous work

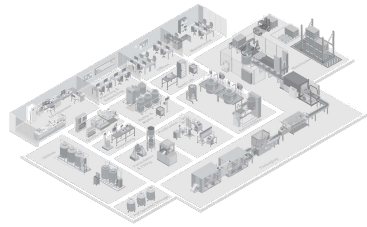
⚠ High Effort

Manual Typing Very Slow

⚠ Time Lost

Not Flexible / Difficult to Change

⚠ High Cost



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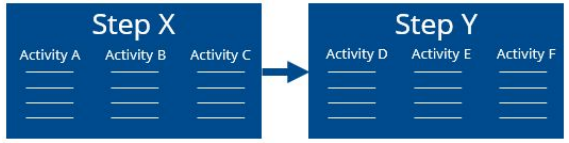
Digitalization in Recipe Parameter Management

Traditional Approach

Recipe is created from scratch without reusable components

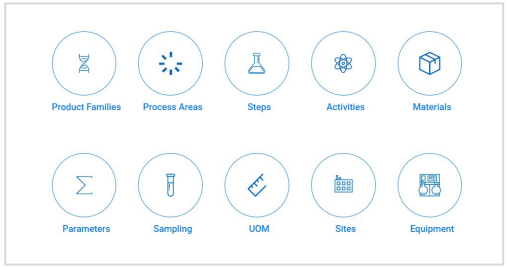


Isolated work for different groups

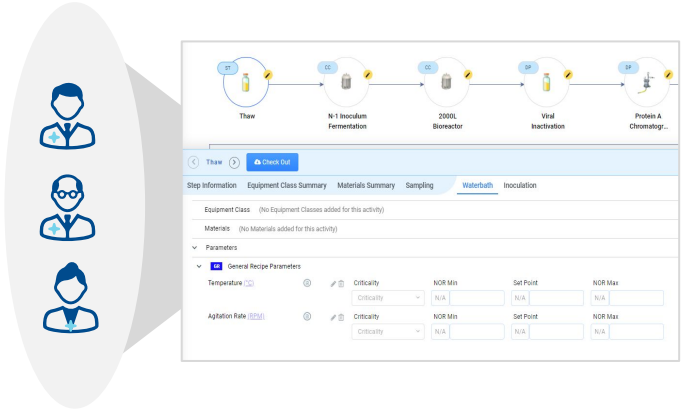
Manual Review/Approval; Physical Meetings

BEST Practice Approach

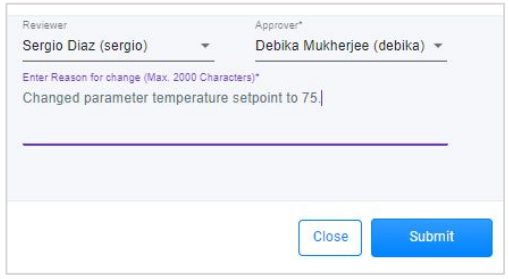
Configuration objects created using reusable components (data model based on S88 standards)



Common Digital Collaboration Platform for multiple personas



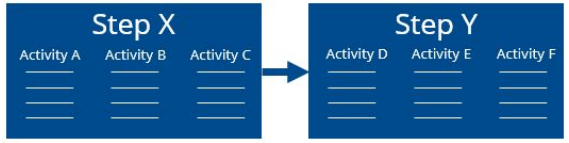
Automated Review & Approval Workflow



Digitalization in Recipe Scale-up and Integration

Traditional Approach

- Individual Recipes with no Scale Up option

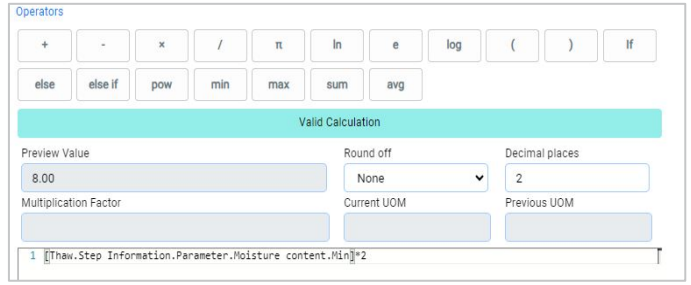


- Separate document management system

- Isolated Files / Separate Handling and Transfer

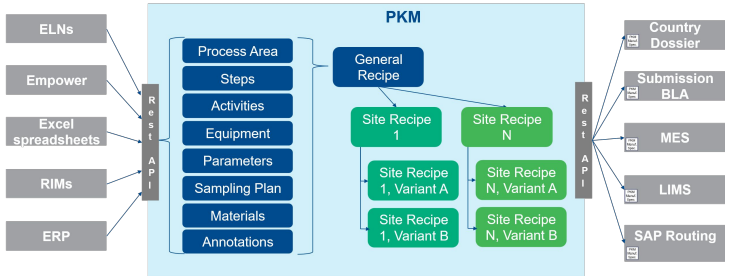
BEST Practice Approach

- **Scale Up Calculations**



- **Electronic Audit Logs & Versioning**

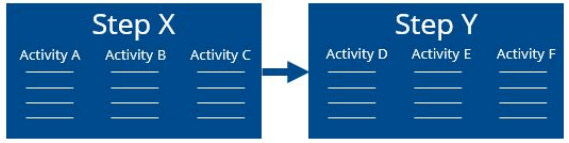
- **Integration with planning and executions systems**



Digitalization in Parameter Risk Assessment

Traditional Approach

Risk study created from scratch without reusable components

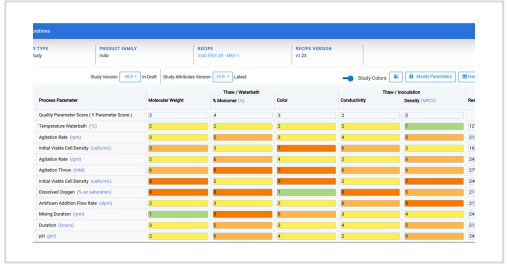


Isolated work for different groups

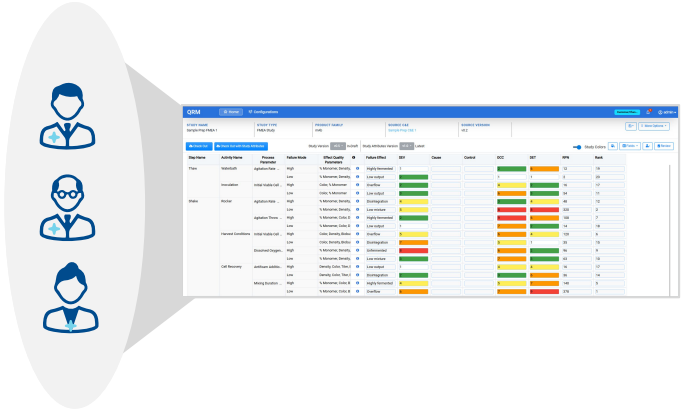
Manual Review/Approval; Physical Meetings

BEST Practice Approach

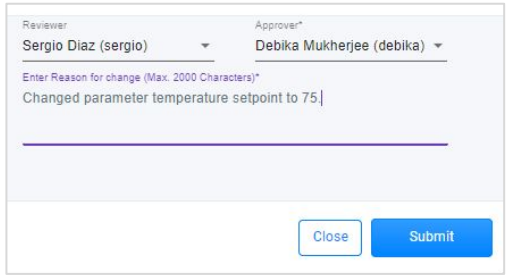
Parameter Relationships created using linked recipe parameters



FMEA Digital Collaboration Platform for multiple personas



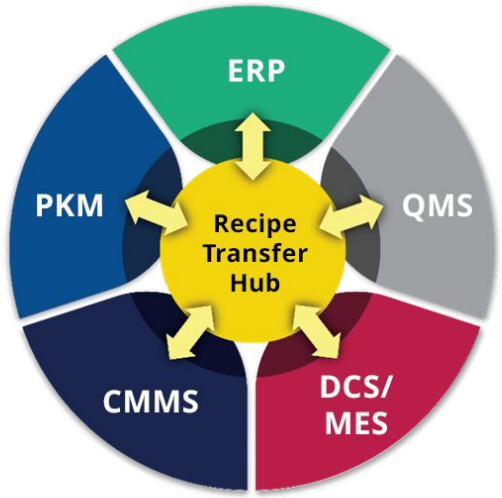
Automated Review & Approval Workflow



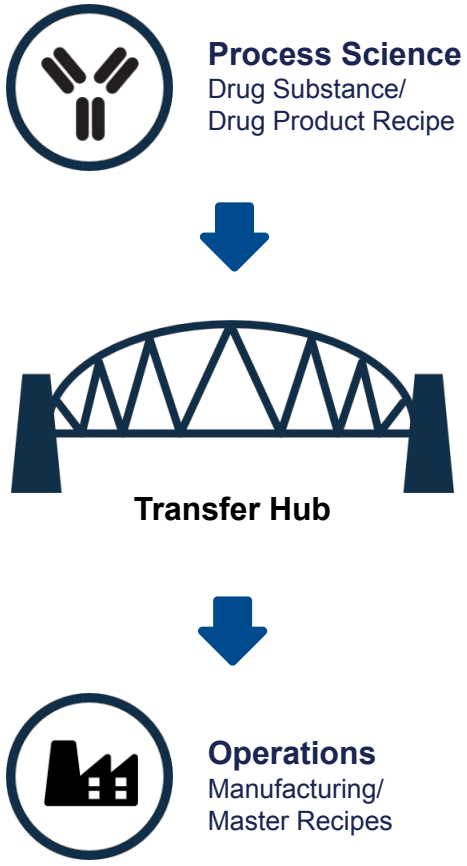
Transfer Hub Platform

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

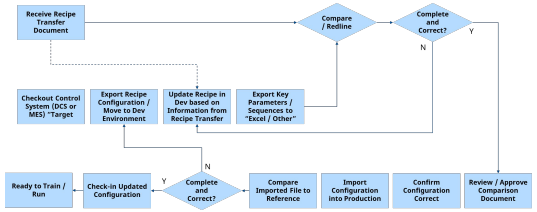
EMERSON · FUJIFILM Diosynth biotechnologies · MERCK · Pfizer · Roche

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

Digitalization in Recipe Parameter Integration with Execution Systems

Traditional Approach

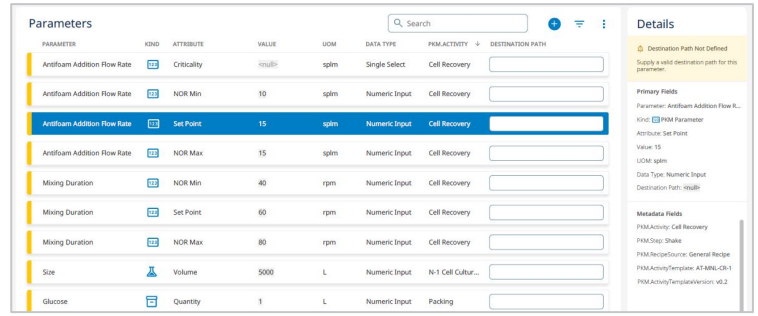
- Manual comparison of process specification to automation system



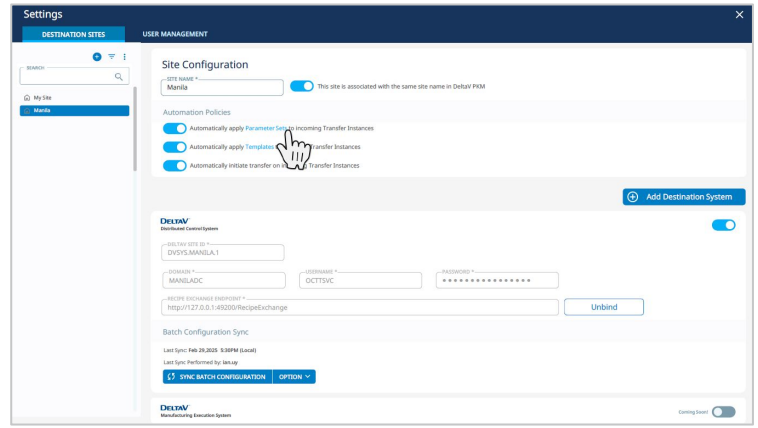
- Isolated Files / Separate Handling and Transfer

BEST Practice Approach

- Digitally compare and map process and automation parameters



- Integration to executions systems



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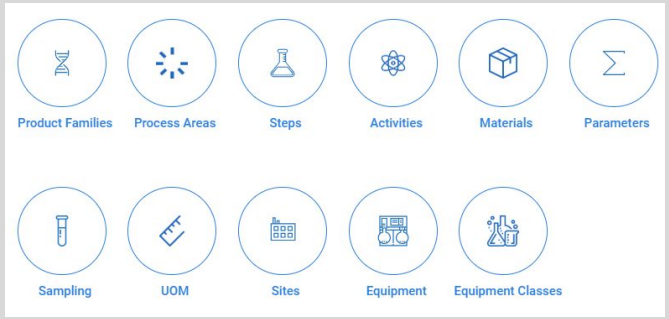
Process Knowledge Management Platform

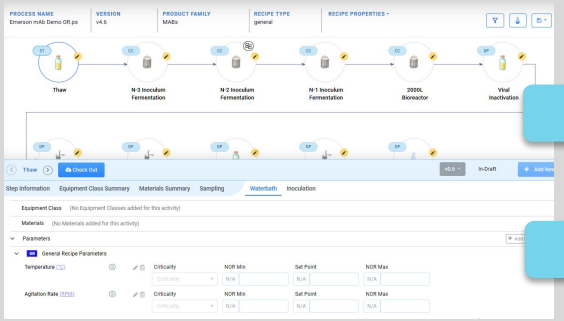
The Right Technology for an Optimized Recipe Parameter Management Work Process

Process Specification Management

Recipe Elements / Template Library



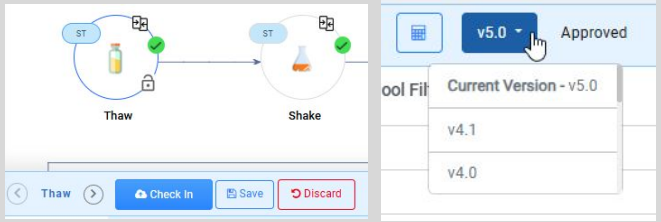
General / Site Recipe Specifications



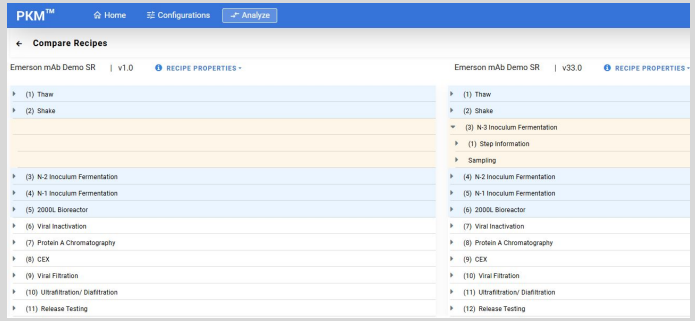
CPPs

CQAs

Change Mgmt / Propagation / Versions

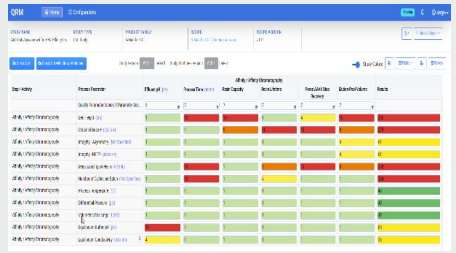


Recipe Comparison / Facility Fit

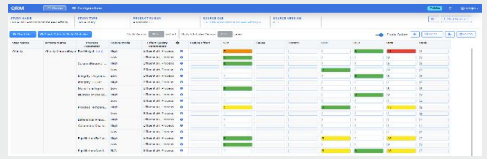


Process Risk Assessment

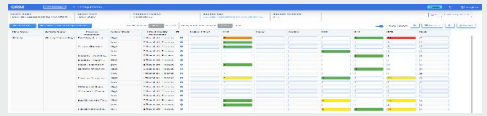
Cause & Effect Study



Failure Modes & Effects Study



Control Strategy Capture



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

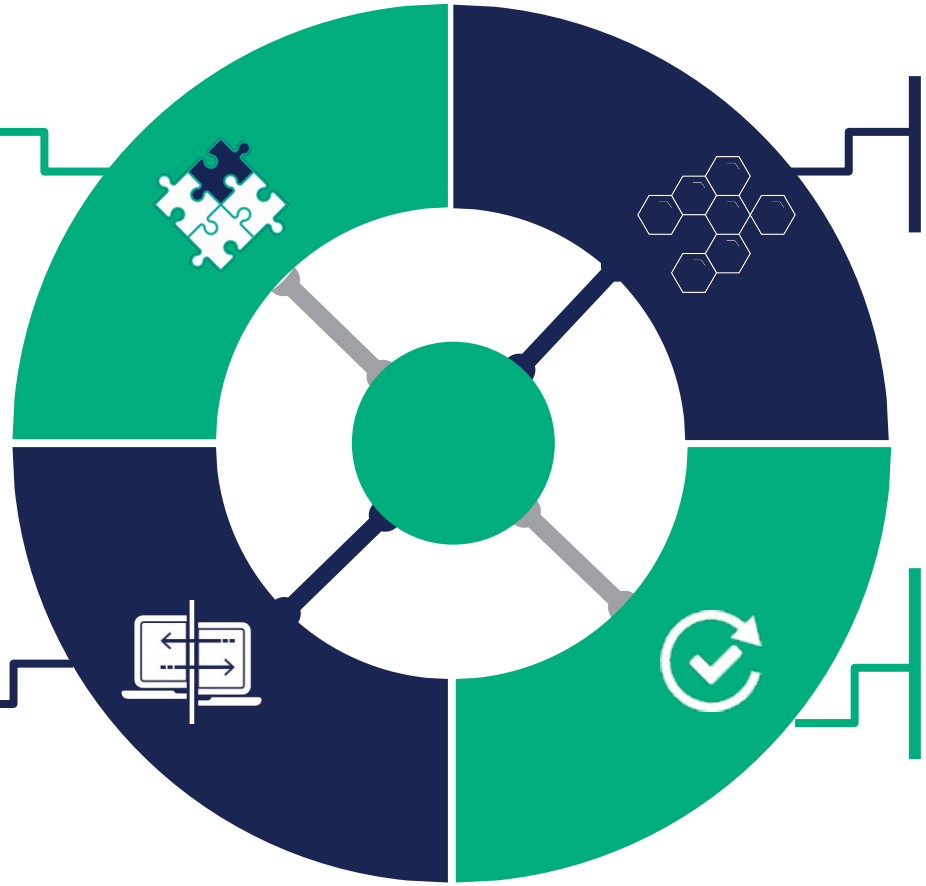
A Better Way to Time to Value for Making Digital Transfer a Reality

Standardization

Biopharmaceutical processes do not vary significantly between products

Modularity

A process is model as an arrangement of re-usable components



Parameterization

Built in flexibility through itemization of each aspect of a process step

Ability to Change

Effective and easy methods to propagate changes

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 + A…ity + Parameter + Attribute syntax creates human… …mbination of context and parameter data within t… …structurally creates unique key-va…

"**Affinity Chromatograp…**

Wash Volume **Targ…**

100 Steps / 100 Activities / 1000 Parameters / 100 Attribute…

1,000,000,000

Individual Terms without Concatenation

OR

1,300

Data Objects with Concatenation

1 Millionfold Reduction in Data Objects!

Examples

Activity + **Process Parameter** — **Mixing Temperature** → **Temperature**

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

…ttribute + **Process Parameter** — **Minimum Working Volume** → **Working Volume**

…contains a standard set of attributes …plicable

The user would fil… …e Working Volume Parameter instead

Wash

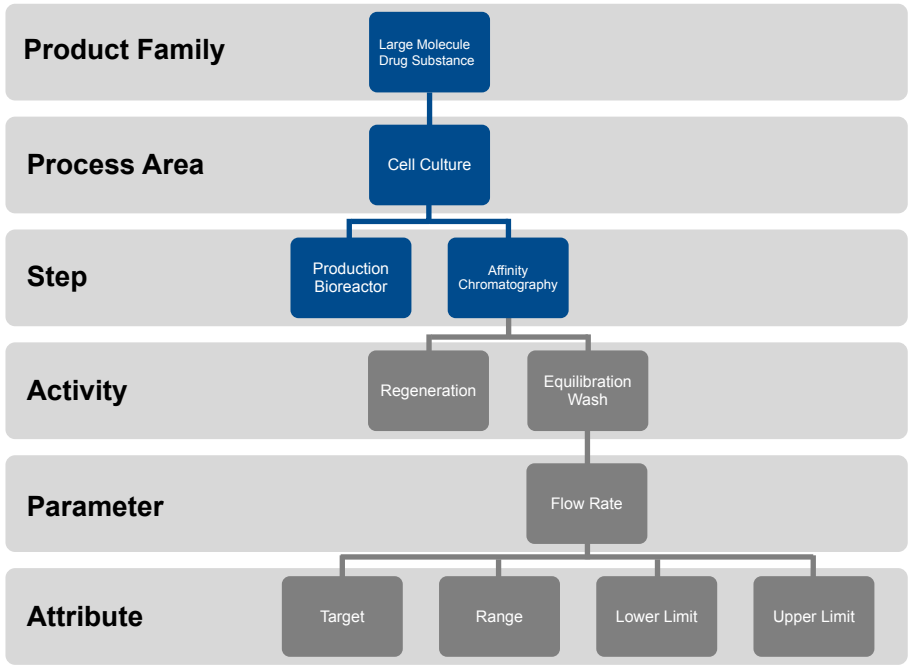
Wash 2

Wash 3

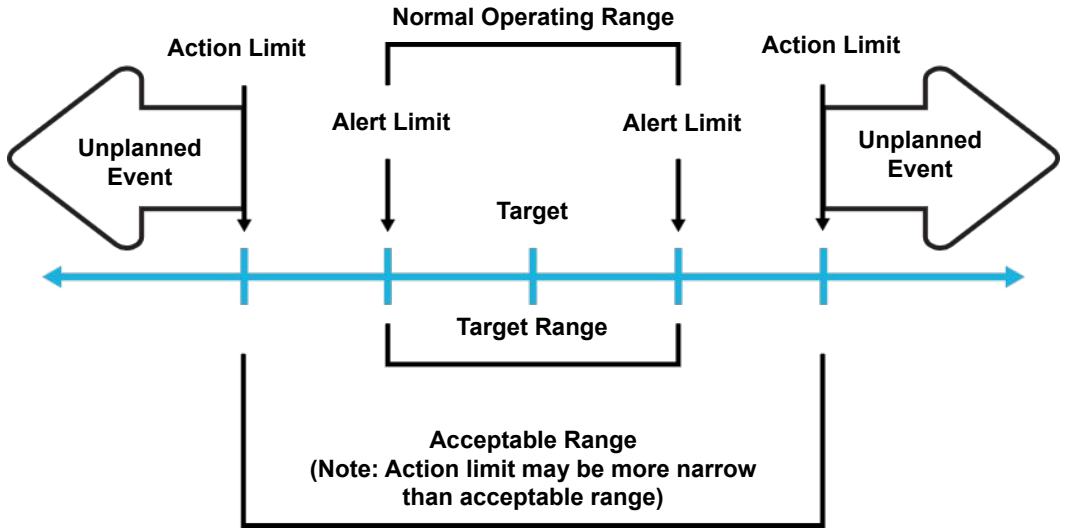
Standardized, Modular Recipe Library: Supports Submission Requirements

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

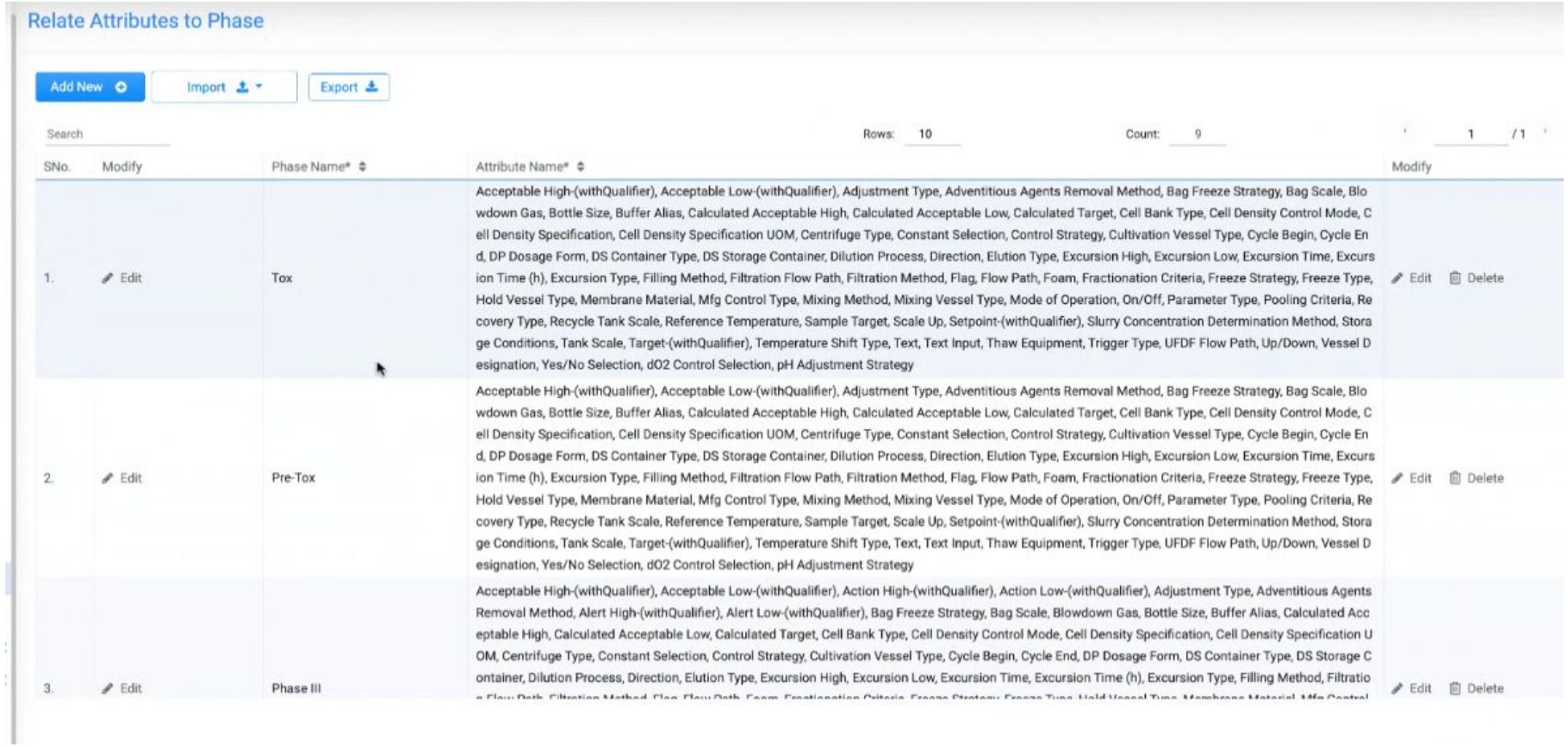


Parameter Attribute	Use	GR or SR
Setpoint	Setpoints is used when a control setpoint is required (i.e. dO2, temperature, flow setpoint) to achieve a target value.	SR
Target	Used for in-process measurements, for example: pool adjusted pH target. batch feed volume target. This attribute will be used as 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

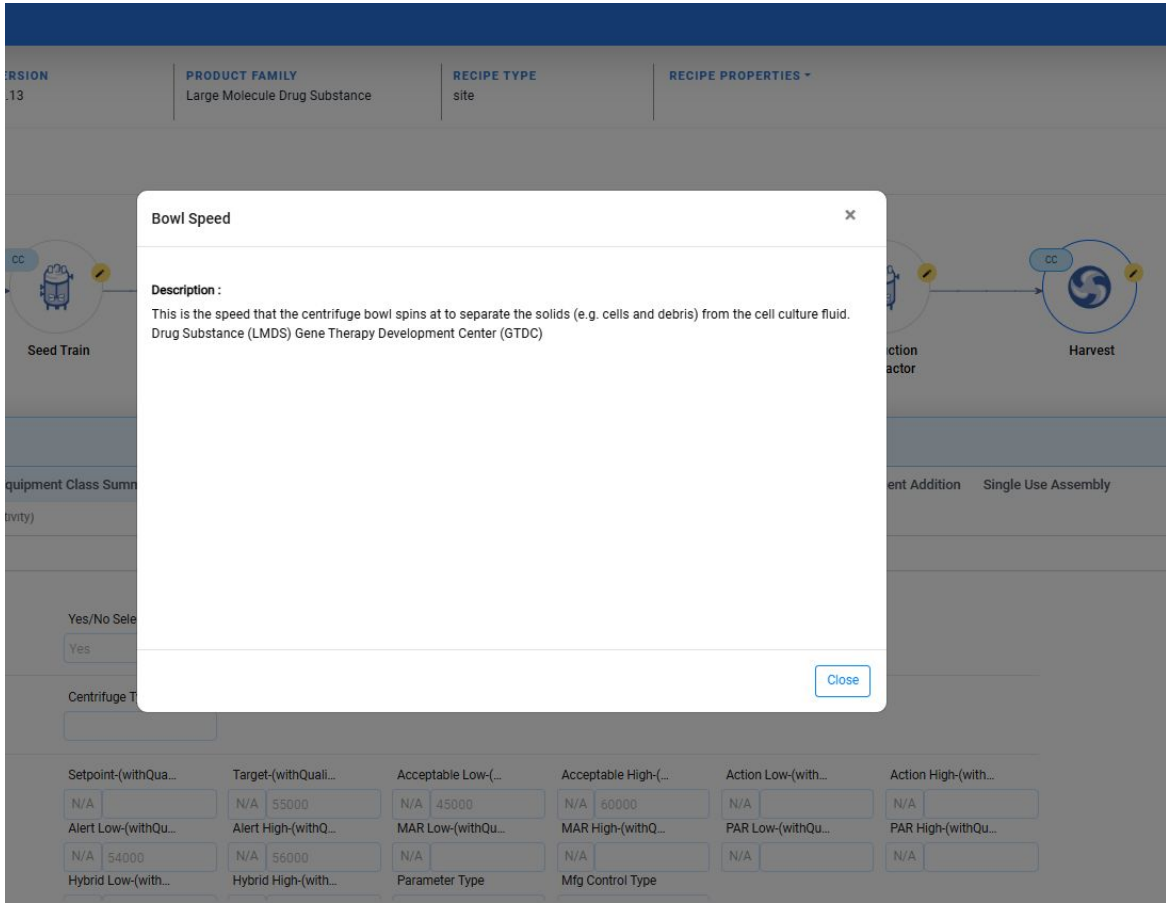
Pre-Defined Phase Appropriate Display

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

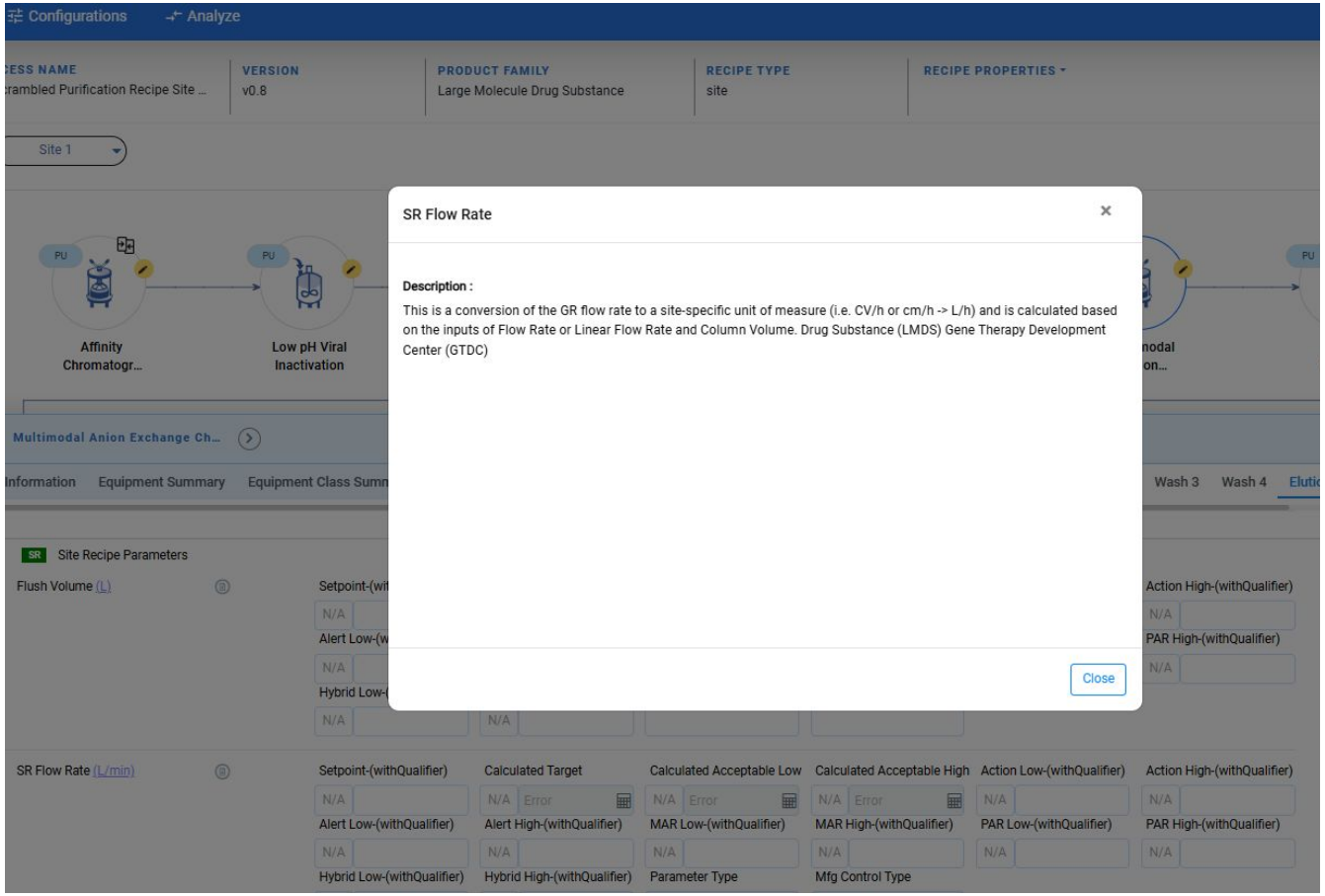


Standardized, Modular Recipe Specification Library: Supports Submission Requirements

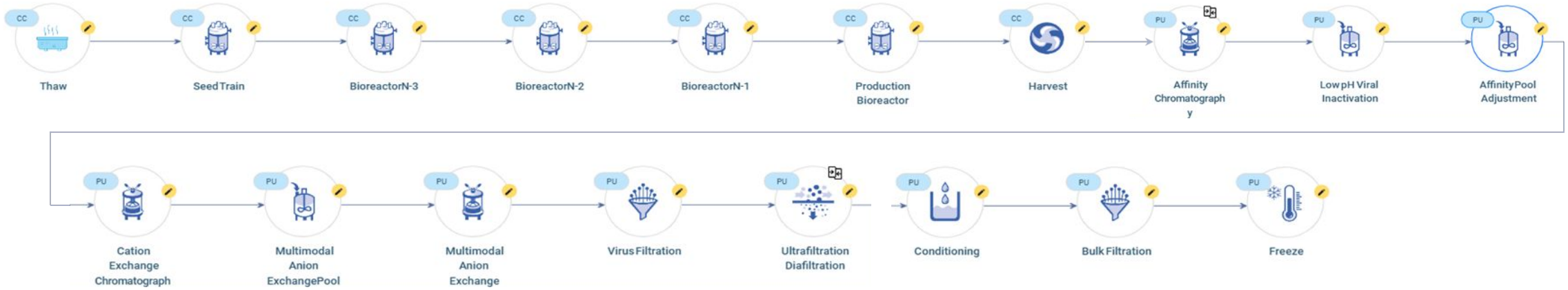
- Pre-Defined Parameter Descriptions



- Consistency Across the Enterprise



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



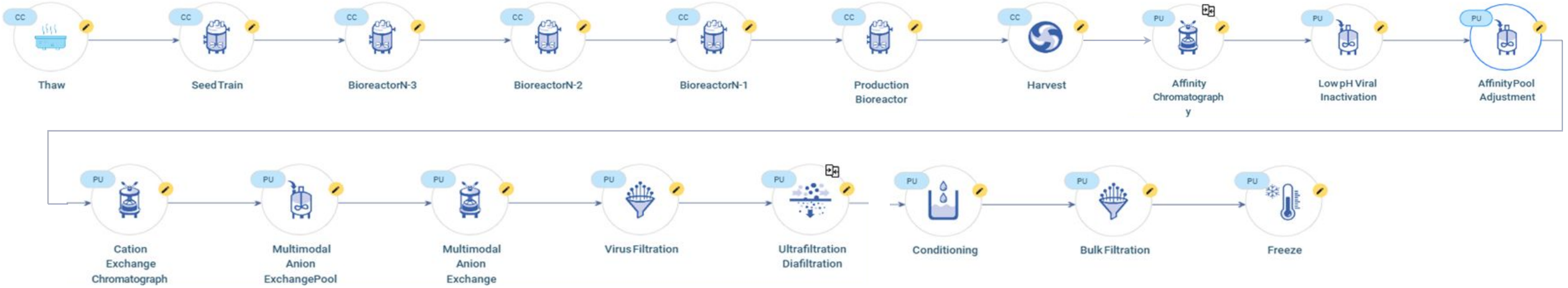
Process Area	Step Name
Media and Buffers	Buffer Preparation
Media and Buffers	Kit Preparation
Media and Buffers	Medium Preparation
Media and Buffers	Solution Preparation
Cell Culture	Bioreactor N-1
Cell Culture	Bioreactor N-2
Cell Culture	Bioreactor N-3
Cell Culture	Bioreactor N-4
Cell Culture	Production 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 Forumlation
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
Assembly	Filters
Assembly	Pool Combination
Assembly	Reductant Addition
Assembly	Single Use Assembly
Media and Buffers	Additions
Media and Buffers	Adjustment
Media and Buffers	Adventitious Agents Removal
Media and Buffers	Filtration
Media and Buffers	pH Adjustment
Media and Buffers	Weigh & Dispense
Cell Culture	Antifoam Addition
Cell Culture	Batch Feed
Cell Culture	Concentration
Cell Culture	Glucose Addition
Cell Culture	Harvest Conditions
Cell Culture	Inoculation
Cell Culture	Manipulation Conditions
Cell Culture	Passage
Cell Culture	Post Batch
Cell Culture	Post-Inoculation Addition
Cell Culture	Pre-Harvested Cell Culture Fluid (PHCCF)
Cell Culture	Pre-Inoculation Conditions
Cell Culture	Quench

Process / Step Area	Activity Name
Cell Culture	Seed Train Expansion
Cell Culture	TFDF Operation
Cell Culture	Thaw
Cell Culture	Thaw into Seed Train Bioreactor
Cell Culture	Thaw into Spinner or Shake Flask
Cell Culture	Thaw into Wavebag
Cell Culture	Transfer
Harvest	Cell Lysis
Harvest	Centrifuge Operation
Harvest	Depth Filtration
Harvest	Detergent Addition
Harvest	Flocculation
Purification	Chilling
Purification	Column Integrity Test
Purification	Column Packing
Purification	Column Unpacking
Purification	Elution
Purification	Equilibration
Purification	Expansion
Purification	Flush
Purification	Heated Hold
Purification	Infrequent Sanitization
Purification	Load
Purification	Pooling

Process / Step Area	Activity Name
Purification	Post-Use Regeneration
Purification	Pre-Cycle Elution
Purification	Pre-Cycle Equilibration
Purification	Pre-Cycle Regeneration
Purification	Pre-Equilibration
Purification	Reageant Addition
Purification	Regeneration
Purification	Regeneration Flush
Purification	Regeneration-Sanitization
Purification	Sanitization
Purification	Sanitization Flush
Purification	Sanitization-Storage
Purification	Storage
Purification	Wash
UFDF	Cassett Installation
UFDF	Conditioning
UFDF	Diafiltration
UFDF	Dilution
UFDF	Integrity Test
UFDF	Low dP Recycle
UFDF	Mini Post
UFDF	Mini Post Flush
UFDF	Normalized Permeability Test (NP)
UFDF	Pool Storage

Process / Step Area	Activity Name
UFDF	Post-Use Flush
UFDF	Post-Use Integrity Test
UFDF	Post-Use Normalized Permeability test (NP)
UFDF	Post-Use Regeneration
UFDF	Post-Use Regeneration Flush
UFDF	Post-Use Sanitization
UFDF	Post-Use Sanitization Flush
UFDF	Pre-Use Flush
UFDF	Pre-Use Integrity Test
UFDF	Pre-Use Regeneration
UFDF	Pre-Use Sanitization
UFDF	Recovery
UFDF	Recovery Blowdown
UFDF	Recovery Buffer Displacement
UFDF	Skid Sanitization and Storage
UFDF	Steam Sanitization
UFDF	Tangential Flow Depth Filtration (TFDF)
UFDF	Ultrafiltration
Cell Banking	Filling
Cell Banking	Formulation
Cell Banking	Freeze
Cell Banking	Freeze in Bags
Cell Banking	Freeze in Bottles
Cell Banking	Freeze in Tanks

Process / Step Area	Activity Name
Drug Product	Automated inspection
Drug Product	Bag to Bag Refiltration
Drug Product	Crimping
Drug Product	Manual Inspection
Drug Product	Mixing
Drug Product	Packing Configuration
Drug Product	Product Definition
Drug Product	Stoppering
Drug Product	Thaw in Bags
Drug Product	Thaw in Bottles
Drug Product	Thaw in Tanks

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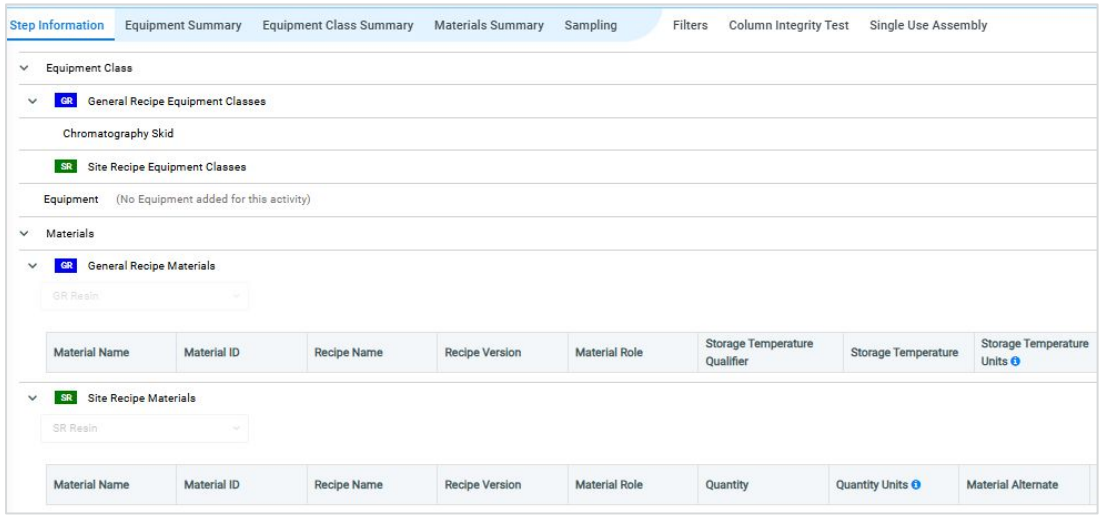
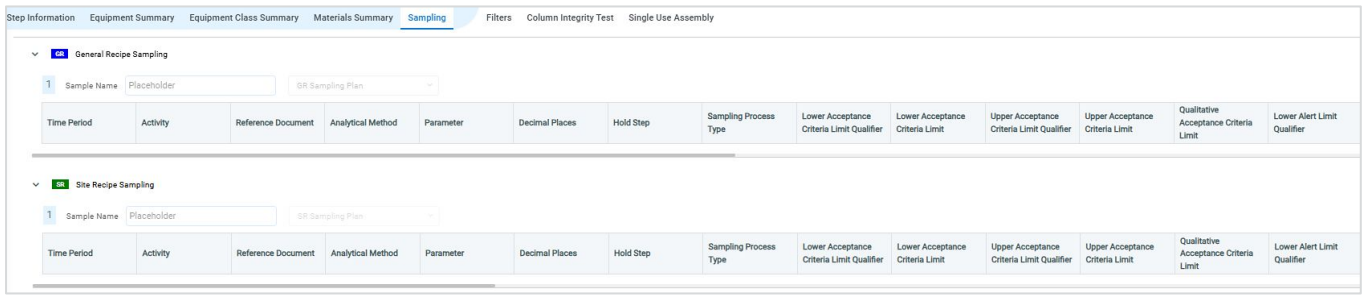
Standardized, Modular Recipe Library: Key Step Elements

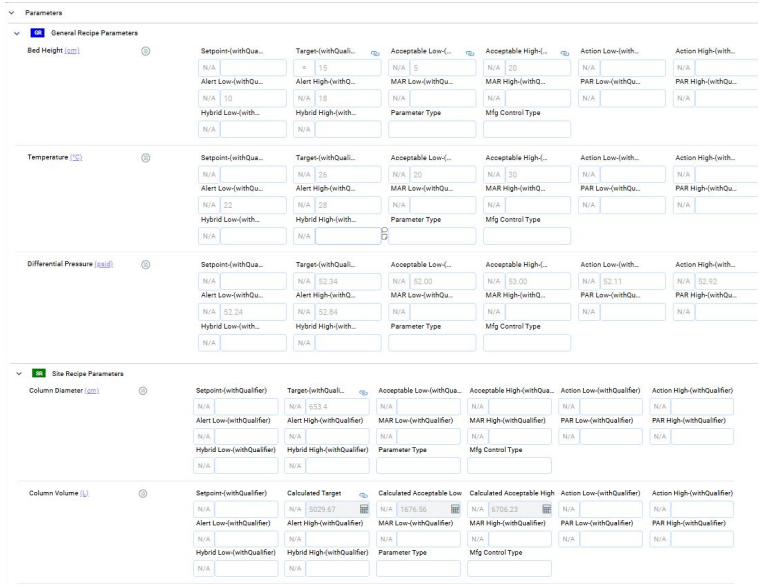
Step Equipment and Materials



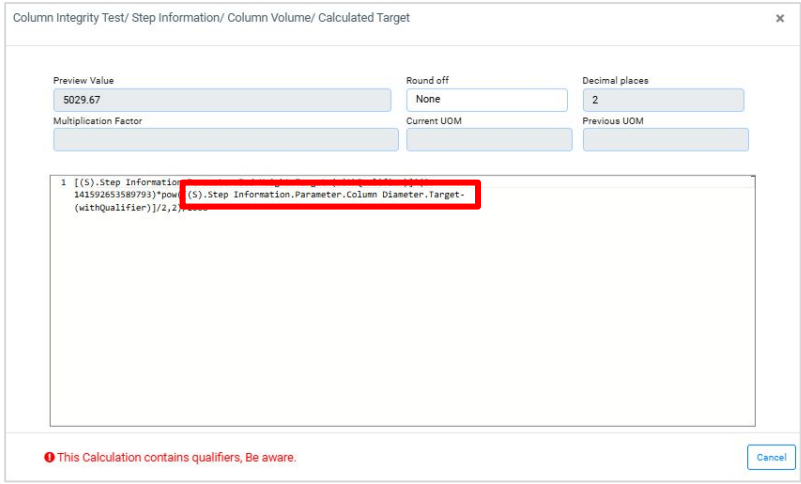
Step Sample Plans



Step General and Site Parameters



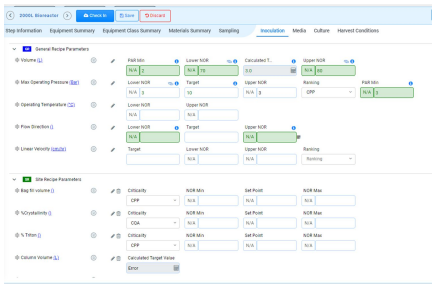
Scalable calculations based on equipment included



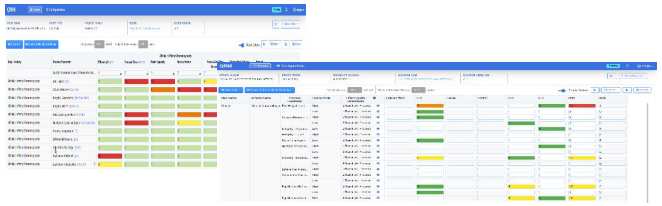
Proposed Solution / Value

- Licensor Process Development Planner
- Licensor Manufacturing Automation Planner

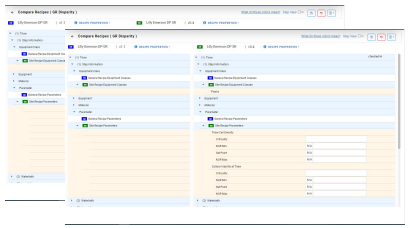
Licensor Process Specification



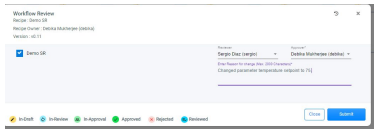
1 Licensor “Blue-print” modality recipe
- Modify to product specific “line” recipe



2a Digitally assess parameter relationships and do FMEA / Control Strategy to manage risk



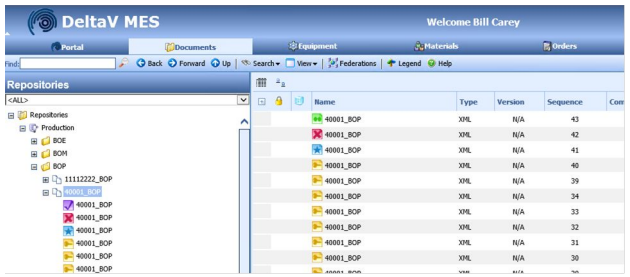
2b Digitally compare “product line recipe” to Licensor production capabilities for best fit



3 Update targeted Licensor site recipe to address gaps
- Versioning / joint digital reviews
- Audit trail

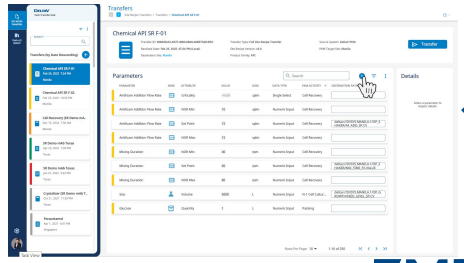
PKM Platform

4 Finalized site recipe on planned Licensor line
- Joint digital reviews
- Versioning



Transfer Hub Integration to Licensor Execution

5 Map of PSM elements to execution system parameters



EMERSON

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

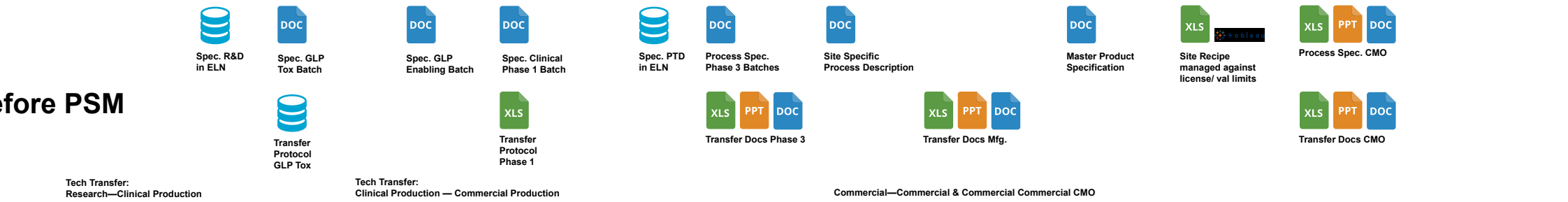
Over **12 disconnected, inconsistent data silos** between phases and departments

Manual translation of specifications between phases and organizations

Zero standardization of step names, parameters, equipment requirements, sample information

Data Integrity Risks throughout: error-prone, manual copy & paste methods to transfer data and synchronize increasingly difficult between distributed systems

Before PSM



PSM Layer

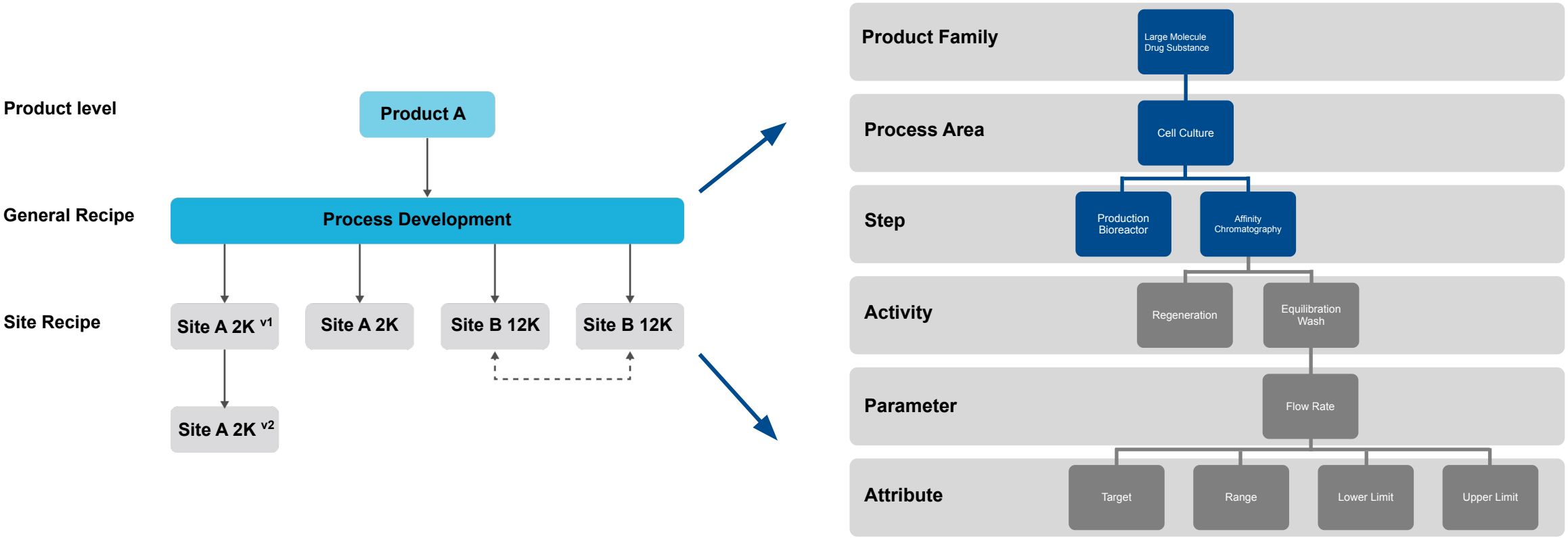
Seamless data flow through different product phases and organizations

Harmonized master data enables standardization of process specifications

Single source of process information independent of originator and elimination of silo synchronization

2-4 month realized Tech Transfer time savings through elimination of "technical translation"

Roche Product Data Architecture Philosophy



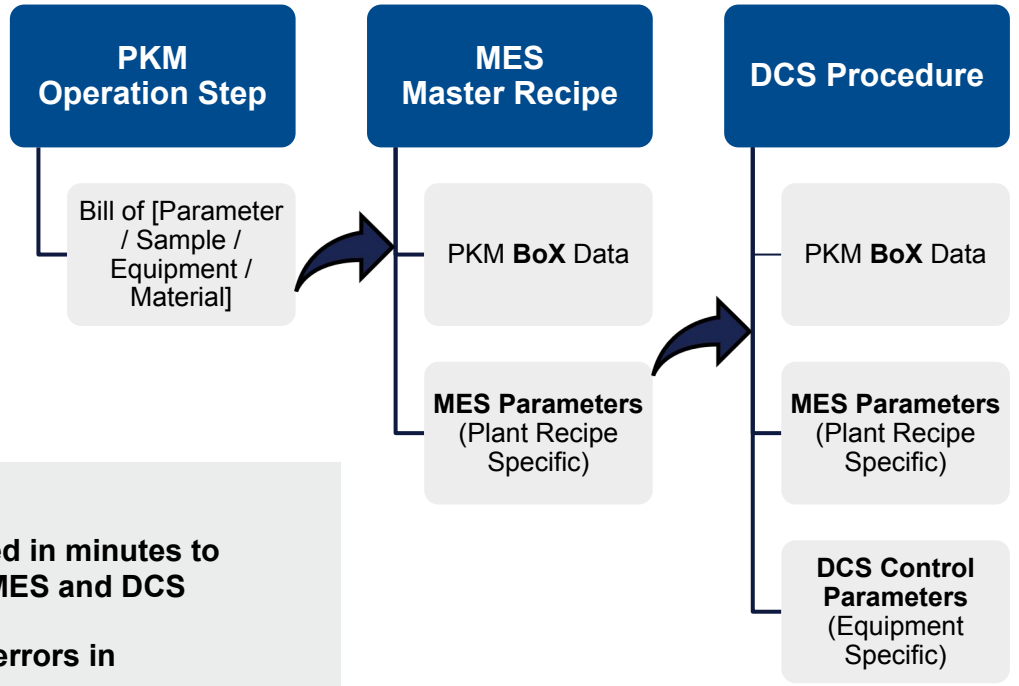
Roche recognized the need to **establish master data ownership** and consistency across development programs to improve process prior knowledge management, accelerate ML data opportunities, and avoid the growth of unstructured product data siloes

Roche PSM Case Study: Genentech Clinical Supply Center

Production Bioreactor

ProdBio_Add_p_Fee2_Tar

Production Bioreactor Additions Feed 2 Target



Result:

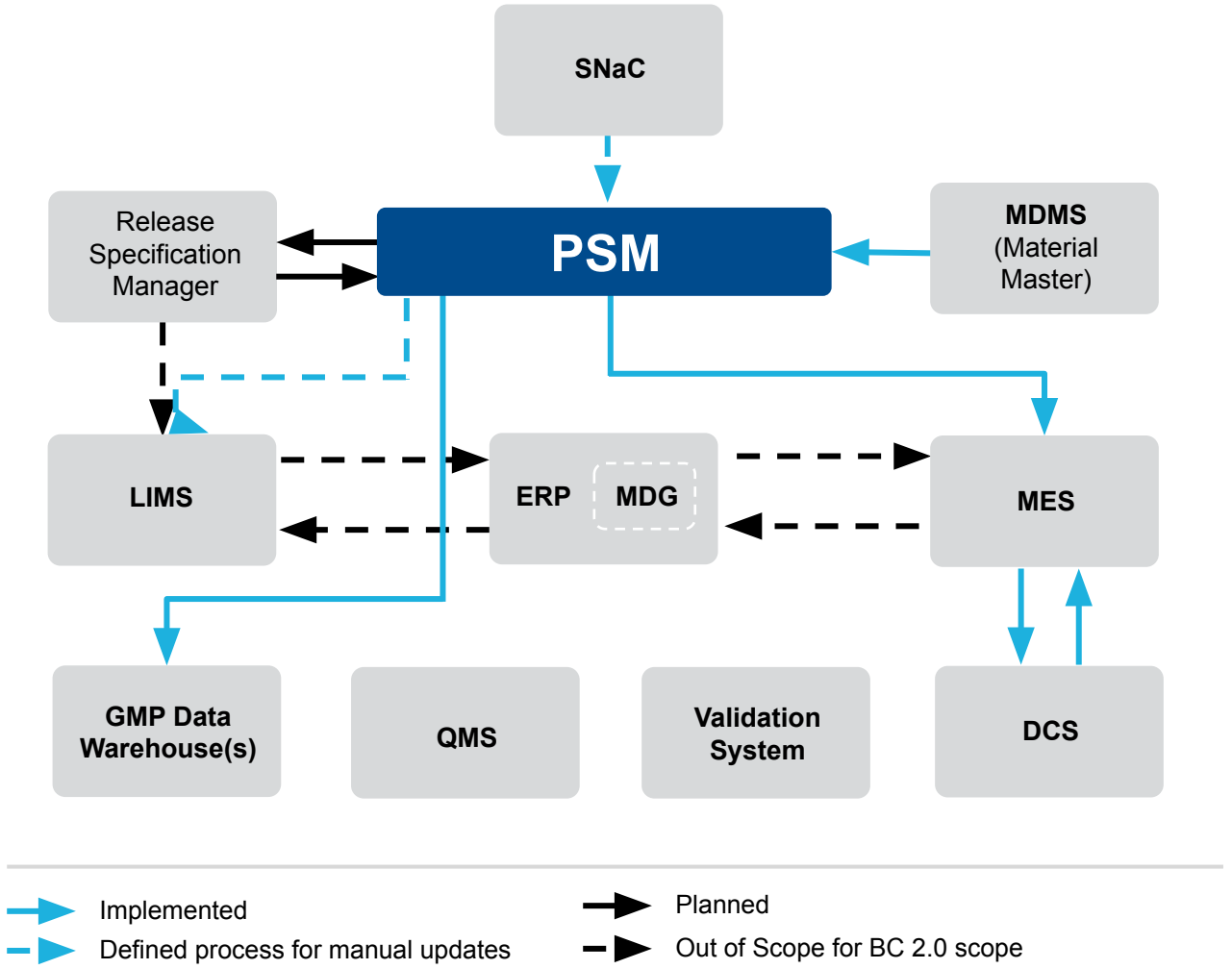
- **Thousands of parameters transferred in minutes to auto-approved recipe templates in MES and DCS**
- **Elimination of human transcription errors in batch creation**
- **Reduction in 7 FTEs for recipe authoring annually for 10 tech transfer per year**

5 Minute Creation of Master Batch Records

Roche Emerson Exchange presentation 2025 May

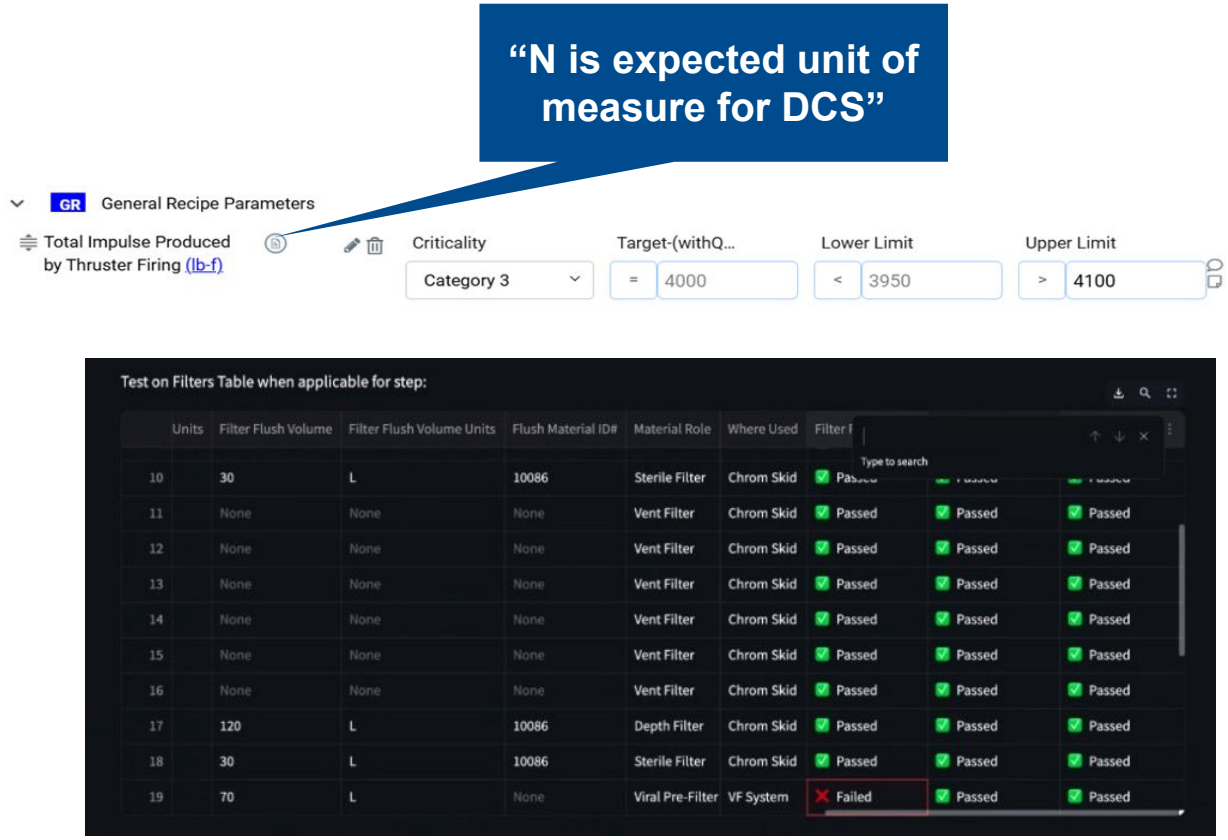
PSM Central to Roche IT Landscape

- 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.



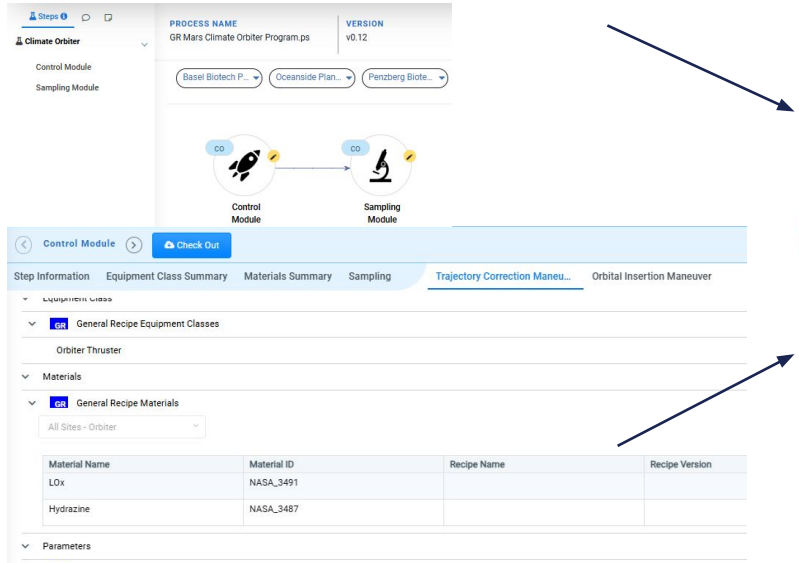
Beyond Roche Execution: PSM Data Accessibility

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



Beyond Roche Execution: PSM Data Accessibility

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



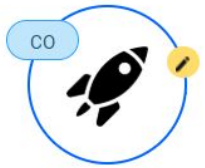
Recipe Name	Most Recent Recipe Version	Recipe Version	Step Name	Activity Name	Component Name	Parameter Type	Field Name
1.0 M NaOH, 1 M NaCl	Yes	v0.5 - 1.0 M NaOH, 1 M Na...	Buffer Preparation	(All)	(All)	N/A	(All)

Recipe Name	Recipe Versio..	Step Name	Step Versio..	Activity Name	Component Ty..	Parameter Ty..	Component Name	UoM
1.0 M NaOH, 1 M NaCl	v0.5	Buffer Preparation	v1.0	Step Information	Parameter	N/A		
1.0 M NaOH, 1 M NaCl	v0.5	Buffer Preparation	v1.0	Step Information	Parameter	N/A		

Beyond Roche Execution: PSM Data Accessibility

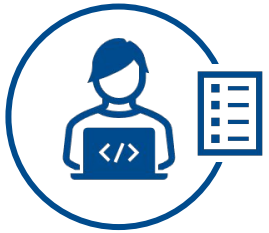
PSM Solution

PKM™



Control Module

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

EMERSON

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
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  - bob.lenich@emerson.com
  - www.linkedin.com/in/bob-lenich

Thank you!

EMERSON