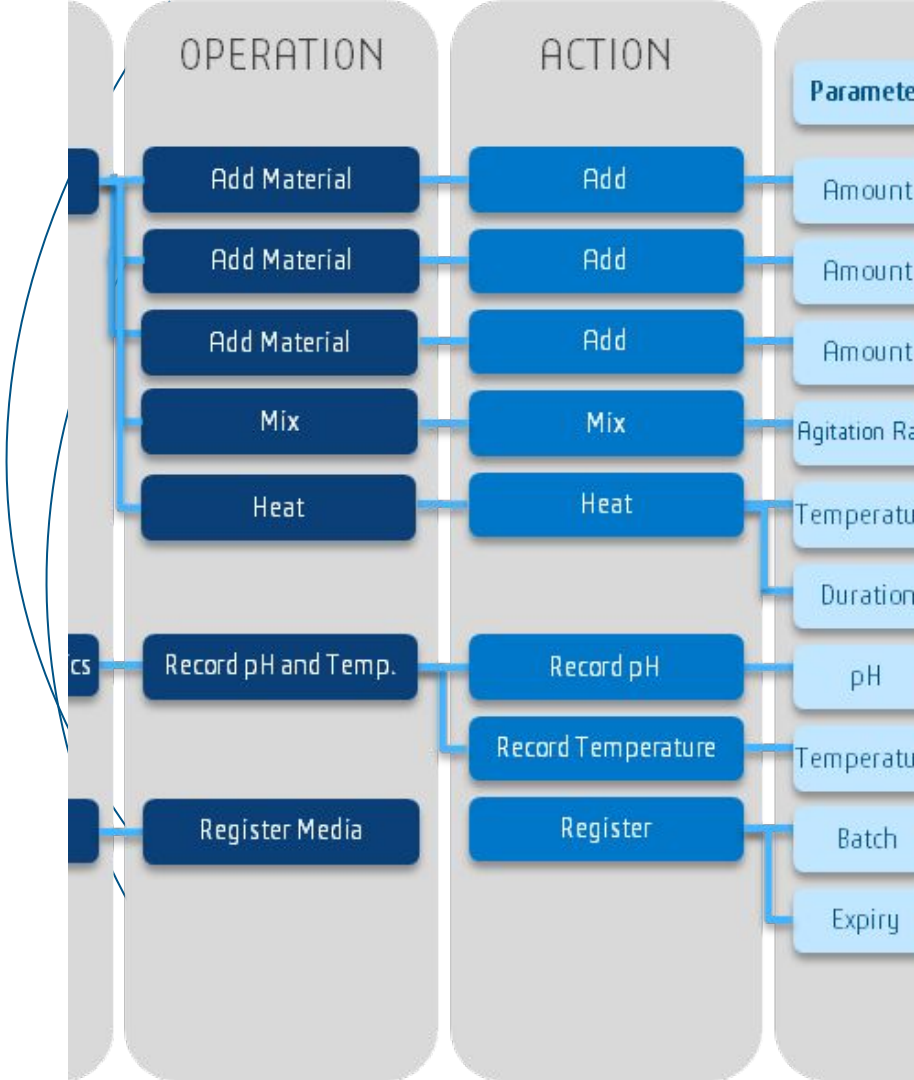
S88 IN THE LAB
NOT JUST FOR BATCH PROCESSING

Gene Tetreault, Sr Director BIOVIA R&D



WHAT AND WHY S88?

- S88, shorthand for ANSI/ISA88, is a standard addressing batch process control. It begun as part of the ISA's standardization activity started in 1988.
- Design philosophy for describing equipment, and procedures (Recipes & Methods)
- Provides a comprehensive and modular methodology for designing, implementing, and managing batch processes.
- Defines what the main building blocks of a recipe (procedure, unit procedure, operation, and phase) look like and how they interact
- Streamlines process authoring and standardize structured data capture

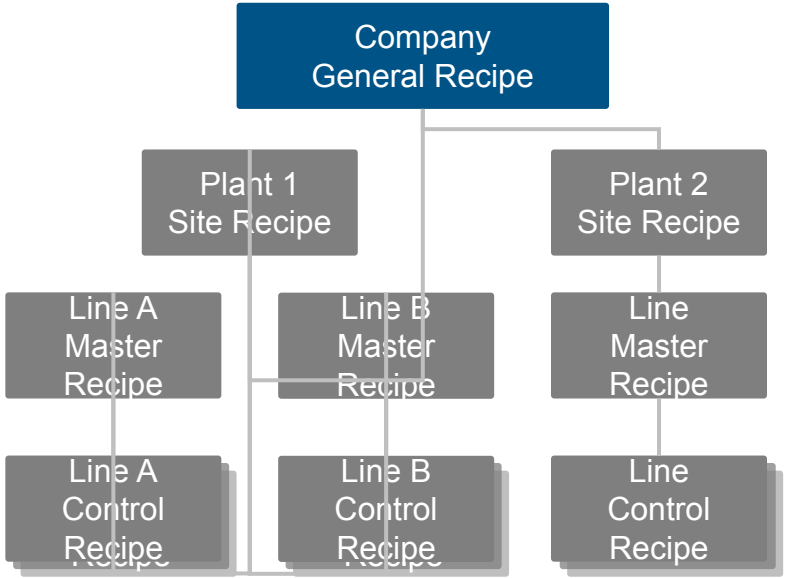
https://en.wikipedia.org/wiki/ISA-88

Meaning of Angel Number 88

Angel number 88 is a sign of great success, abundance, and prosperity. When this number keeps appearing in your life, it indicates that exciting and positive changes are on the horizon. Your guardian angels or spirit guides are trying to prepare you for the wonderful opportunities that lie ahead.

DASSAULT SYSTEMES

S88 CONCEPTS FOR RECIPE AUTHORING



- Enterprise / Site / Master / Control levels for proper harmonization.
- Process / Stage / Operation / Action building blocks for proper parametrization.
- Enables Tech Transfer from Development to Manufacturing.

DIGITAL PRODUCT DEVELOPMENT □ DIGITAL TECH TRANSFER

Development

Manufacturing

API	Composition	Process Investigation Formulation	Analytical Methods Manufacturing Recipe Formulation	Specification Analytical Methods Manufacturing Recipe Formulation

Unmet Medical Need
TPP, QTPP

QbD
DoE

Instrument Data
Samples
Registered entities

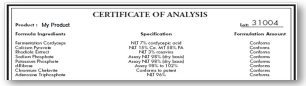
Materials
CQAs

Equipment
Instructions
CPPs

Site
Manufacturing Line
Batch Record

Design of Experiments

Scale and Transfer

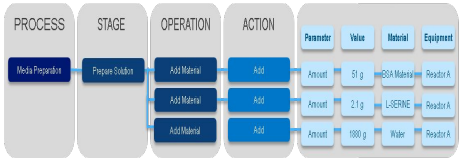


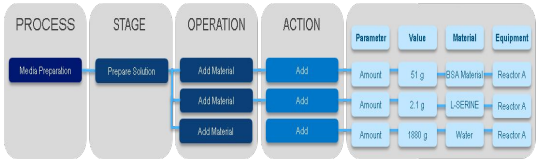
Experiment

Process

Ontology

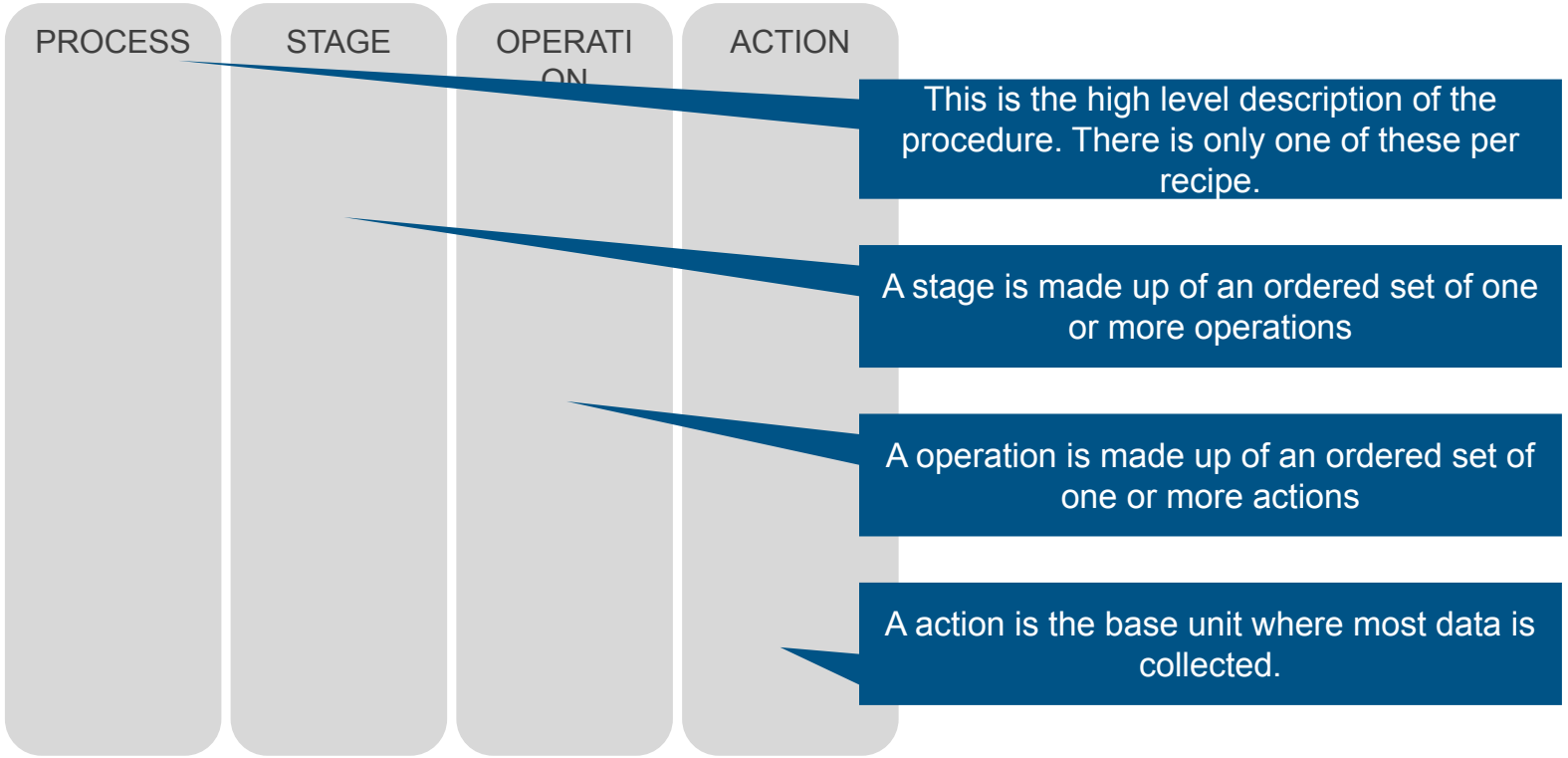
Adhoc Process & Data Capture



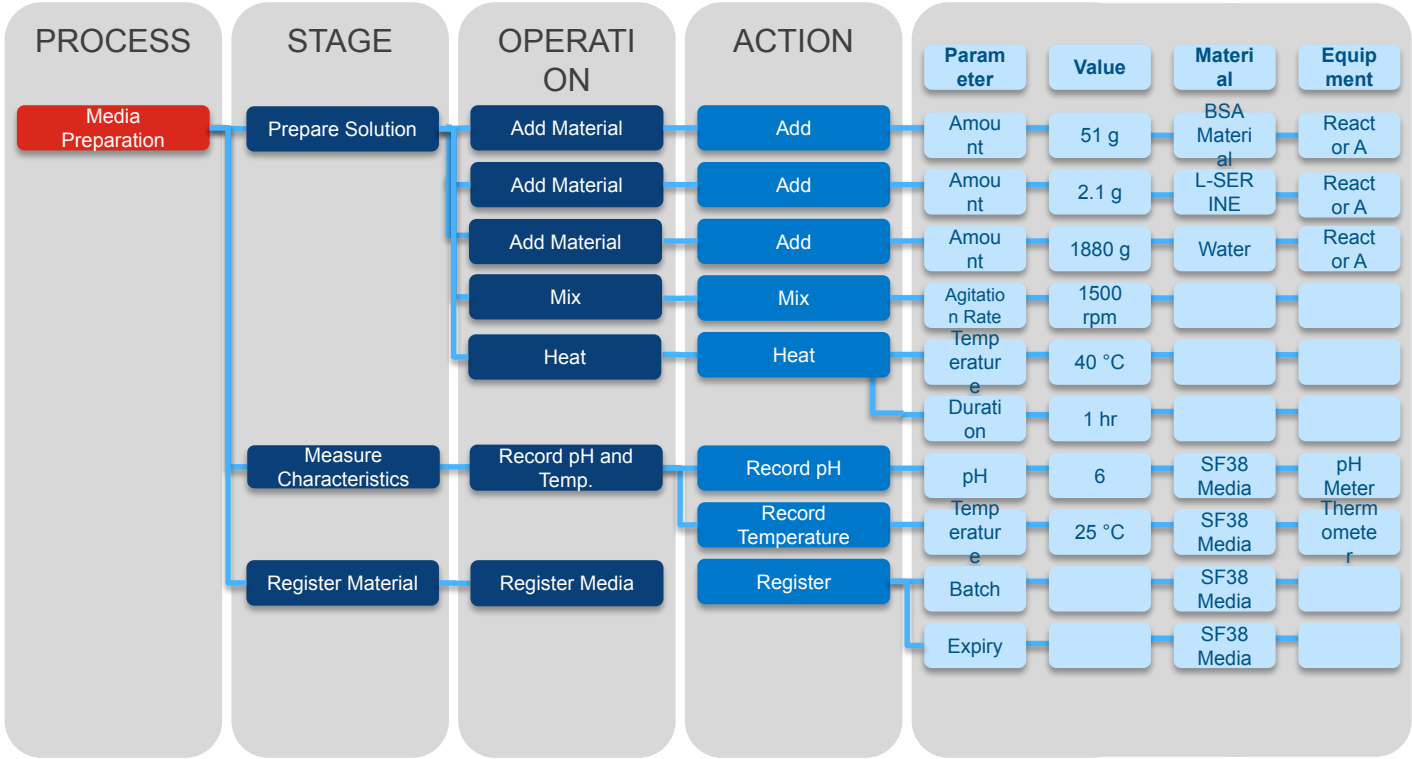


Materials, Equipment, Operations, Parameters, …

S88 CONCEPTS FOR PROCESS AUTHORING



S88 CONCEPTS FOR PROCESS AUTHORING



ONTOLOGIES FOR LIFE SCIENCE

Upstream Thinking

Unmet Medical Need
Biological Target
Drug landscape
Therapeutic Indication

Population
Cohort
Subject
Characteristics

Living System
Biological Entity
Biological Function
Organism
Organ
Tissue
Cell
System
Influence

Company / Organization
Business Interaction
Pipeline
Drug Portfolio
Location

Research & Development

Material Substance
Cell Line
Nucleic Acid
Protein
Sequence
Conjugate
Small molecule
Structure

Materials
Material
Composition
Characteristics
Supplier
Package
Lot
Container
Chain of Custody

Resources
Equipment
Measurement
People
Skills
Capacity
Schedule

Experiments
Study
Experiment
Plan
Expectations
Parameters
Result
Analysis
Outcome

Process
Process
Stage
Operation
Action
Method
Formulation
Recipe
Ingredient
Reaction
Reaction Scheme
Process Transfer Doc

Clinical Trials
Clinical Site
Patient
Prescriber
Trial Protocol
Trial Master File

Regulatory
IND Authorization
Common Technical Document (CTD)

Product
Part
Assembly
Label
Artwork
Packaging

Specification
QTPP

Manufacturing

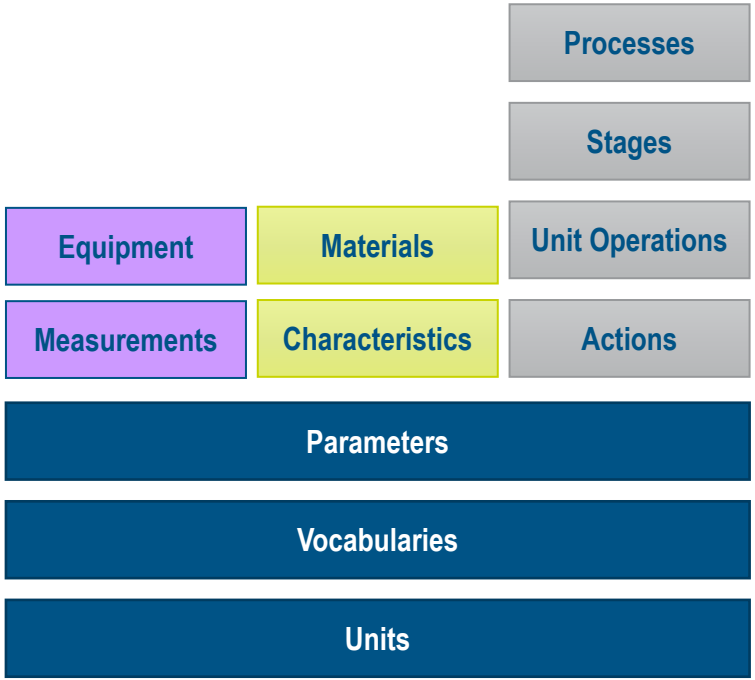
Plant
Manufacturing Site
Production line
Production unit
Equipment

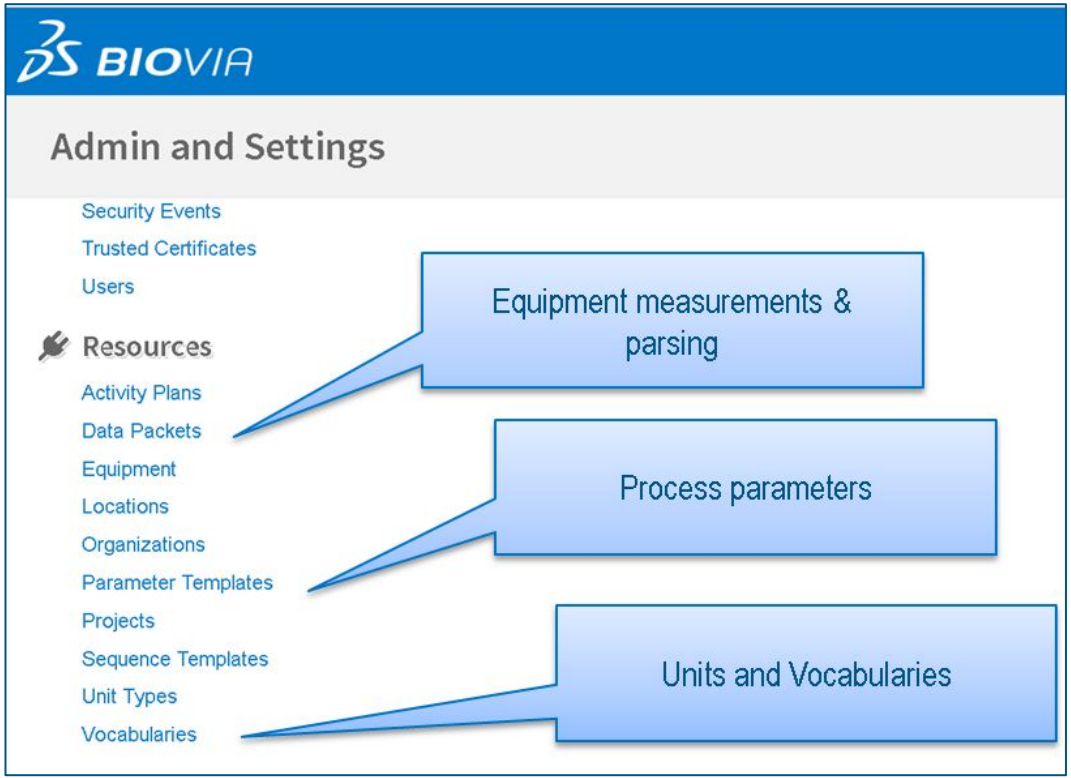
Quality/change control
Incident
Deviation
CAPA

Pharmaceutical Product
Active Pharmaceutical Ingredient (API)
Administration Route
Administrable Dose Form
Mode of Action
Batch Record

DASSAULT SYSTEMES

REFERENCE DATA



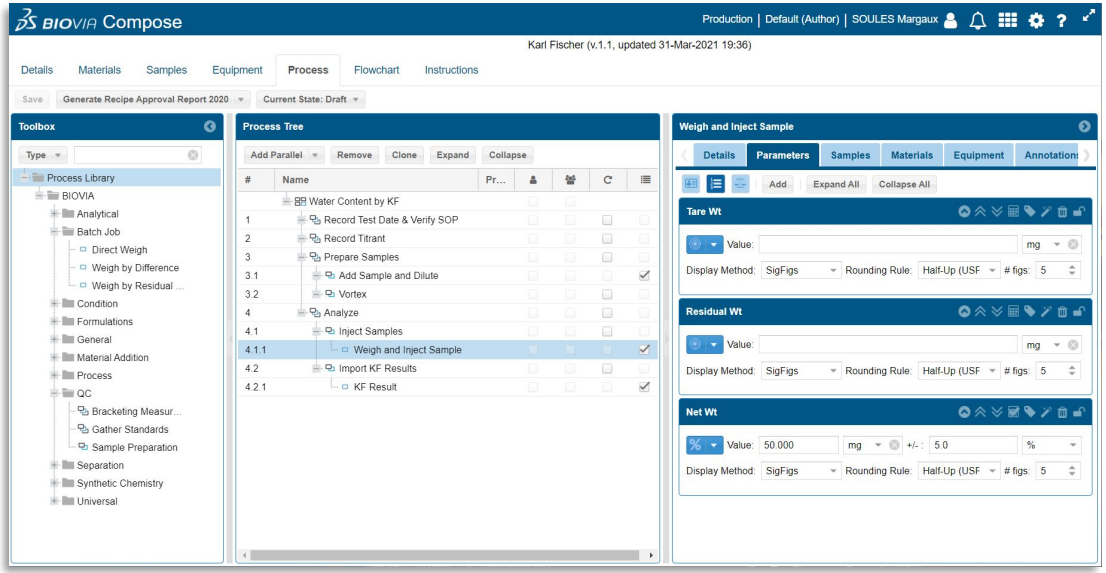


STANDARD UNIT OPERATIONS

RECIPE AND METHOD MANAGEMENT

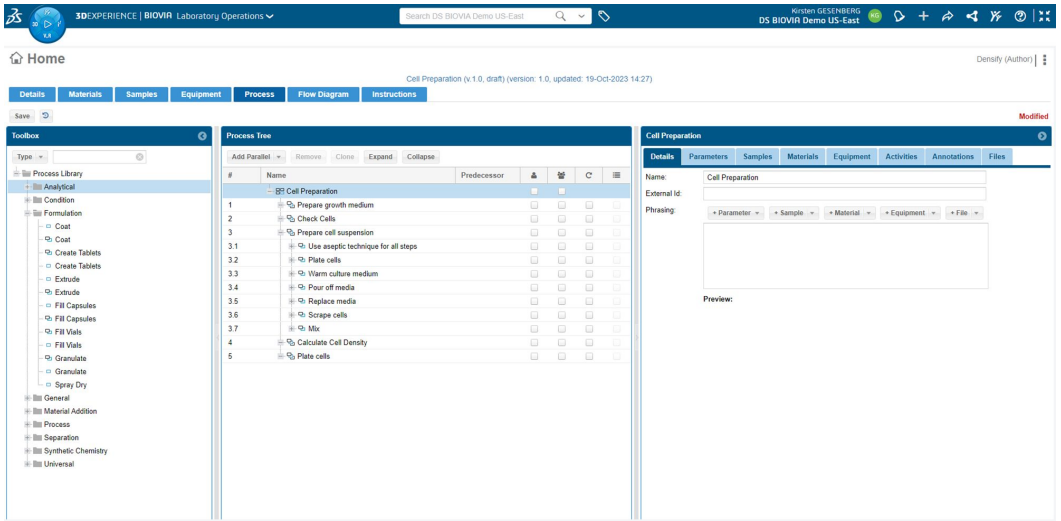
Create and store recipes and methods with standardized libraries of operations

- S88/S95 standard design for procedure authoring
- Harmonization of recipes and methods:
- Process elements library managed by super-users (master data)
- Generic method capabilities to optimize procedure management
- Enabling deployment scalability



THE MAIN CHALLENGE IMPLEMENTING A LAB EXECUTION SYSTEM (LES)

Digitizing the processes to run electronically in the solution



THE MAIN CHALLENGE IMPLEMENTING AN LES

Simplified HPLC method as an example

HPLC Method

Abstract

Materials

Reagents

- Buffer – R1 +R1 bis
- Diluent A – R1 + R2
- Eluent A – R1 + R2
- Eluent B– R3 + R4
- Washes – R5 + R6

Std prep

- Std1 – diluent + std
- Refstd – diluent + refstd

Sample prep

- Sample Weight 1 – diluent + sample
- Sample Weight 2 - diluent + sample

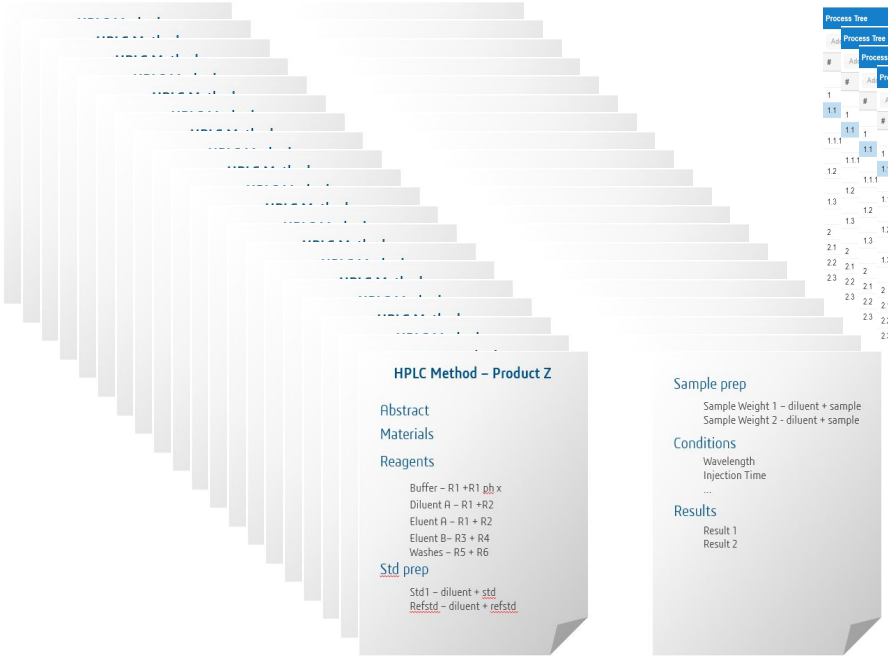
Conditions

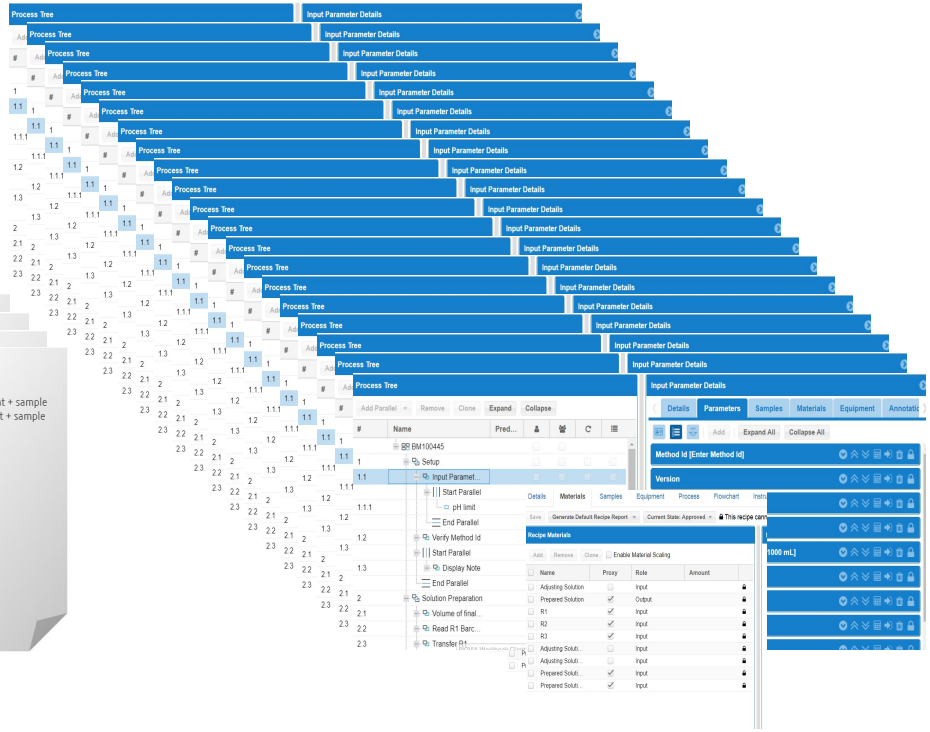
- Wavelength
- Injection Time

Results

- Result 1
- Result 2

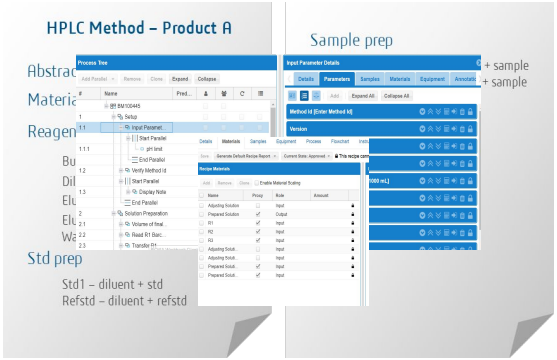
CREATE AN ELECTRONIC VERSION

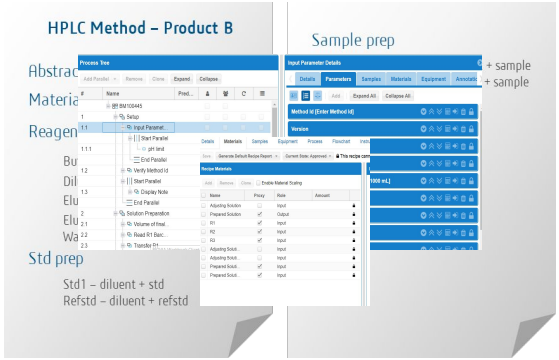


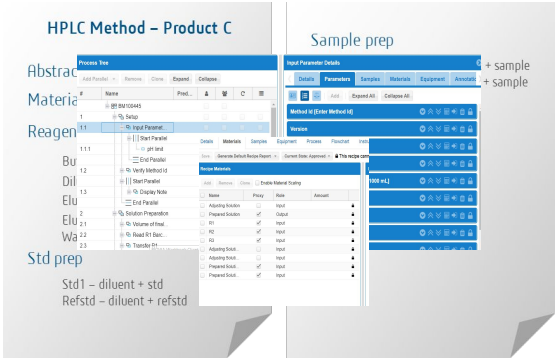


100’s of methods

EACH METHOD NEEDS TO BE QUALIFIED FOR USE







Qualify each method

Repeat for all the different processes that are executed for each product

LET US LOOK AT THE SIMPLIFIED HPLC AGAIN

Simplified HPLC method as an example

HPLC Method

Abstract

Materials

Reagents
- Buffer – R1 +R1 ph X
- Diluent A – R1 +R2
- Eluent A – R1 + R2
- Eluent B– R3 + R4
- Washes – R5 + R6

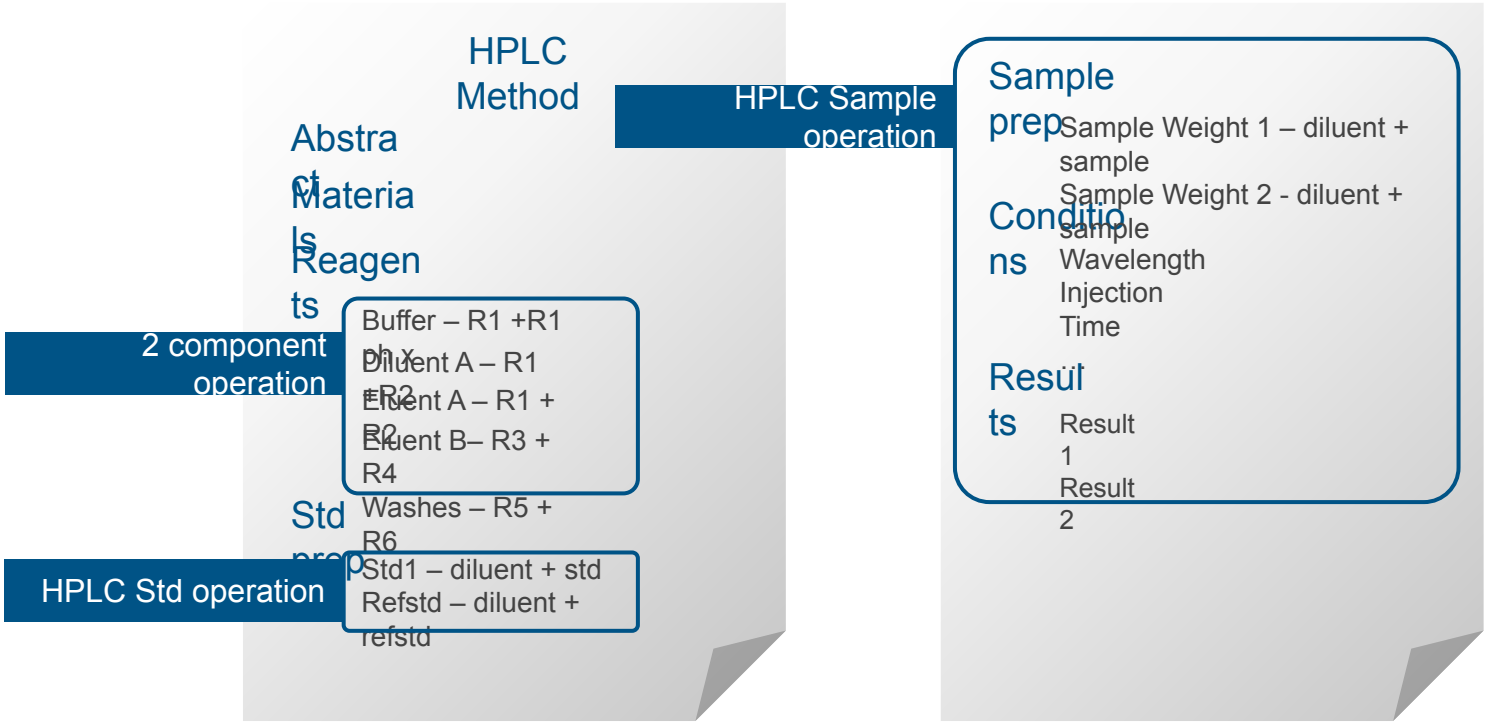
Std prep
- Std1 – diluent + std
- Refstd – diluent + refstd

Sample prep
- Sample Weight 1 – diluent + sample
- Sample Weight 2 - diluent + sample

Conditions
- Wavelength
- Injection Time

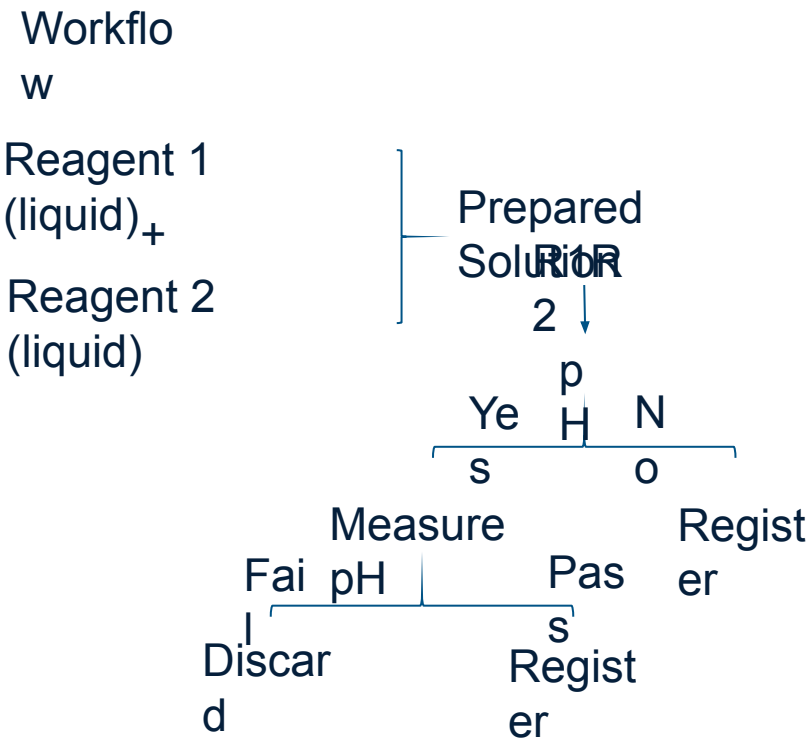
Results
- Result 1
- Result 2

BREAK UP THE METHOD



GENERIC TEMPLATE CONCEPT

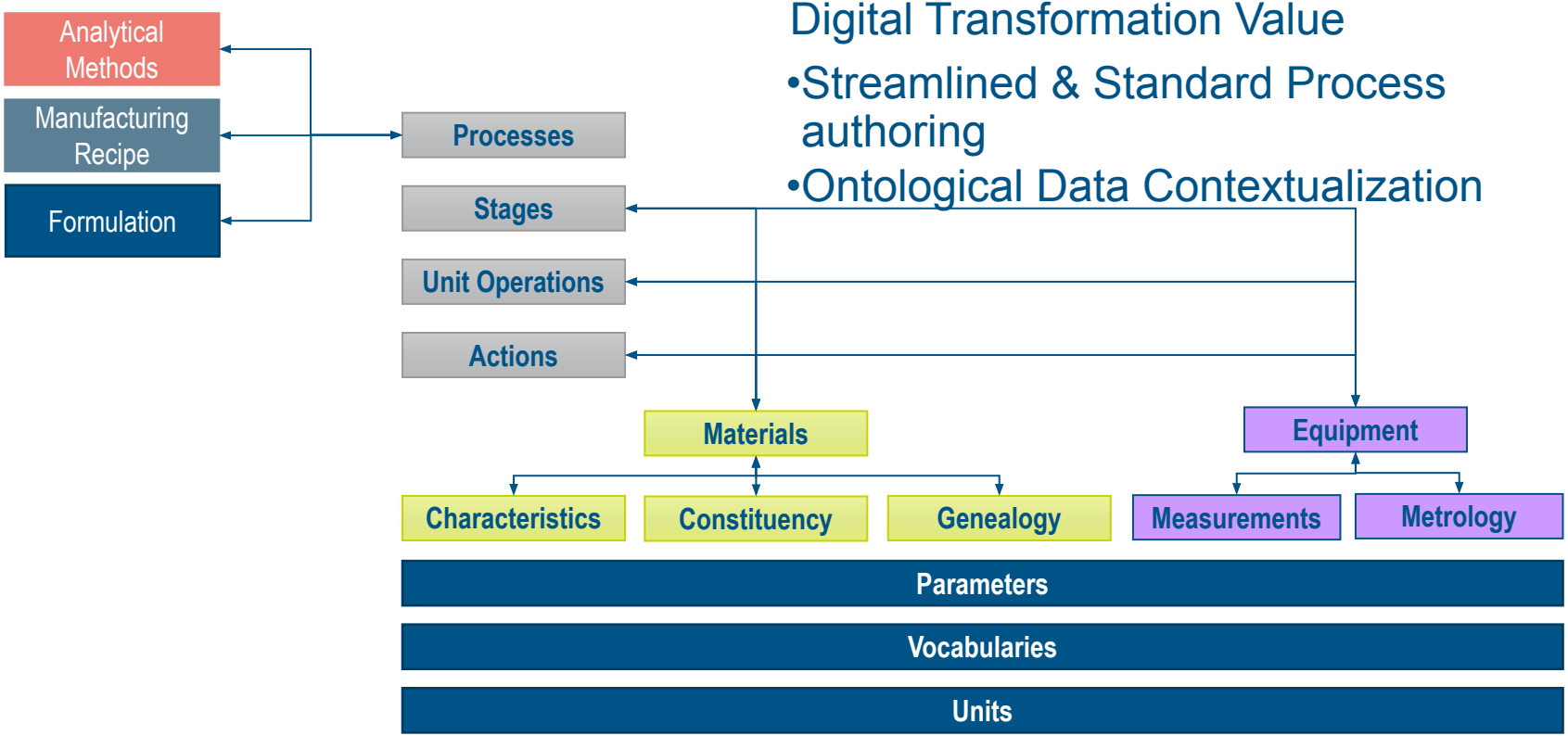
- *Solution Preparation*



Input Parameters

- The Name of the Reagents/Materials
- How much you are making
- The volume to add (the scaling factor)
- The units
- The format
- Does it need a pH?
- Yes
- …

DIGITAL TRANSFORMATION FROM DEVELOPMENT TO MANUFACTURING



Digital Transformation Value

- Streamlined & Standard Process authoring
- Ontological Data Contextualization

DASSAULT SYSTEMES