



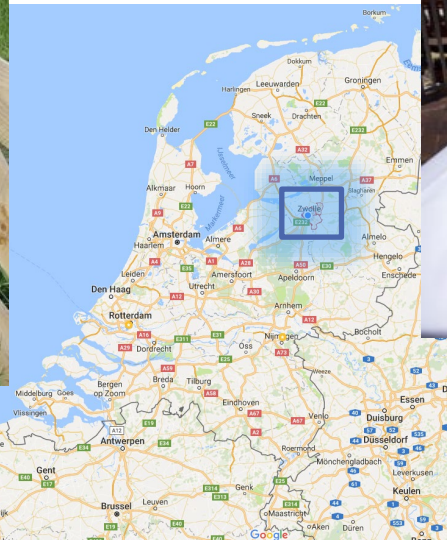
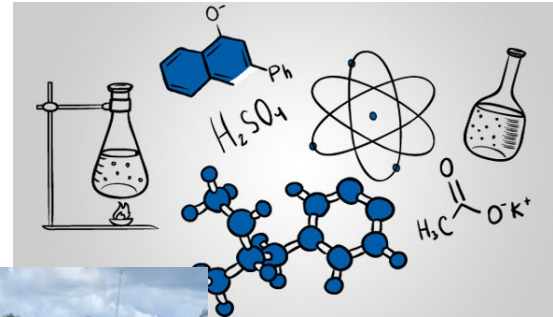
Abbott



Sophisticating NPD with Devex Advanced Formulation Suite

September 28, 2023

Who am I



Who am I @ Abbott?

- **Started @ Abbott in 1987**
- **Since then:**
 - QC Laboratory Technician
 - PR&D Product Developer
 - QA Operations manager
 - BEx Project Manager (LSS BB)
 - R&D Program Manager Europe
 - OnePLM/Devex Program Manager



life. to the fullest.®

Shaping the future of health: putting more control of your health in your hands

DIGITIZE

Connect people with meaningful, timely, accurate and actionable information about their health

DEMOCRATIZE

Make health tech accessible, personal and convenient so more people in more places can benefit from it

DECENTRALIZE

Deliver care where and when it's needed beyond the hospital or clinic



Abbott at a glance

115,000

PEOPLE

135

YEARS IN BUSINESS

160+

COUNTRIES

\$43.7B

2022 SALES

TRUSTED PRODUCTS

FreeStyle Libre[®]

MitraClip[™]

Similac[®]

Alinity

Ensure

pediasure[®]

Duphaston[®]
Dydrogesterone

BinaxNOW[™]

Pedialyte[®]

Eterna[™]
SCS System

BurstDR[™]
Stimulation

Xience[™]

BRUFEN

AVEIR[™] VR
Leadless Pacemaker

Products may not be available in all markets.

NUTRITION

Science-based products for every stage of life

PEDIATRIC

ADULT

MEDICAL

REHYDRATION



NUTRITION

Pediatric

#1 brand fed in hospitals (U.S)*

SIMILAC®

Our line of infant and toddler formulas designed to support healthy growth and development



PEDIASURE®

Designed to support children's growth with high-quality protein and essential vitamins and minerals



PEDIALYTE®

Oral electrolyte solution specially formulated to help prevent mild to moderate dehydration in children and adults



*Similac is the #1 brand fed in U.S. hospitals; data on file.





NUTRITION

Adult

#1 worldwide

ENSURE®

A line of complete, balanced and targeted nutrition products that can help people stay active and at their best



SPECIALIZED NUTRITION

- Glucerna® (diabetes)
- Juven® (supports wound healing)
- Nepro® (kidney disease requiring dialysis)
- Tube-feeding products



ZONEPERFECT®

Nutrition beyond protein to fuel busy adult lifestyles



OnePLM Vision

Technical information about Abbott Nutrition products will be managed through one Product Lifecycle Management (PLM) process and governance.

AN will use Devex as the tool to manage data throughout the lifecycle of our products: ingredients & packaging; formulations & product recipes; finished product labels; regulations; safety & quality guidelines; and commercial nutrition claims.

All information in Devex will be approved, and readily available to support business functions requiring this evidence:

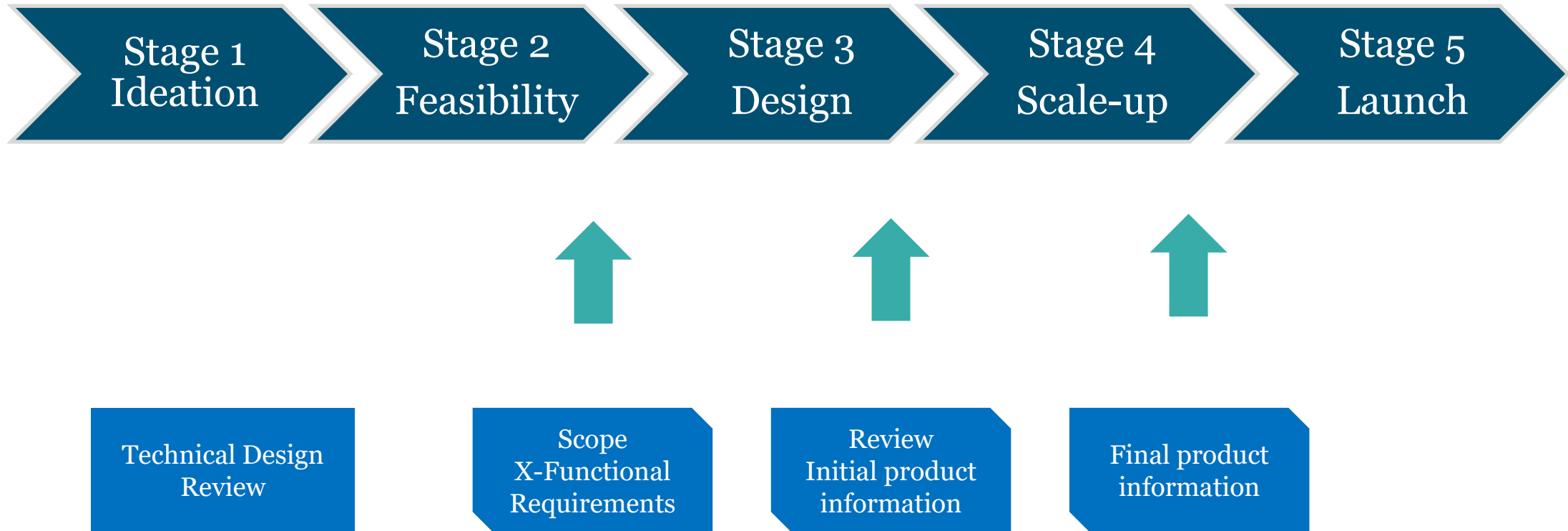
e.g. country registrations, compliance assessments, product & packaging development, sourcing moves, product manufacture, digital marketing, cost improvement initiatives and customer queries

OnePLM ‘Guiding Principles’

Basic Ways of Thinking for Everyone engaged in some way with OnePLM Program

1. **Define the ideal Future State. Then define the changes, resources and steps needed to get there. Then prioritize those steps (including intermediate stages).**
2. **Learn from the past – Focus energy on the future**
3. **There are no Sacred Houses (for US: Sacred Cows)**
4. **Focus on getting the Inputs right. Trust the process & system to drive reliable Outputs.**
5. **Global implementation requires Global teams – assure inputs from all Regions and all Cross-functional Areas**
6. **Devex is intended for Abbott Nutrition’s end-to-end lifecycle management of information**
7. **Data in devex should be owned & managed by the business area nearest the source/origin of that data**
8. **One Point of data entry within devex. One Parent for data across systems. Duplication of data to be avoided.**
9. **Minimize system customization through understanding of Core devex capabilities; and assuring Selerant has solid understanding of AN business processes**
10. **Stay positive, Share successes, Internalize the future**

NPD Stage Gate



Product Development in Devex



- Design Input Specifications (DIS)

- Product Requirement Specifications (PRS)

- Single Formulation Editor (SFE)

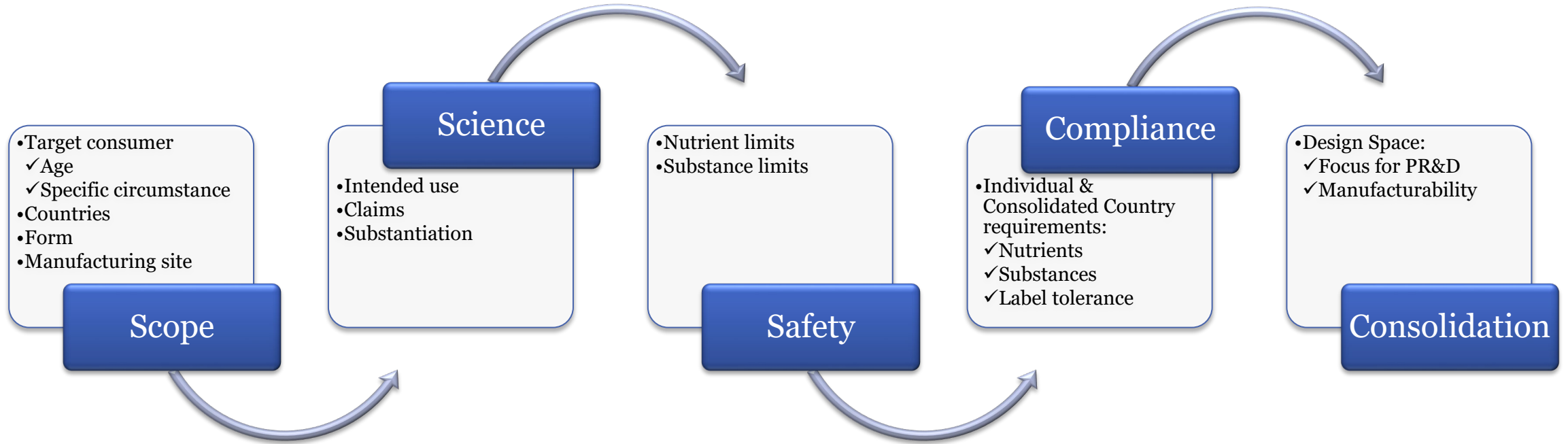
- Batch & Recipe

- Reports
- Assessments

- Product Related Documents (PRD)



X-Functional Design Intent Build



Specification 9025_DIS001 v. 0 of Type Design Input Specification (0)

Actions ▾ Approval ▾ Export Limits Security Audit

Manage Panels < ⋮

- General
- Sections
 - Product Technical Scope
 - Current Product Refer...
 - Regulatory Considerati...
 - Medical Safety Consid...
 - Nutrition Science Cons...
 - Country Specific Limits
 - Composite Recommen...

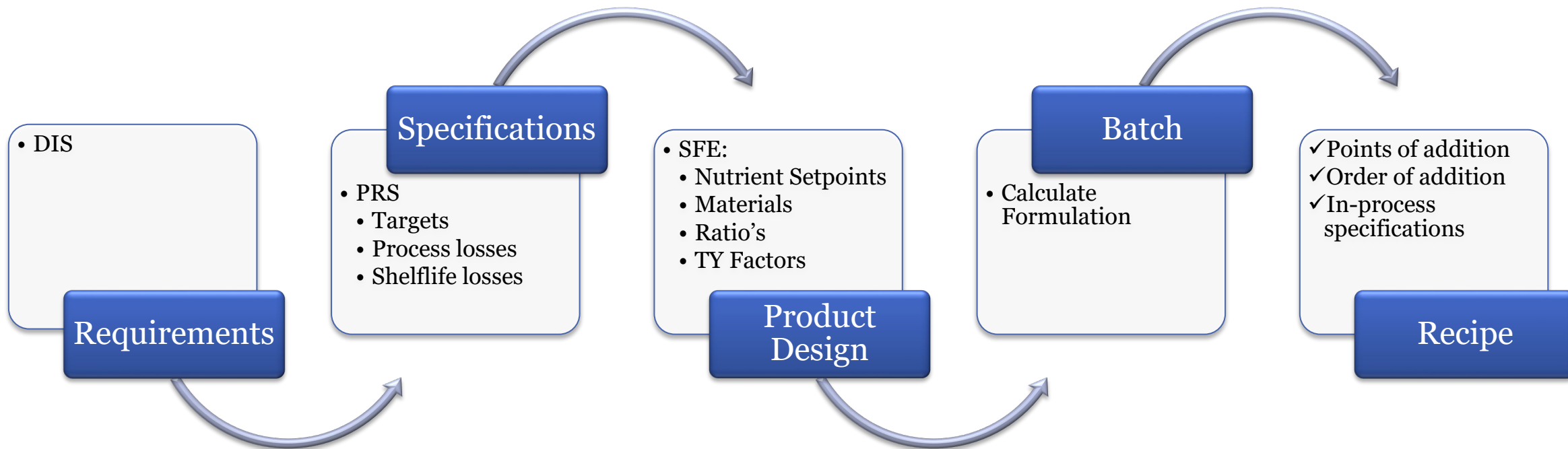
Positioning

Country	Guideline	Application 2
PHILIPPINES	Philippines Label Tolerance - %LC - 0	
SINGAPORE	Singapore Label Tolerance - %LC - 2	80% minimum per AN 5
THAILAND	Thailand Label Tolerance - %LC - 5	All Age Groups
VIET NAM	Vietnam Label Tolerance - %LC - 3	
VIET NAM	Vietnam Upper Limit Per Day Regulation - Daily Values (Pro...	20-29 years old
MALAYSIA	Malaysia Criteria for Compliance of Analytical Level Accordin...	
MALAYSIA	Malaysia Food Regulation 26: Max Amount Permitted Daily (...)	

DIS - Applicable Guideline Example

Regulatory Considerations							
Country	Guideline	Application 2	Application 3	Application 4	Min/Max/Min & Max	EER (kcal)	%DV Min/%UL
VIET NAM	Vietnam Label Tolerance - %LC				Min & Max		
VIET NAM	Vietnam Upper Limit Per Day Regulation - Daily Values	≥70 years old			Max		100
INDONESIA	Indonesia Tolerance Limits of Substances Nutritional				Min & Max		
INDONESIA	Indonesia RDA - Daily Values	General			Max		173.67
SINGAPORE	Singapore Label Tolerance - %LC				Min & Max		
MALAYSIA	Malaysia Criteria for Compliance of Analytical Level A				Min & Max		
MALAYSIA	Malaysia Food Regulation 26: Max Amount Permitted				Max		100
PHILIPPINES	Philippines Label Tolerance - %LC				Min & Max		
THAILAND	Thailand Label Tolerance - %LC	All Age Groups			Min & Max		
TAIWAN	Taiwan TDA Specification Adult FSMP Label Claim - %	Adult % Label Claim			Min & Max		
TAIWAN	Taiwan Adult FSMP (Category III Part 1) Nutrient Limi	Adult			Min & Max		
TAIWAN	Taiwan Adult FSMP (Category III Part 2) Daily Values	Adult			Min		11.4
INDIA	INDIA FOOD SAFETY AND STANDARDS (IF, FUF, F				Min & Max		
INDIA	India Daily Values Guideline (Max.)	Man (sedentary work)			Max		100
PERU	Peru Label Tolerance - %LC				Min & Max		
BRAZIL	Brazil - Standard Formula for Enteral Nutrition Limits f	Adult			Min & Max		
PERU	Codex Guidelines on Nutrition Labeling - Daily Values	Older than 36 months			Max		100
INDIA	India Daily Values Guideline (Max.)	Woman (sedentary wo			Max		100
Medical Safety Considerations							
Country	Guideline	Application 2	Application 3	Application 4	Min/Max/Min & Max	EER (kcal)	%DV Min/%UL
UNITED STATES OF AMERICA	US DRI: Tolerable Upper Intakes	Females (19-30 y)			Max		36
UNITED STATES OF AMERICA	US DRI: Tolerable Upper Intakes	Females (31-50 y)			Max		100
UNITED STATES OF AMERICA	US DRI: Tolerable Upper Intakes	Females (51-70 y)			Max		60
UNITED STATES OF AMERICA	US DRI: Tolerable Upper Intakes	Males (19-30 y)			Max		60
UNITED STATES OF AMERICA	US DRI: Tolerable Upper Intakes	Males (31-50 y)			Max		60
UNITED STATES OF AMERICA	US DRI: Tolerable Upper Intakes	Males (51-70 y)			Max		60
UNITED STATES OF AMERICA	US DRI: Tolerable Upper Intakes	Males (> 70 y)			Max		60
UNITED STATES OF AMERICA	US DRI: Tolerable Upper Intakes	Females (> 70 y)			Max		60

DIS to Recipe



Compliance by Design

Targets & Limits

Calculation Source: SELERANT USER CONFERENCE 2023 - LABEL CLAIM (VALID) <DEVELOPMENT> Specification SELERANT_USER_CONFERENCE_2023_PRS001 v. 0 of Type Product Requirements Specification (3)

Export Highlight Selected all

#	Code	Category	Description	UM	Minimum	Maximum	Target	Total	Projected Minimum	Projected Maximum
68	NP010091	Minerals	Calcium	mg	342.40	767.75	436.00	428.67	390.24	478.65
69	NP010113	Minerals	Chloride	mg	480.80	1,381.96	664.00	594.11	578.34	612.51
70	NP010125	Minerals	Chromium	µg	60.80	760.00	82.20	95.73	91.23	99.92
71	NP010148	Minerals	Copper	µg	256.00	1,279.59	509.00	586.76	472.48	665.11
72	NP010212	Minerals	Fluoride	mg	0.51	2.24		0.01	0.01	0.01

Recipe: Associate ingredients to stages

BATCH TRAINING DEMO Batch Base (manufacturing): Generic plant / MMH000620001

File View Undo Redo Save Updates Reload Data

View RECIPE STAGES MFE

Components / BATCH TRAINING DEMO / MMH000620001

Remark Mode Show Remarks

#	Plant	Code	Description	Quantity	UM	Stage A	Ratio A	Stage B	Ratio B
BATCH TRAINING DEMO									
1	Generic plant	01734-3	Oil 1	89.158	lb	PIF	1.000		
2	Generic plant	01111-4	Oil 2	55.724	lb	PIF	1.000		
3	Generic plant	R1142-1	Oil 3	133.737	lb	Oil Blend	1.000		
4	Generic plant	R0639-1	OSV	75.000	g	Oil Blend	1.000		
5	Generic plant	01234-1	Anti oxidant	157.300	g	Oil Blend	1.000		
6	Generic plant	12462-1	OSV	186.462	g	Oil Blend	1.000		
7	Generic plant	01254-2	Vitamin	2.283	g	Oil Blend	1.000		
8	Generic plant	R0824-1	Mineral	1.539	lb	PIF	1.000		
9	Generic plant	01492-2	Mineral	4.994	lb	PIF	1.000		
10	Generic plant	21818-5	Emulsifier	1.665	lb	PIF	1.000		
11	Generic plant	18001-1	Protein 1	71.350	lb	PIF	1.000		
12	Generic plant	01022-2	Protein 2	246.147	lb	PIW	1.000		
13	Generic plant	01081-6	CHO 1	120.351	lb	CHO/MIN	1.000		
14	Generic plant	R0967-1	CHO 2	265.388	lb	CHO/MIN	1.000		
15	Generic plant	01418-4	Mineral	1.293	lb	CHO/MIN	1.000		

Totals & Targets

Plant	NONE
Matcode	MMH000620001
Alternate	0
Version	0
Status	Valid
Creation Date	12/04/2020
Batch Size	1,000
Batch Size UM	lb
Total Quantity	464.50 kg
Nbr of compon...	24

Recipe for Trial Manufacturing

Create Recipe from Template

Recipe Template:

STAGES SETTINGS

Stage	Batch	Final TY		TS (%)	Group	Master?	Water Source?
PIF	Batch 1	1,000.00	lb		1		
PIF	Batch 2	1,000.00	lb		2		
PIF	Batch 3	1,000.00	lb		3		
PIF	Batch 4	1,000.00	lb		4		
CHO/MIN	Batch 1	1,000.00	lb	35.00	1		
CHO/MIN	Batch 2	1,000.00	lb	35.00	2		
CHO/MIN	Batch 3	1,000.00	lb	35.00	3		
CHO/MIN	Batch 4	1,000.00	lb	35.00	4		
Oil Blend	Batch 1	1,000.00	lb		1		
Oil Blend	Batch 2	1,000.00	lb		2		
Oil Blend	Batch 3	1,000.00	lb		3		
Oil Blend	Batch 4	1,000.00	lb		4		
PIW	Batch 1	1,000.00	lb		1		
PIW	Batch 2	1,000.00	lb		2		
PIW	Batch 3	1,000.00	lb		3		
PIW	Batch 4	1,000.00	lb		4		
Blend	Batch 1	1,000.00	lb	40.00	1		Yes
Blend	Batch 2	1,000.00	lb	40.00	2		Yes



Trial Recipe: Generic plant / GC000790

Actions Security Audit

Report

Global Weigh Sheet Report

Manage Panels

Formulation

New Formula Export

Formula Type

Base (manufacturing) (Recipe)

Show 15 per page

Generation Settings

In process estimations

Standardization

Documents

References

Verification

CRISP – Consolidated Review of Interchangeable Suppliers by Plant

1	Nutrient Name	NPCODE	Nutrient Unit	Label Claim	Inherent + Added Totals Absolute			Assumption	Assumption	SPEC	Projected values at 0-time testing Inherent + Added Totals Absolute			SPEC	Assumption	SPEC	Projected values at end of shelf life testing Inherent + Added Totals Absolute				SPEC
					Fortification Minimum	Fortification Target	Fortification Maximum	Manufacturing Loss %	Other variability %	0-Time Lower Release	0-Time Minimum	0-Time Target	0-Time Maximum	0-Time Upper Release	Shelf life loss %	ESL Lower Release	ESL Minimum	ESL Target	ESL Maximum	ESL Upper Release	
33	Calcium	NP010091	mg	428.00	394.33	430.97	479.05	0.00	0.00	342.40	394.33	430.97	479.05	767.75	0.00	342.40	394.33	430.97	479.05	767.75	
36	Chloride	NP010113	mg	601.00	631.38	658.36	683.46	0.00	0.00	480.80	631.38	658.36	683.46	1381.96	0.00	480.80	631.38	658.36	683.46	1381.96	
42	Chromium	NP010125	µg	76.00	78.52	83.35	87.53	0.00	0.00	60.80	78.52	83.35	87.53	760.00	0.00	60.80	78.52	83.35	87.53	760.00	
44	Copper	NP010148	mg	0.32	0.41	0.58	0.68	0.00	0.00	0.26	0.41	0.58	0.68	1.28	0.00	0.26	0.41	0.58	0.68	1.28	
79	Fluoride	NP010212	mg	0.00	0.02	0.02	0.02	0.00	0.00	0.00	0.02	0.02	0.02	0.00	0.00	0.00	0.02	0.02	0.02	0.00	

General | per 100g Ingredient | **per 100g Product** (+)

Regulatory Assessment

POSITIONING

#	Country	Guideline	Application 2
1	INDONESIA	Indonesia FSMP for Adults with Diabetes - Nutrient Limits - 0	

INFORMATION TYPICALLY FOUND IN MASTER SPECIFICATION AND PTI

Source	Nutrient	U	Selerant User Conference 2023 - Label Claim - Label Claim per 100 kcal (INT)	Selerant User Conference 2023 - Label Claim - Shelf Life - Min per 100 kcal (INT)	Selerant User Conference 2023 - Label Claim - Shelf Life - Max per 100 kcal (INT)	Indonesia F...	Indonesia F...	Indonesia F...	Indonesia F...	Indonesia F...	Indonesia F...	Indonesia F...	Indonesia F...	Indonesia FSMP for Adults with Diabetes - Nutrient Limits
Master Specification	Fat, Total	g	3.8215103	3.43935927	4.58581236	2.22	2.78	g	100 kcal (INT)	HIGH 172.140%	HIGH 154.926%	HIGH 164.957%	HIGH	Avoid fatty sources that contain trans fatty acids
Master Specification	Protein, Total	g	4.46224256	4.01601831	44.62242563	2.5	5	g	100 kcal (INT)	OK 178.490%	OK 160.641%	HIGH 892.449%	HIGH	
Master Specification	Fiber / Dietary Fiber (USA)	g	1.71395881	1.37116705	17.1395881	1	1.75	g	100 kcal (INT)	OK 171.396%	OK 137.117%	HIGH 979.405%	HIGH	
Master Specification	Total Carbohydrate (per policy)	g				11.25	16.25	g	100 kcal (INT)	MISSING 0%	MISSING 0%	MISSING 0%	MISSING	
Master Specification	Saturated fatty acids, Total	g	0.43478261	0.43478261	1.24816934	NS	0.78	g	100 kcal (INT)	OK	OK	HIGH	HIGH	

Output

☆ BATCH SELERANT USER CONFERENCE 2023 (VALID) <DEVELOPMENT> | 🔔

Specification VXH001200001 v. 0 of Type Product Related Documents (3)

Reports ▾ Actions ▾ Delete

Manage Panels < ⋮

General

Sections

Formula Tree View

Product Information

Master Specification

Master Specification E...

BM

BM REG

LIDO

Properties Specification

Properties Specificatio...

PTI Attributes

MO

PCAN

Supplemental Informa...

Materials

Documents

Tasks

DMS Settings

BM

Create New

Edit Section

Report

View Section

BM ▾

▶ 1. Positioning

LIST/FE NUMBER: Commercial code/

BILL OF MATERIAL

▼ 2. Formula

Level Num...	Ingredient ...	Ingredient Name	Qty %	BOM Name	BOM Declar...	BOM Repl...	COMMODITY NUMBER	INGREDIENTS	APPROXIMATE AMOUNT PER 1000 KG
							22987	Oil 1	350.0 kg
							01146	Oil 2	100.0 kg
1	01103-5	Oil 1	3.00000000	Oil 1			13691	CHO	75.0 kg
2	SB000058	Oil 1	3.00000000	Oil 1	Non-Declaration		01103	Oil 3	60.0 kg
1	01146-4	Oil 2	10.00000000	Oil 2			31961	CHO	50.0 kg
2	SB000006	Oil 2	10.00000000	Oil 2	Non-Declaration		19543	Minerals	1 kg
1	01103-5	Oil 3	3.00000000	Oil 3				Mineral 1	500 g
2	SB000058	Oil 3	3.00000000	Oil 3	Non-Declaration			Mineral 2	400 g
1	21818-1	emulsifier	0.50000000	emulsifier				Mineral 3	50 g
2	SB000016	emulsifier	0.50000000	emulsifier	Non-Declaration			Mineral 4	10 g
1	01234-1	Anti oxidant	0.01000000	Anti oxidant				Mineral 5	1 g
2	SB000089	Anti oxidant	0.01000000	Anti oxidant	Non-Declaration			Mineral 6	1.2 g
1	15748-2	Vitamin	0.03000000	Vitamin				Mineral 7	900 mg
								Carrier	q.s.

What's Next?

- Country specific information
- Data approval in Devex – becoming system of reference
- Build on recipe capabilities

QUESTIONS

