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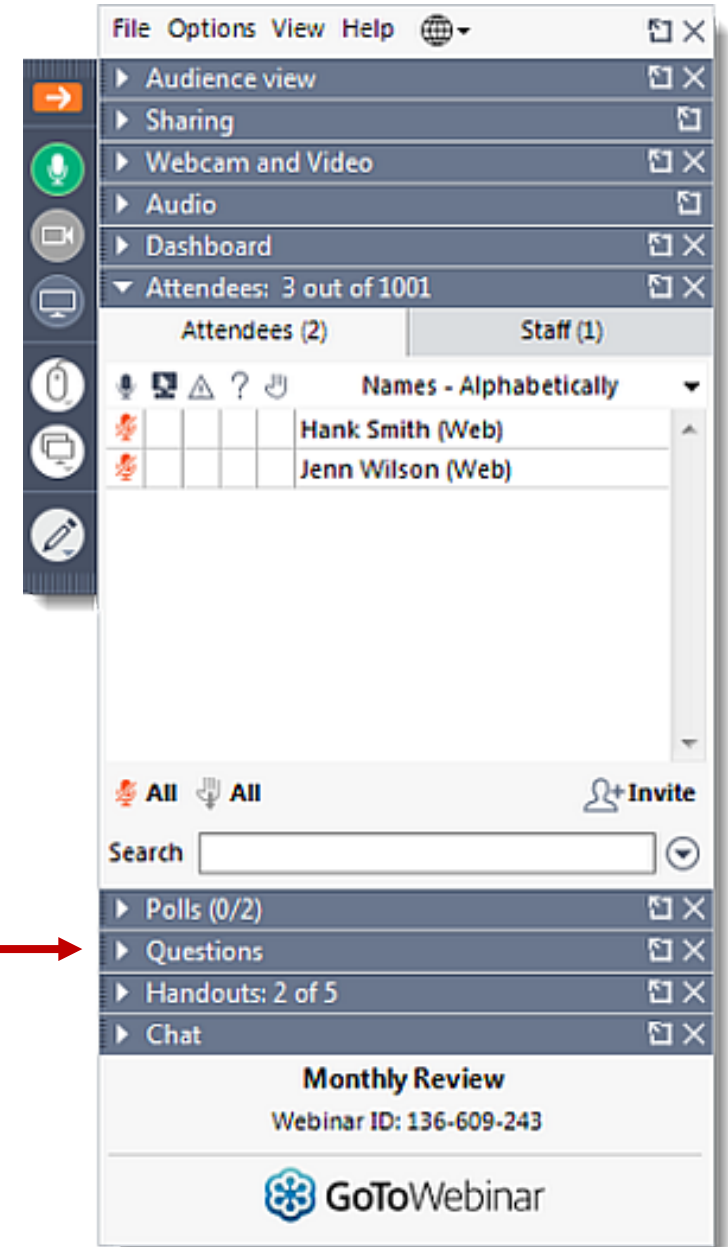
SMART Validation

Modernize your process validation with a proven, cloud-based solution

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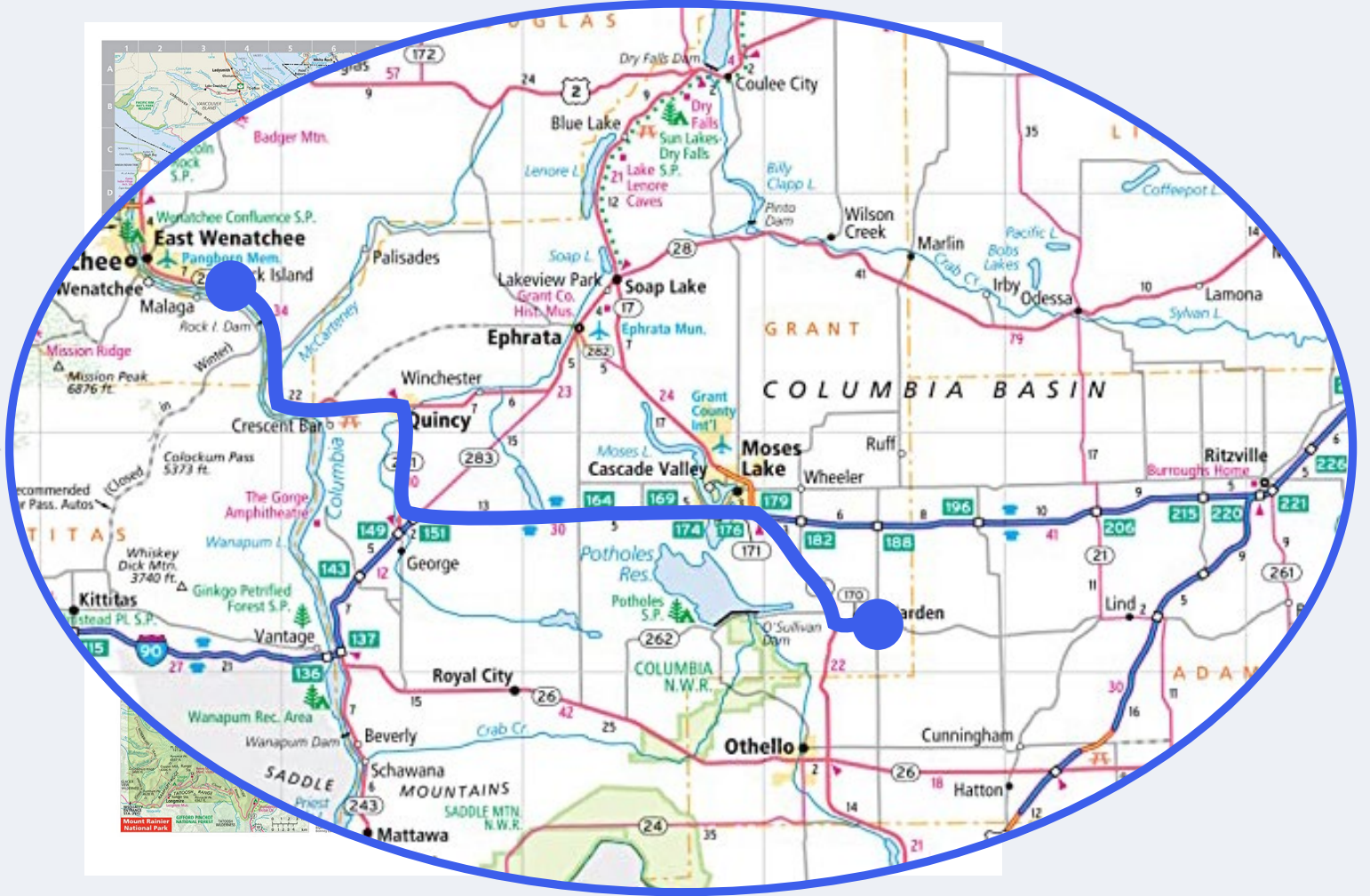
Welcome to our Webinar

- We welcome your questions. Please use the Questions panel to submit your questions and we will answer at the end of the webinar. If you have a question after the webinar, please email us at marketing@novolyze.com
- If you are having trouble, please try logging out and logging back in.
- You can also join by web with the webinar ID, at goto.com/webinar/join
- The webinar is being recorded. All registrants will receive a link to the recording the day after the webinar is complete.

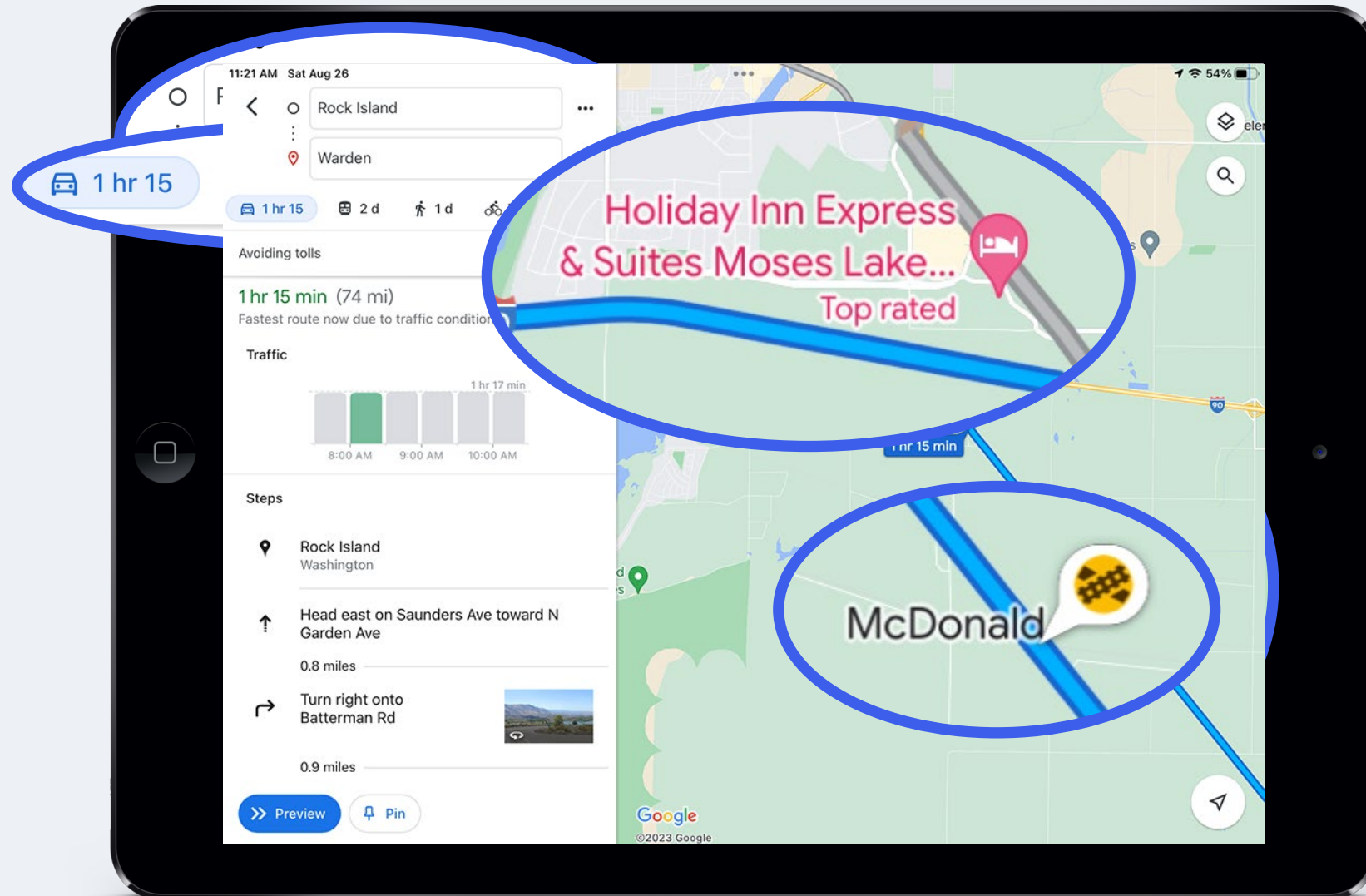




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GPS Revolutionized Approach **AND** Options



Driving Innovation in Process Validation



Laure Pujol, PhD
Customer Success Manager
Novolyze



Mayur Desai
President
Bioactive

Process Validation Methods & Technologies

Novolyze SMART Food Safety & Quality

- 10+ years delivering FSQ Solutions to the F&B Industry
- Global Headquarters: Bethesda, MD
- EMEA Headquarters: Dijon, France
- East Delivery: Serbia
- Global Solutions deployed in 38 countries
- **15** of the top **20** largest Food & Beverage companies in the world **Protect their Brand & Reduce their Cost of Quality** through at least one Novolyze solution



cyber**v**adis



Why validation?

Pathogen testing misses low prevalence bacteria such as *Salmonella*, *Listeria*, *E. Coli*, etc.

Product Pathogen Testing does not Make Food Safe (or Unsafe)



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2017-2018 Salmonella Crisis

12M boxes recalled in 83 countries

“This recall will cost us several hundred million euros...we don’t understand how the 16,000 analyses we did in 2017 didn’t prevent the risk”

CEO of a Global Food Company



Validation

Obtaining evidence that a control measure or combination of control measures, if properly implemented, is capable of **controlling the hazard** to a specified outcome.

e.g: Kill step validation with the surrogate



Monitoring

Conducting a **planned sequence of observations** or measurements of control parameters to assess whether a control measure is **under control**.

e.g: Monitoring of the temperature



Verification

Ensuring that preventive controls are **consistently implemented** and are **effectively** carried out.

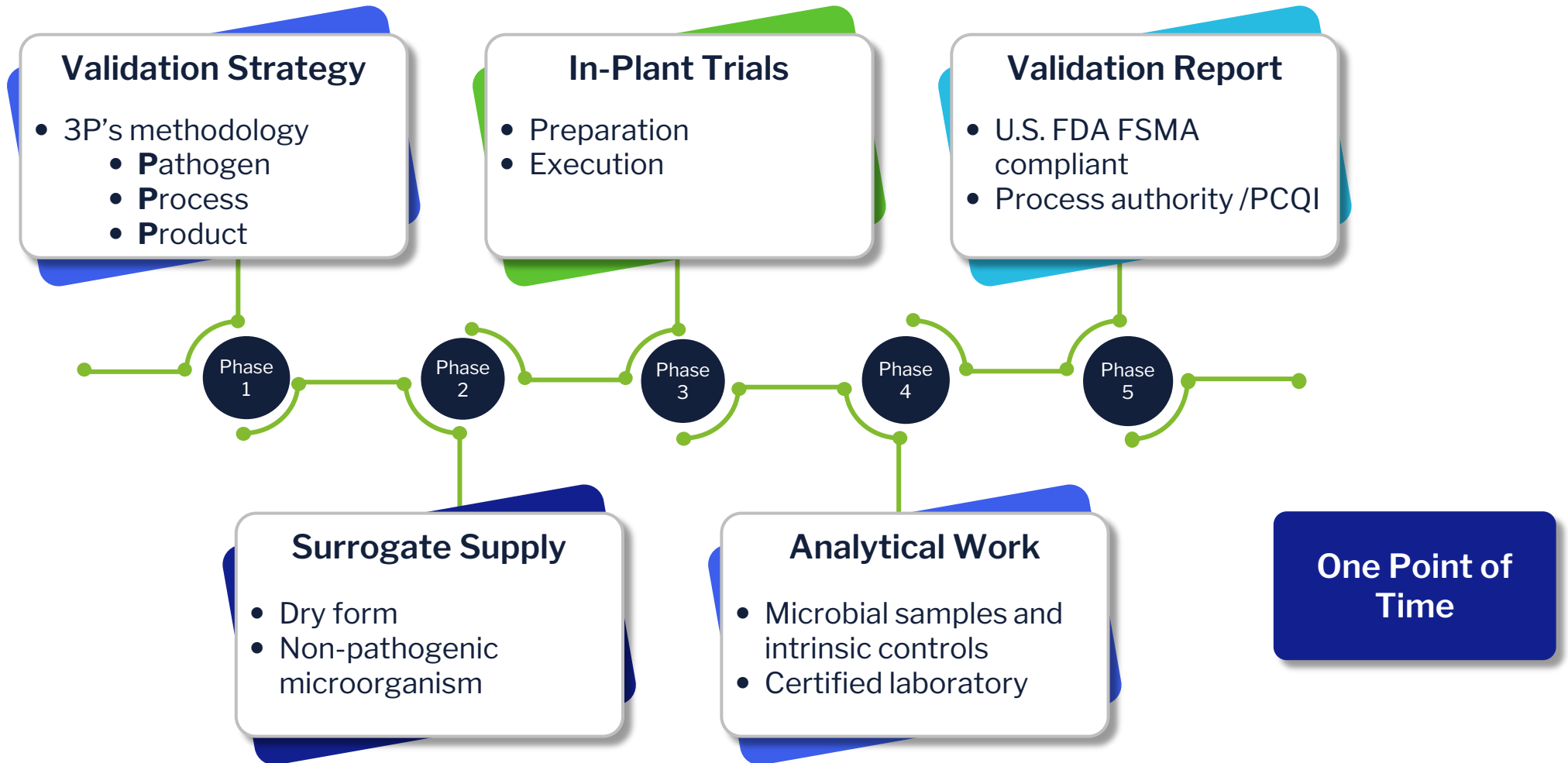
e.g. Confirmation that CCPs and other Preventive Controls are kept under control



Spot Validation

Spot Validation

Sequential Phases



Spot Validation – Documents

- Certificate of validation
- Full validation report
 - Introduction & Objective of the study
 - Product, process, parameters description
 - Validation methodology
 - Calculation of the log lethality
 - Conclusion and Recommendations



SMART Validation

SMART Validation

ALL IN ONE

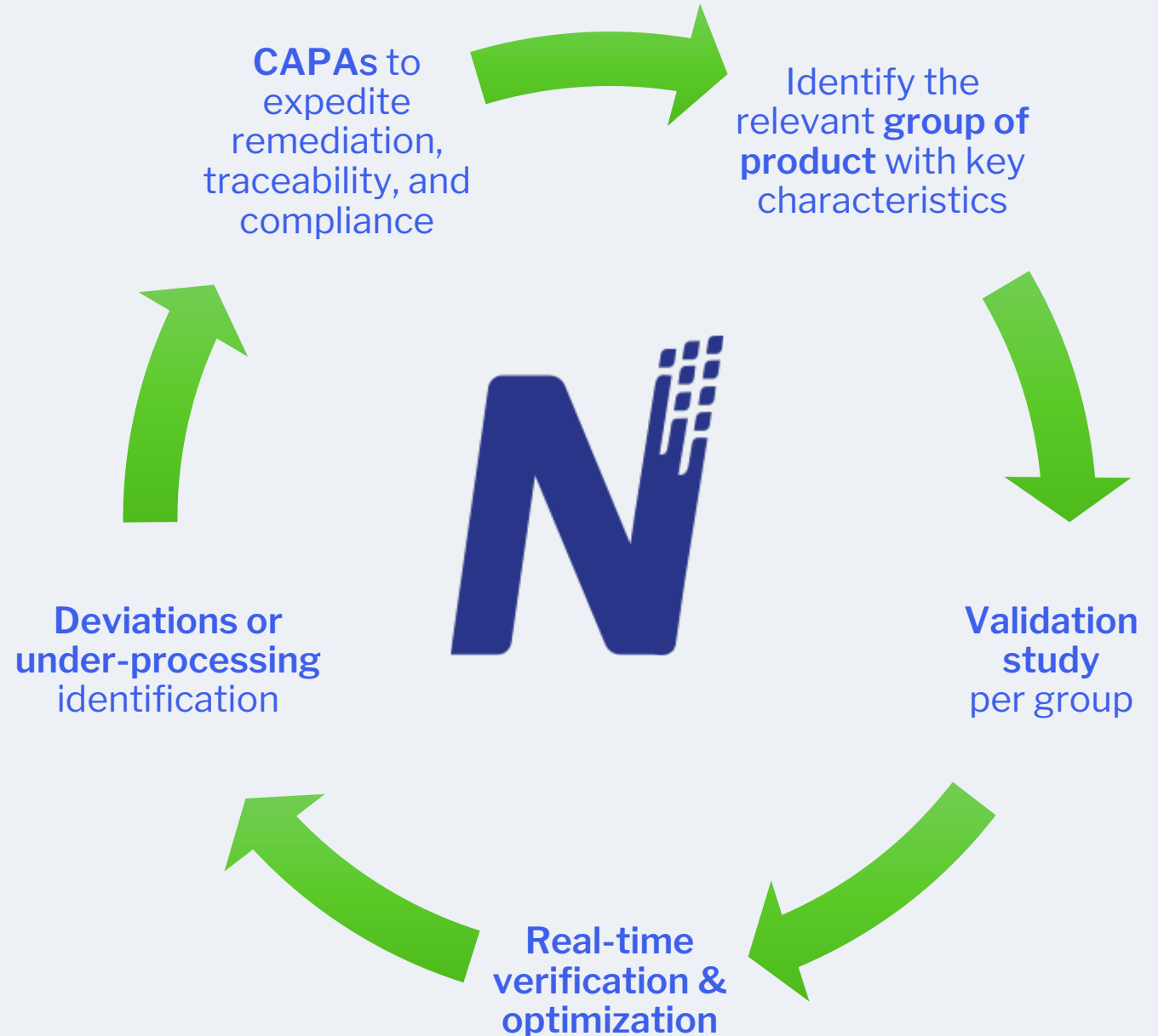
Validation, Verification, Optimization

- Spot Validation

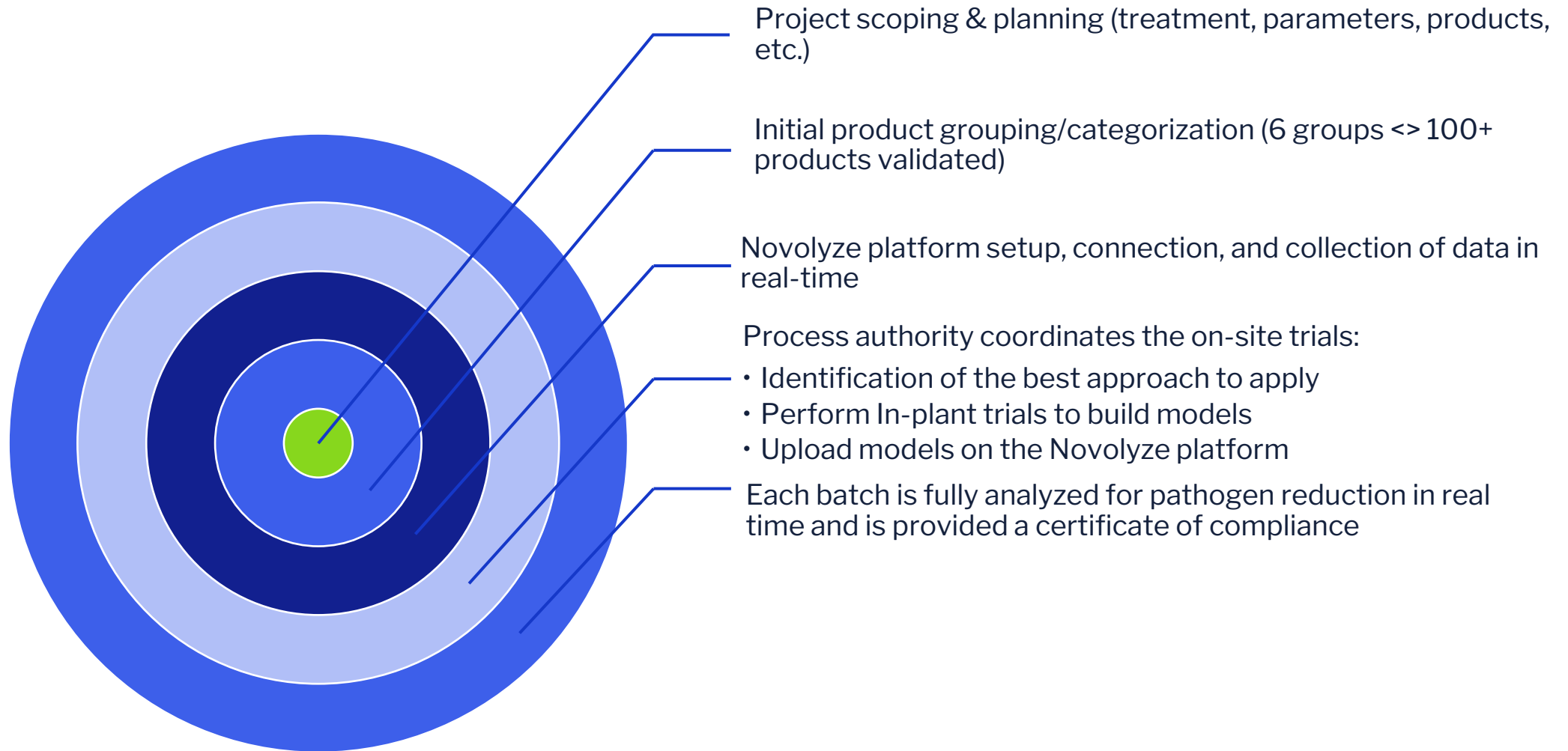


- Traceability
- Real time monitoring
- Batch Conformity certificates
- CAPA management
- Process optimization

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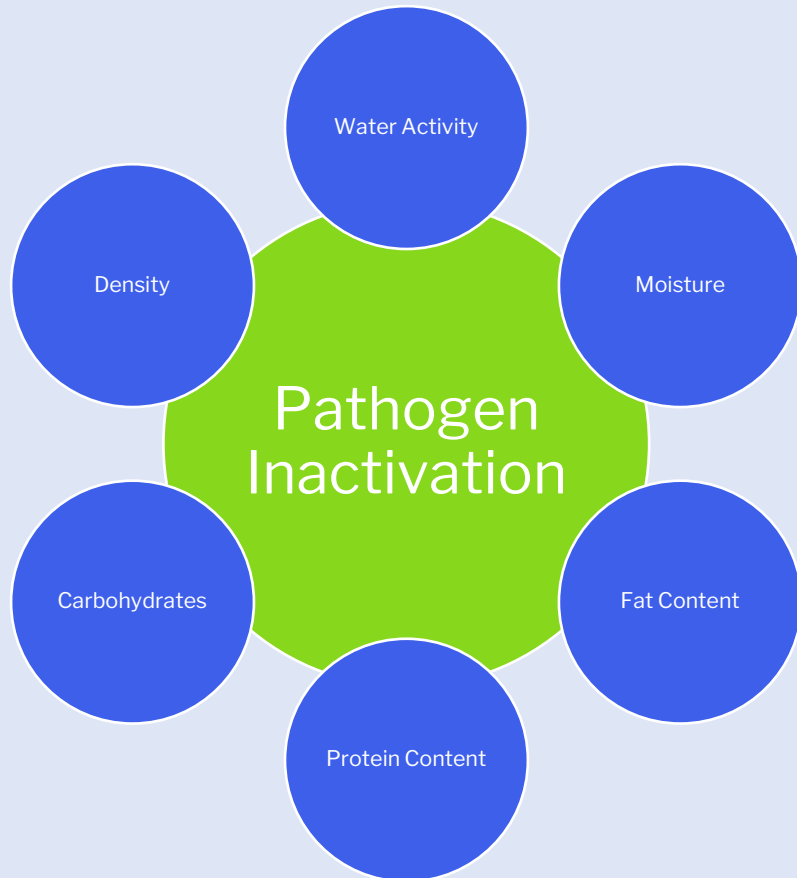
The SMART Validation Approach



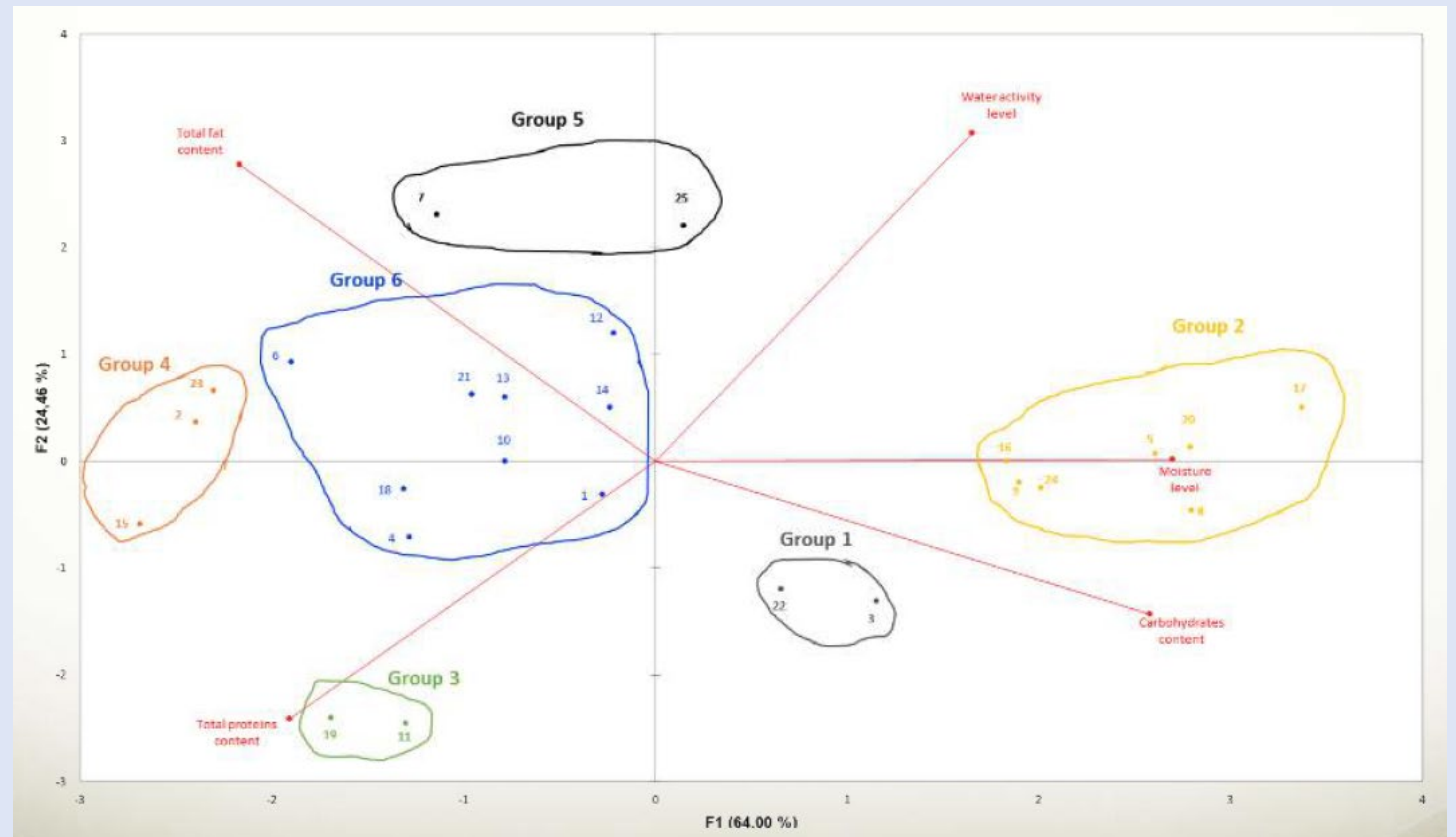
SMART Product Grouping

(proprietary method)

Categorization: 6 parameters



Statistical Analysis: 6 Groups



Example: Grouping of 25 seed products

Spot vs. SMART Validation

Spot Validation vs. SMART Validation approaches

**Spot
Validation
approach**



Validation

Defines a **fixed set** of **process parameters** to reach **target log reduction** in a “**worst-case**” scenario

Verification

Verifies application of predefined process parameters (time, temperature...)

Limitations

- Validated vs Worst case
- Risk due to variability
- Specific conditions

**SMART
Validation
approach**
(patent pending)



Validation

Defines a **model** to reach target log reduction

Verification

Calculates in real time the adequate process parameters (time, temp) and **informs operator** to reach target log reduction

Benefits

- Monitors Food Safety standards
- Adequate time / temperature
- Lower costs
- Increased capacity
- Improved traceability

Spot Validation vs. SMART Validation approaches

SPOT VALIDATION

SMART VALIDATION

DELIVERABLE

- Surrogate
- Validation Report

- All in one: validation, verification, optimization
- Process Authority letter
- Batch Conformity certificates
- Real time monitoring
- CAPA management
- Process optimization

ADVANTAGES

- Compliance
- Best in class validation approach
- Regulatory & industry recognition

- Continuous conformity to all batches
- Enhanced traceability
- Centralization of data (CFR compliant)
- Audit-readiness
- Improved OEE & CO2 footprint
- Continuous service

LIMITATIONS

- Cost efficiency
- One point of time “worst case“ validation
- Over processing
- No traceability
- No deviation management possibility

Examples and Features

Thermal Processing Automation

Cocoa Liquor Manufacturer

- Thermal treatment (tanks) to control *Salmonella* (6-log reduction objective)
- Real-time collection of thermal parameters
- *Salmonella* reduction algorithm implemented real-time calculation of *Salmonella* reduction
- Outcome: “Just necessary” thermal dose applied for each processed batch

Operational gains:

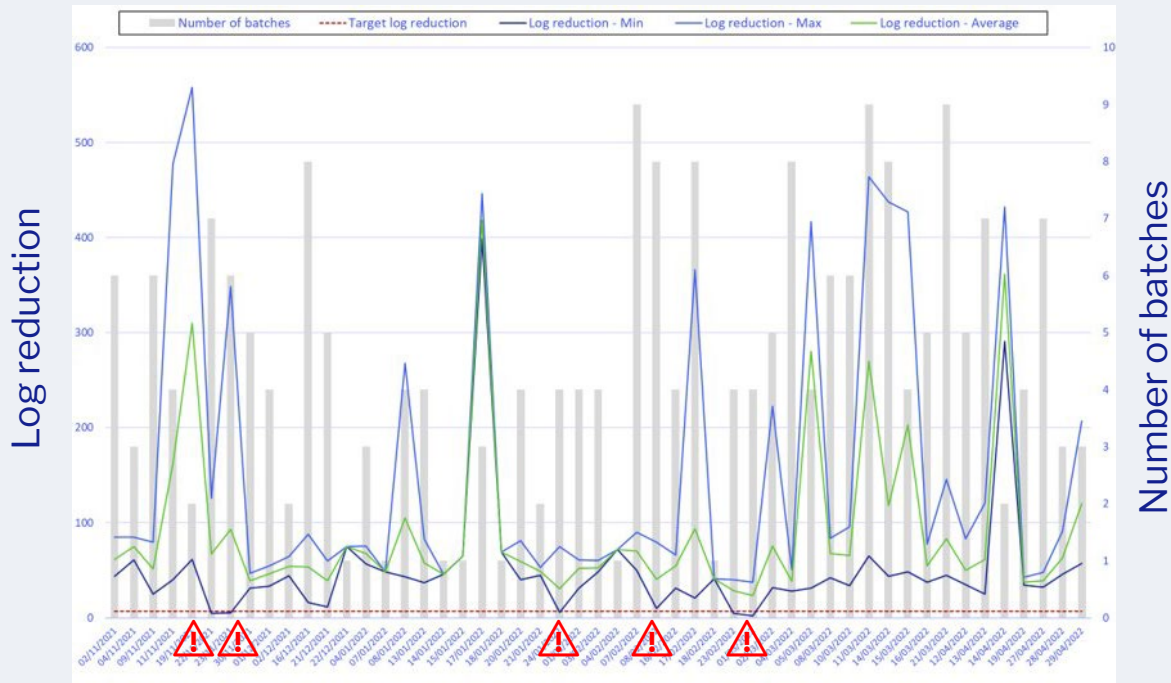
- Increase manufacturing productivity by 15% a day
- Allow real time batch validation



Thermal Processing Automation

Meat Manufacturer

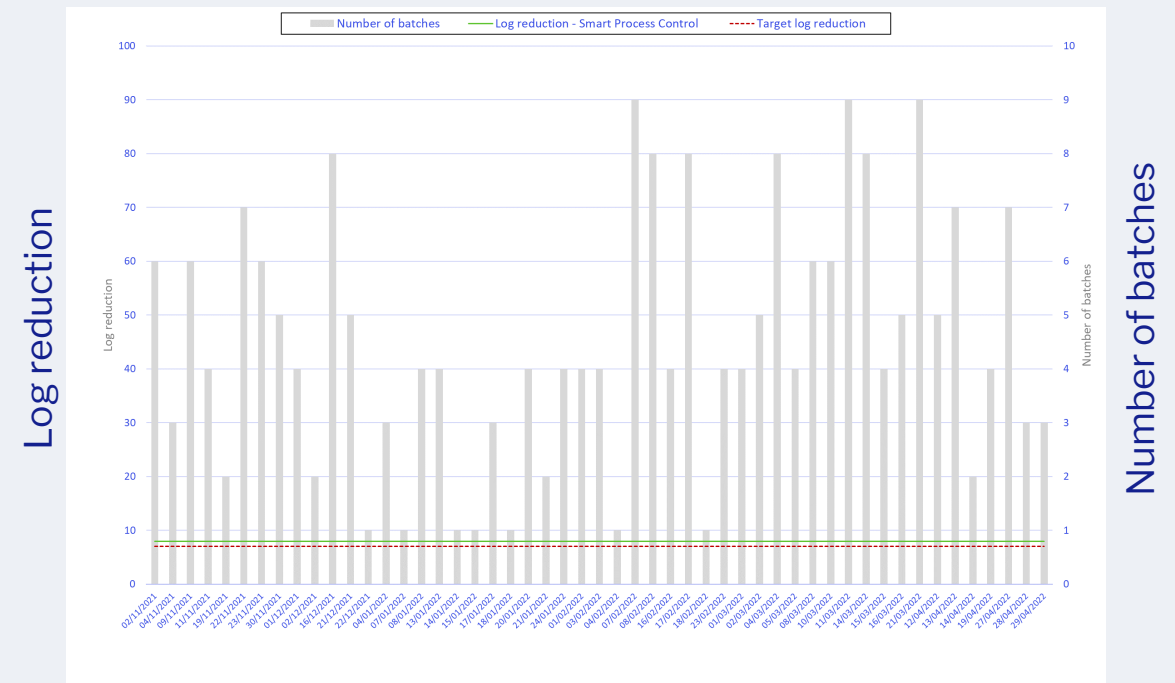
Without SMART Process Control



High variability in log reduction:

- 5/229 batches were non-conforming (= at risk)
- 222/229 batches were too long (=overprocessed)

With SMART Process Control

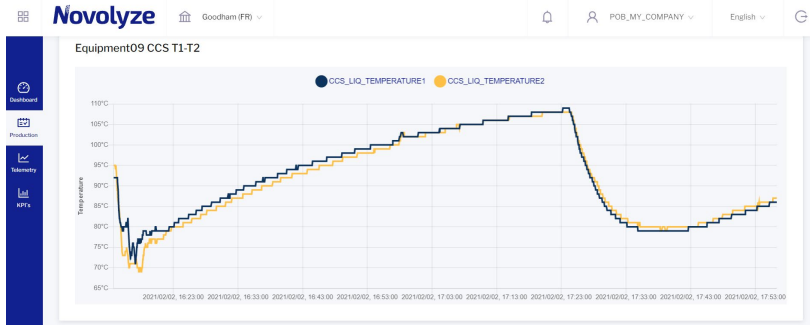


No risk – No overprocessing

- All batches reach the Food Safety Objective (7 logs)
- 17% throughput increase
- 1% yield increase due to less overcooking

Platform features enable integrated FSQ

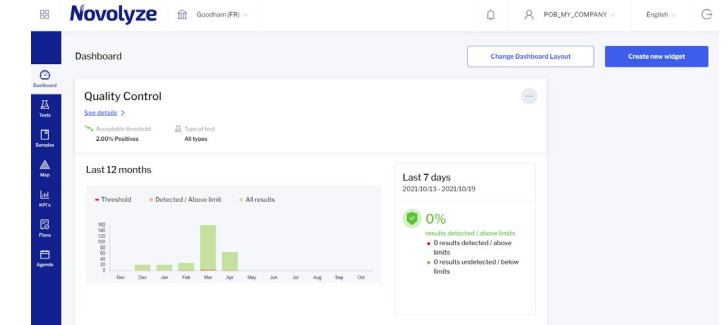
REAL-TIME TELEMETRY



RECORD-KEEPING

ID	Equipment	Sequence	Product	Batch	Starting	Complete	Recipe of control	Status	Raw result
278465	Oven1	1900	COCOA LIQUOR	210202_02	2021/02/02 19:14	2021/03/05 12:22	Oven1 LogRef	Conform	14.51 Log CFU
278447	Oven3	1901	COCOA LIQUOR	210202_03	2021/02/02 19:08	2021/03/11 18:38	Oven3 LogRef	Conform	7.79 Log CFU
278445	Oven2	1900	COCOA LIQUOR	210202_02	2021/02/02 16:13	2021/03/11 18:30	Oven2 LogRef	Conform	13.19 Log CFU
278444	Oven1	1900	COCOA LIQUOR	210202_02	2021/02/02 16:13	2021/03/11 18:27	Oven1 LogRef	Conform	6.59 Log CFU
278440	Oven1	1909	COCOA LIQUOR	210202_01	2021/02/02 13:20	2021/03/11 17:39	Oven1 LogRef	Non conform	2.99 Log CFU

KPIs, DASHBOARDS, ANALYTICS



DOWLOAD CERTIFICATE, EXPORT DATA

Oven 1 / 1733
 Conform

SEQUENCE GENERAL INFO
 Operator name: COCOA LIQUOR
 Product: COCOA LIQUOR
 Batch: 210809_01
 Recipe of control: Oven 1 LogRef

SEQUENCE TIME PERIOD
 Time zone: Romance Standard Time
 Starting: 2021/08/31 18:33
 Complete: 2021/08/31 22:15

Download certificate of processing: Get certificate, Download telemetry

Export raw data as a CSV/Excel file

REAL-TIME ALERTS

Notification Setup
 Notifications: New notifications are added to the list of active notifications.
 Alerts: New alerts are added to the list of active alerts.
 Comments: New comments are added to the list of active comments.

In App Notification
 A new comment was added on the Ticket DEV_M_200002
 Ticket comment: DEV_M_200002
 A new comment was added on the Ticket DEV_M_200002
 Ticket comment: DEV_M_200002
 A new comment was added on the Ticket DEV_M_200002
 Ticket comment: DEV_M_200002
 Ticket notification has been assigned to you: PMS1000005

Email Notification
 Subject: New comment in Novolyze from 'DEV_M_200002'
 Body: A new comment was added on the Ticket DEV_M_200002
 Ticket comment: DEV_M_200002
 A new comment was added on the Ticket DEV_M_200002
 Ticket comment: DEV_M_200002
 A new comment was added on the Ticket DEV_M_200002
 Ticket comment: DEV_M_200002
 Ticket notification has been assigned to you: PMS1000005

CAPA/REMEDIATION

TICKET ACTIONS LIST

ID	Title	Type	Activity	Due date	Ticket owner	Persons to notify	Status
4226	Verify Equipment Probes	Preventive	Maintenance	2021/04/23 23:59	POB_MY_COMPANY	-	Done
4230	Reprocess Batch	Corrective	Production	2021/04/16 23:59	ID_MY_COMPANY	-	Active

COMMENTS
 POB_MY_COMPANY
 2021/04/16 08:49
 Origin Wrong recipe loaded

Add a comment:

Signature for Conformity – Compliant with CFR

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Novolyze
Sequence 549439242 Report

Conform to Validation

A minimum confidence of 51% has been computed on this treatment assuming the reported conformity.

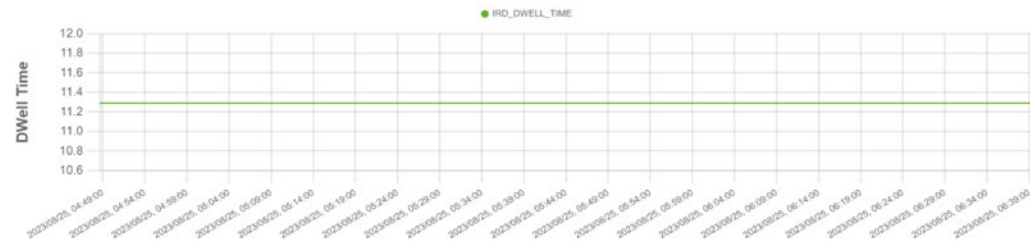
Validation report reference	Recipe	Validation date	Expiration date
	Kreyenberg Validation Conformity	1990-01-01	2999-12-31

Sequence Information

Product name	
Product weight (kg)	
Sequence start	2023-08-25 04:48:39
Sequence end	2023-08-25 06:40:54
Batch number	230222_01

Machine information

Manufacturer name	_GENERIC_
Machine name	Kreyenberg Validation Conformity
Machine type	
Time zone	Romance Standard Time



Process Validation In Practice

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About Bioactive Services

Bioactive Resources, established 2004 and Safe Sterilization USA, established 2009, were united under one new corporate name, Bioactive Services, llc in 2022.

With that transition, we brought on a new CEO to lead us into our next stages of expansion.

Bioactive Services is a full spectrum provider of all natural powdered ingredients, products and processes. With East & West coast locations strategically placed to meet customers needs.

Providing Services:

Safe Sterilization

Roasting

Blanching

Drying

Pasteurizing

Toll Blending

Package Filling

Providing Products:

Single Ingredients

Herbs

Botanicals

Fruits & Vegetables

Extracts

Turn-Key Mixes

Custom Formulations



Services & Capabilities

Toll Blending

<u>Capacity</u>	<u>Batch/Day</u>
a) 250kg	2
b) 1000kg	2
c) 5000kg	1-2*

* dependent on product density

Offered for Dry or
Powdered Ingredients

Safe Sterilization

Processing Capacities:

270 to 500 kg/hour

(dependent on various factors)

Capabilities:

Powder, Pieces, Slice, Whole,
Leaf, Crushed, Cut.

Inline quality checks- sifter,
REM, metal detector

Treatment Options:

- Sterilization
- Pasteurization
- Roasting
- Blanching
- Drying

≥ 5 Log Validated Outcomes
No Chemicals * No Radiation

Package Filling

Package Options

- Single Jar
- Twin Pack
- Pouch Filling

Jar Sizes

100 grams minimum

Production Capacity

- Semi-automated
- 7000 Units / day

Best Practices In Process Validation

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Validation, Verification & Process Validation

- **Validation** → evidence that a control measure, if properly implemented, is capable of controlling the hazard to a specified outcome (CODEX).
- **Verification** → confirmation that control measures are operating as intended.
- **Process Validation** → collection and evaluation of data, which establishes scientific evidence that a process is capable of consistently delivering quality/safe products.

Pathogen Elimination and Microbial Reduction

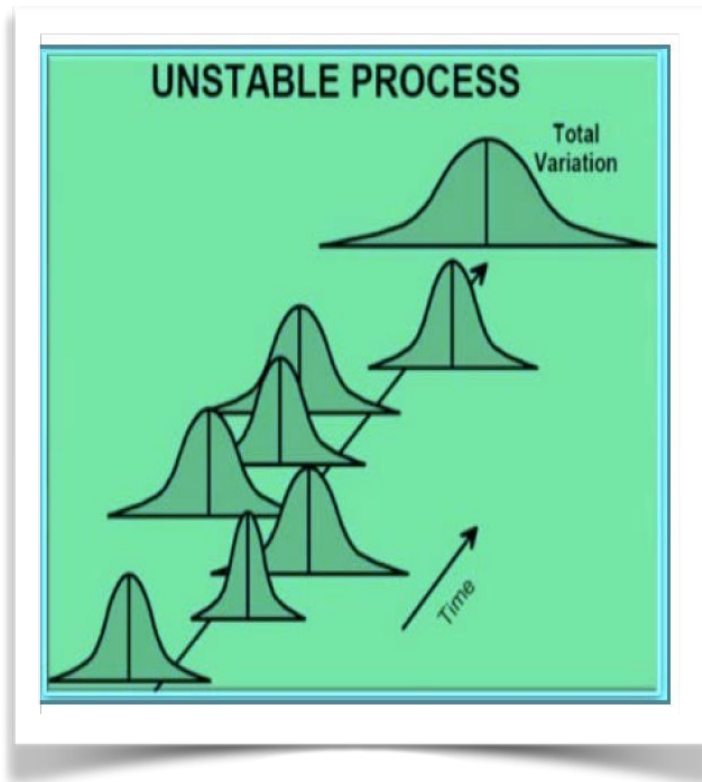
Collection and evaluation of data, from the process design stage through commercial production, which establishes scientific evidence that a process is capable of consistently delivering quality product.

- Process Design
- Process Qualification
- Continued Process Verification

Responsibilities

- **Understand** → sources of variation
- **Detect** → presence and degree of variation, impact of variation on the process and product attributes.
- **Control the variation** → commensurate with the risk it represents to the process and product.

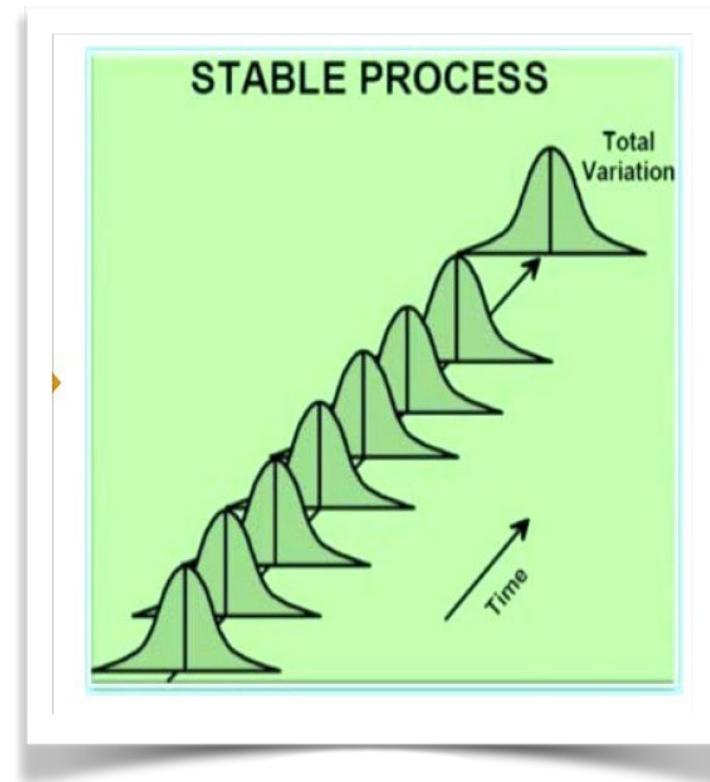
Achieving Process Stability



Unstable

Process is constantly changing

-VS-



Stable

Processes produce a consistent level of performance

Examples & Case Studies

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Results from Recent Studies

2013 Study

- Grouping approach was used in collaboration with a third-party laboratory who conducted the validation study for both plants on same ingredients under the identical conditions.
- Grouping was based on material densities and material type (i.e., leaf product, root product , seeds etc).
- Salmonella surrogate, Enterococcus faecium, was employed.
- Demonstrated a minimum 5-log reduction at 95 degree C for 5-minutes.

2022 Study with Novolyze

GUIDANCE DOCUMENT

Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food

JANUARY 2018

[Download the Draft Guidance Document](#)

[Read the Federal Register Notice](#)

Draft

Not for implementation. Contains non-binding recommendations.

Grouping to Improve Efficiency

Four Groups → Based on the intrinsic properties of products, using a statistical approach to bring out their similarities.

Factor	Effect on Microbial Heat Resistance
Water	As the humidity or moisture goes down, in general the heat resistance increases
Fat	As the fat content increases, there is a general increase in heat resistance of some microorganisms
Salts	The effect of salt varies and depends on the kind of salt and concentration. Some salts that decrease water activity appear to increase heat resistance of microorganisms while other salts that may increase water activity (e.g., Ca^{2+} and Mg^{2+}) appear to decrease heat resistance.
Carbohydrates	The presence of sugars can increase the heat resistance of microorganisms due in part to the decrease in water activity. However, the impact can be variable, particularly among sugars and sugar alcohols.
pH	Most microorganisms are more heat resistant near their optimum pH for growth. Generally, as the pH increases or decreases relative to this optimum pH, the microorganisms become more sensitive to heat.
Proteins	Proteins have a protective effect and, thus, increase the heat resistance of microorganisms.

Novolyze supplied SurroNov® → concentration of 9-log CFU/g.

Certifications

- In-process monitoring and Certificate from Novolyze
- Additional Certification by Bioactive Services



Thank You

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services

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