Developing New Products with Compliance in Mind

Steps to consider throughout the process

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Selerant Company Background
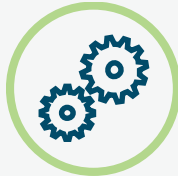
27
Years in business
Founded in 1990.

35%
YoY growth
Privately held & profitable. Continuous reinvestment in R&D and Quality.

200
Global customers
Nestle, Bacardi and Brown-Forman, to name a few.

350
Global resources
Extensive in-house professional services team across 4 continents.

Process PLM Pioneers
Launched web-based PLM software DevEX in 2003.

Global presence
Offices in Europe, United States, Asia and Australia.

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Process Industries Served

Food & Beverage

Specialty Chemicals

Personal Care

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Customer Sampling

Food & Beverages

Personal Care

Specialty Chemicals

SARGENTO

Abbott Nutrition

Nestlé

Hillshire BRANDS

McKee A FAMILY BAKERY

SENSIENT

GORTON'S SINCE 1849

Welch's

YANBAL COSMO International Fragrances

AVON the company for women

intercos GROUP

SHISEIDO GROUP

gurwitch PRODUCTS

SHERWIN WILLIAMS

McCormick The taste you trust®

CM CONTINENTAL MILLS FOODSERVICE DIVISION

GHIRARDELLI CHOCOLATE

ASHLAND

WRIGLEY

FMC

B&G

NCH CORPORATION

parmalat

BOULDER BRANDS

LUNDS&BYERLYS

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Selerant PLM System – Core Modules

Innovation Process Management

Product Development

Regulatory Compliance

Product Data Management

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Introduction to Compliance

> All food manufacturers know that regulatory compliance is a mandatory and crucial part of new product development

- Recipes, and the raw materials that comprise each recipe, must undergo several different compliance assessments to ensure that the product can be legally sold in the intended countries of sale

- Keeping compliance top of mind throughout the innovation process will produce favorable results

> Performing compliance activities <u>before</u> the project starts is highly beneficial

> Creation of a compliance strategy is highly recommended

Compliance Strategy

> Building a solid compliance strategy and integrating with a PLM system will move your business forward efficiently, accurately, and quickly

> It will keep your consumers safe

> Knowing when to perform compliance assessments and who is responsible is the key

> Have representation at business initiative planning meetings so you are aware of upcoming projects that might require ingredient approvals or use level changes

Types of Compliance to Consider

- Determine the compliance types needed to ensure your products are <u>fully</u> compliant
  - The types may depend on your product categories
  - Don't take for granted that you haven't had issues
- **Validate your data!** It must be complete and current for the countries of sale
- Use automated data collection tools to obtain data to address gaps and legislation updates (example: added sugars) from suppliers

Compliance Checklist

- ☑ **Additives**
- ☑ **Micro**
- ☑ **Contaminants**
- ☑ **Pesticides**
- ☑ **Allergens**
- ☑ **Raw Materials**
- ☑ **Labels**
- ☑ **Product Standards**
- ☑ **Other**

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Who Should Perform Compliance Assessments?

› Determine who is the best informed and qualified to perform specific compliance checks (Regulatory, Quality, Product Developers)

   › Consider a Product Developer check early on to reduce the dreaded **compliance loop**

› Develop processes and workflows for efficient communication and to reduce the duplication of efforts

› Ensure all aspects of compliance are covered by dedicated resources

› Determine who is responsible for monitoring legislation changes, updating data, performing impact assessments to recipes, raw materials, labels, etc.

Polling Question #1

Does your company perform compliance checks during the formulation stage?

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The Problem with Last Minute Compliance

> Don't get to the finish line and find that your product is out of compliance
>> ○ Waste of valuable time & resources
>> ○ Jeopardizes launch dates
>> ○ Frustrates project teams & leadership
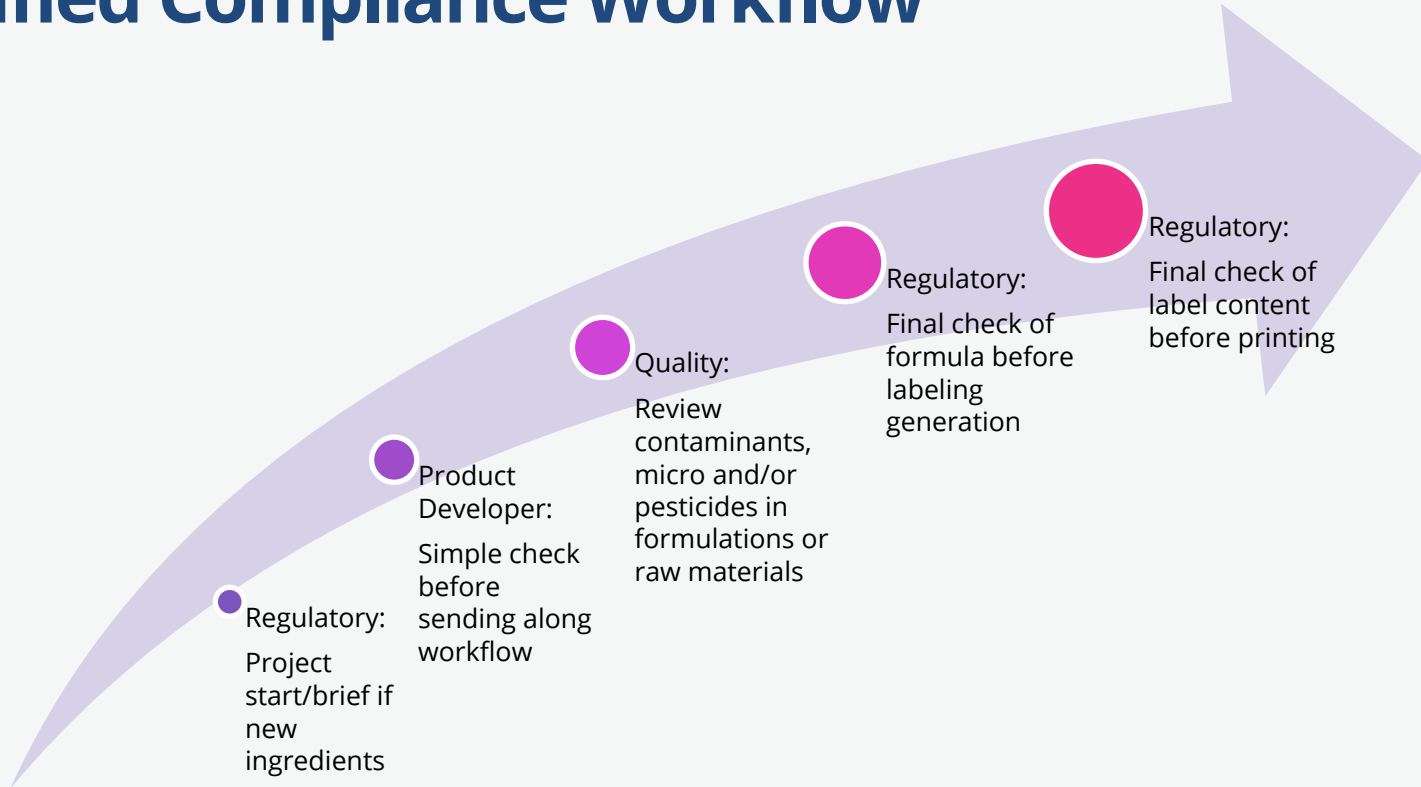>> ○ Decreases competitive advantage if late to market

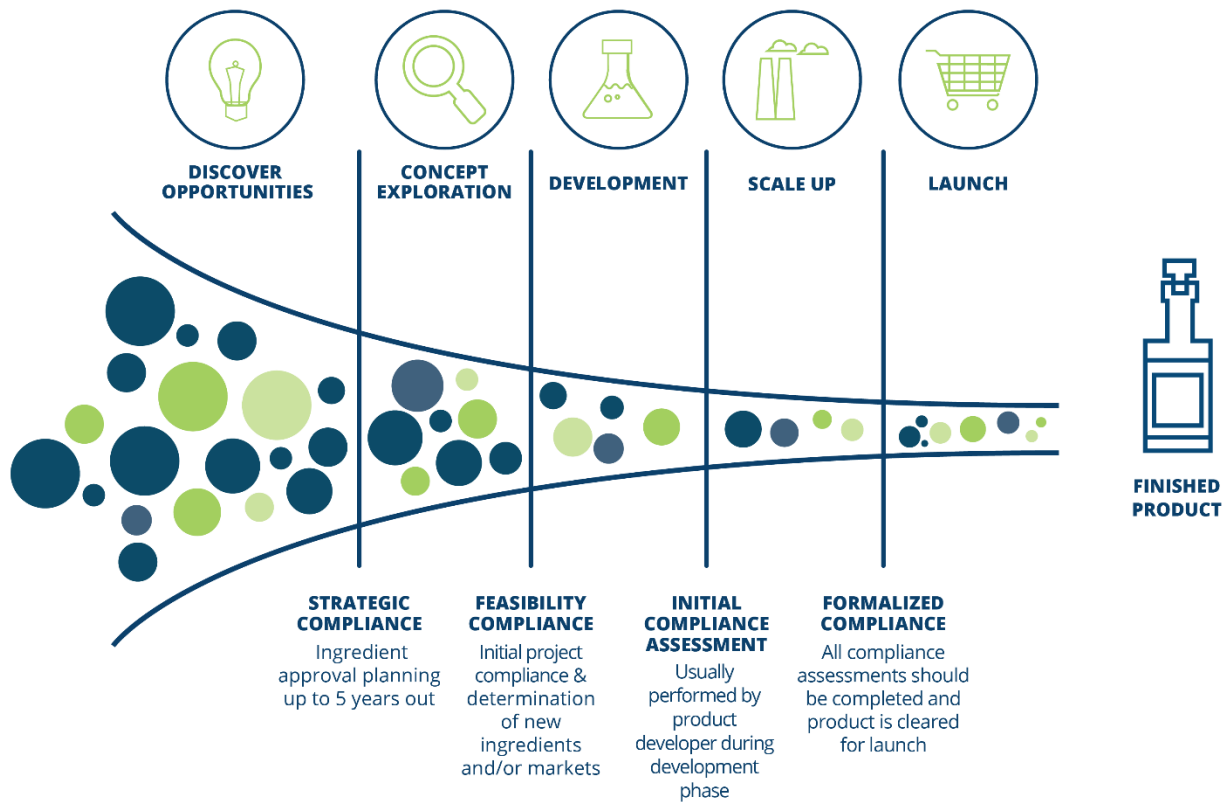> Timing is everything!

When to perform Compliance Assessments

❯ Early and at key points throughout the development process such as:

  ○ During the initial phases of a project if there are **unique ingredients** or a **new country of sale**

  ○ Before plant trials (save money, effort and production time if not compliant)

  ○ Before product labels are printed (costly if formula changes occur)

  ○ Before launch to ensure label compliance

❯ Utilize material and formulation status management along with workflow tools to reduce the number of repeated unnecessary compliance checks and increase confidence if formulations are not editable after the review is complete

  ○ Setting up a workflow will ensure assessments are completed and can inform if formulation changes are made

Polling Question #2

Does your company have a compliance strategy that includes a formalized workflow?

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Simplified Compliance Workflow

Regulatory:

Project start/brief if new ingredients

Product Developer:

Simple check before sending along workflow

Quality:

Review contaminants, micro and/or pesticides in formulations or raw materials

Regulatory:

Final check of formula before labeling generation

Regulatory:

Final check of label content before printing

DISCOVER OPPORTUNITIES

CONCEPT EXPLORATION

DEVELOPMENT

SCALE UP

LAUNCH

FINISHED PRODUCT

STRATEGIC COMPLIANCE
Ingredient approval planning up to 5 years out

FEASIBILITY COMPLIANCE
Initial project compliance & determination of new ingredients and/or markets

INITIAL COMPLIANCE ASSESSMENT
Usually performed by product developer during development phase

FORMALIZED COMPLIANCE
All compliance assessments should be completed and product is cleared for launch

Polling Question #3

Are your compliance assessment tools integrated with your formulation and product development system(s)?

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Benefits of Integrated Data

› Using integrated compliance data in a PLM system helps you become more efficient and consistent since you have all data and information in **one place** to perform assessments

- o Users from different functional groups (quality, product development, regulatory etc.) can easily assess compliance tools without system hopping

- o Data maintenance and upkeep is mandatory to remain accurate. Updates from legislative bodies need to be updated in PLM in a timely manner.

- o Integrating compliance data in PLM along with formulation and raw material information, will help you respond faster during your proactive outreach to Governing Bodies or Trade Associations. You can utilize query results to determine levels needed and impact to your products

Polling Question #4

Estimate the number of hours spent monitoring regulatory legislation changes each month

a. 1-5
b. 6-10
c. 11-20
d. 21 or more

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Regulation Monitoring

> Stay **alert** to upcoming regulation changes and emerging risks using news aggregation tools

  o Finding out that a regulation has been published once it is already in force, means you are too late

  o You will have a competitive advantage if you're prepared

> Responding quickly to proposed changes through your business, trade associations, or NGO's can provide great benefits

> Quickly running queries in PLM to determine the impact and provide data output to Government Bodies during comment periods

> Keep your compliance data updated. It is crucial to remain compliant

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Recap

› Build a compliance strategy

› Revisit the Compliance Checklist to ensure no compliance gaps

› Develop processes and workflows

- Including product developer check to minimize the compliance loop
- Timing is crucial, early is best and during the key phases of a project

› Key benefits of integrated data

› Regulation monitoring – stay alert and consider tools to maintain accurate data

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Questions?

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Thank You!