



Ingredient Supplier Information & Use of SIDI™ Protocol

*Global Supplement
Manufacturer Perspective*

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NUTRILITE® Brand

- Best of Nature, Best of Science
- 200+ nutritional supplement products:
 - tablets
 - capsules
 - powder drink mixes
 - nutritional snacks and bars
- Over 1300 raw materials
- 500+ raw material suppliers/locations
- Global Supply Chain

Global Reach

- sold by millions of Amway distributors
- in over 54 countries & territories
 - China, Japan, Korea
 - SE Asia
 - North America
 - Europe
 - Russia
 - Latin America



What Raw Material Information do we need?

- Manufacturing information
- Physical/Chemical Properties
- Nutritional Information
- Specifications
- Allergens
- GM Status
- BSE Status
- Halal, Kosher, Organic Status
- Non-irradiation, Non-ETO status

Who uses it?

- Product Development
- Marketing
- Quality Assurance
- Technical Regulatory Affairs
- Government authorities
- 3rd party certifying agencies

Why do we need it?

- Support Development & Claims
- Regulatory Acceptability
- Traceability
- Supplier Qualification Process
- GMP compliance

Goal of Supplier Qualification

Protect company from quality or reputation risks associated with raw material

KNOW YOUR SUPPLIER!!!!

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Documentation is a MAJOR component

What are we doing to Qualify Suppliers?

- Dedicated Supplier Quality Development (SQD) team
- Harmonizing procedures to develop a global approach to supplier management
- Identify, Quantify, Mitigate & Control risks

Complex supply chain with multiple suppliers & several tiers of suppliers

Supplier Qualification Process

- Step 1 – Technology Assessment
 - Acquire Documentation
 - Raw material information
 - Facility information
 - Evaluate if meet quality requirements
 - Evaluate if meet regulatory requirements
 - Evaluate if meet development needs

Supplier Qualification Process

- Step 2 – Capability Assessment
 - Facility Audit (visit or 3rd party data)
 - Additional information
- Step 3 – Performance Verification
 - Establish reliability of meeting requirements
 - CofA compared against original raw information
 - Testing to confirm supplier results

Supplier Qualification

- Supplier Qualified after showing consistent reliability over time
- Supplier Scorecard (maintain approval)
 - timely documentation & reliability are important!
 - on time delivery
- “Go to” supplier when need to quickly source a raw material (i.e. supply issue)
- Critical for complying with the US Dietary Supplement GMPs - subpart E §111.75

FDA GMP Audit

- Questions from FDA official
 - How do you obtain information on raw materials? (i.e. Allergen, Country of Origin)
 - How do you use the information?
 - How do you qualify a supplier?
- Compared internal specifications against material specifications
- Compared CofA to raw material information used in qualification (i.e. SIDI™ data)

How is Raw Material Information Obtained?

- Raw Material Questionnaire (1294 form)
- Turnaround average = 1 to 4 weeks
- Challenges
 - Completion and providing the necessary attachments usually involves several departments
 - Supplier contact information changes frequently
 - Distributor often point of contact, documents must be collected from manufacturers, which further delays the process



SIDITM Protocol

- Tool to use as alternative to questionnaire
- Industry identified major information needed
- Goal to drive consistent content & order/location of information
- Information readily available since part of supplier's knowledge management system



SIDI™ Implementation for NUTRILITE® Products

- Evaluated SIDI™ content for gaps compared to internal questionnaire (minimal)
- Gained buy-in from key stakeholders to accept instead of questionnaire
- Adjusted process for requesting information to include SIDI™ as option



SIDI™ Protocol Benefits compared to Questionnaire

- Quicker Turnaround time
 - Average 1 to 3 days (some instances within 1 hour)
- Accuracy
 - Less differences in SIDI information provided when compared to CofA when raw materials received
- Change Control

***** All are Important to avoid supply ***
chain disruptions or delays**



SIDI™ Protocol

Benefits to Suppliers

Benefits expressed by Ingredient Suppliers:

- **Internal Knowledge Management** vs. questionnaire
 - Reduced time to respond to request
 - Increased accuracy, reduce risk of error in transcribing data
- **Change control/notification**
 - Liability risk potentially reduced
- **Electronic data exchange**
 - Electronic format can be provided
 - Some Suppliers provide password to finished good manufacturer for download SIDI™ Data from website

Challenges

Questionnaire & SIDI™ data

- Incomplete or missing data:
 - **Sub-Ingredients**: Percent breakdown, function and source
 - **Manufacturing** Process Details or Flowchart
 - **Copy of Certificates**: Kosher, Halal, Organic, BSE
 - **GMO Status Details**: IP quality process details, PCR test results
 - **Allergens Statement** - indicating the of absence and/or presence of
 - Artificial Colors, Artificial Flavors, Artificial Preservatives, Barley, Buckwheat, Caffeine, Celery, Corn, Crustaceans, Egg, Fish, Gluten, Kamut, Lactose, Lupin, Milk, Molluscs, Mustard, Oats, Peach, Peanut, Rye, Sesame, Shellfish, Soy, Spelt, Sugar, Sulfites (natural occurring? ppm?), Tomato, Tree nuts, Wheat, Yeast, Other Nuts (specify)



Our Considerations for using SIDI™ protocol in the future

- Use SIDI™ protocol to set up information for raw materials we supply
- Training tool when on-boarding a new supplier
- Preferential status to suppliers that use SIDI Protocol

Thank You!



NUTRILITE®

BEST OF NATURE. BEST OF SCIENCE.

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