

# Don't let FDA dietary supplements regulations drain your business

FIND OUT MORE

**With the Sage X3  
Nutraceutical bundle from  
SWK Technologies, your  
compliance concerns are over.**

Sometimes it seems that while you're supplementing the nation's dietary needs, FDA regulations are sapping your business' energy. Truthfully, FDA regulations are only draining if don't have the right tools to help you run your business. When it comes to complying with 21 CFR Part 11 and cGMP, SWK can help supplement your operations.



# Capturing everything your product touches, and where it goes.

It's a worst-case scenario, but being able to trace the production and path of your products and then notify your supply chain if there's a recall beats agonizing over the penalties from lack of compliance—and a potential onslaught of law suits.

Unfortunately, many manufacturers are still burdened with:

- Solutions that don't provide end-to-end supply chain compliance.
- Legacy systems implemented before August, 1997, which lack most, if not all, of the features necessary to comply with DS cGMP.
- Systems that do not have inherent traceability functionality.
- Systems that previously used add-on software that might not comply with traceability requirements.

The Dietary Supplement Current Good Manufacturing Practice (DS cGMP) has been in place for nearly a decade, and **compliance is now an expectation.**



RAW MATERIALS

MANUFACTURER

RE/PACKAGERS

WAREHOUSING

DISTRIBUTION

WHOLESALER

DISPENSER

END CUSTOMER

## SWK Technologies offers the only complete, FDA-compliant bundled solution.

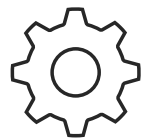
Anticipating that challenge, SWK Technologies assembled a fully integrated, end-to-end, bundled solution specifically designed for the dietary, vitamins, and nutritional supplements industry that need to comply with FDA electronic system requirements internally and across the supply chain.

The Sage X3 Vitamin and Nutraceutical bundle combines the power of the Sage business management solution with electronic data interchange (EDI), warehouse management automation, and shipping management automation software to satisfy cGMP mandates for:

- Product tracing.
- Illegitimate raw material and drug detection and notification abilities.
- Time-stamped audit trails to retain, archive, and generate copies of records, and to ensure electronic signatures on electronic records.

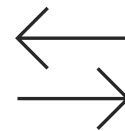


## How to manage and automate the critical FDA regulatory components:



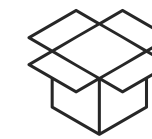
### Business management solution requirements

- Solution captures data around product production
- Solution “traces” the products for use when an issue arises
- Manufacturer notifies stakeholders (the FDA, corporate executives, production line, wholesalers, distributors, and dispensers)



### EDI requirements

- EDI captures the traceable product identification data
- EDI communicates the purchase orders and invoicing transactions between the manufacturer and the supply chain



### Shipping and warehousing requirements

- Shipping management software moves the product through the supply chain
- Warehouse management software automates the “pick-pack-ship” process

# Solution components:

## Sage X3

Business management solution

Sage X3 is a customizable business management solution that offers enterprise ERP functionality without the complexity. Components include electronic document management (EDM), fixed asset functionality, and timesaving efficiencies for financial, sales, and inventory management.

## EDI: MAPADOC and SPS Commerce

MAPADOC and SPS Commerce combine to translate the serialized EDI data between your trading partners, your supply chain, and Sage X3, which eliminates the need to manually key in orders and invoices.

## Warehouse management automation: Datalinx

Datalinx provides “pick-pack-ship” capabilities in the warehouse, allowing your staff to be wirelessly connected to Sage X3. Datalinx customers enjoy a 99.9% stock accuracy in receipting and picking orders.

## Multi-carrier, multi-channel shipping management: ProcessWeaver

ProcessWeaver offers an innovative multi-carrier, multi-modal, and multi-platform solution to automate shipments from the repackager to the warehouse.

## Optional capabilities enhance your Sage X3 Vitamin & Nutraceutical bundle

In addition to offering its own network services solution, SWK has partnered with Expedient for data center hosting solutions, Lascom for product lifecycle management (PLM) services, and Provenio Technology's Procession for quality control and compliance.

### SWK Network Services

SWK Network Services keep your business data safe—whether you need business continuity, backup and disaster recovery, comprehensive computer network and mobile device support, or email and web security.

### Expedient Hosting Services

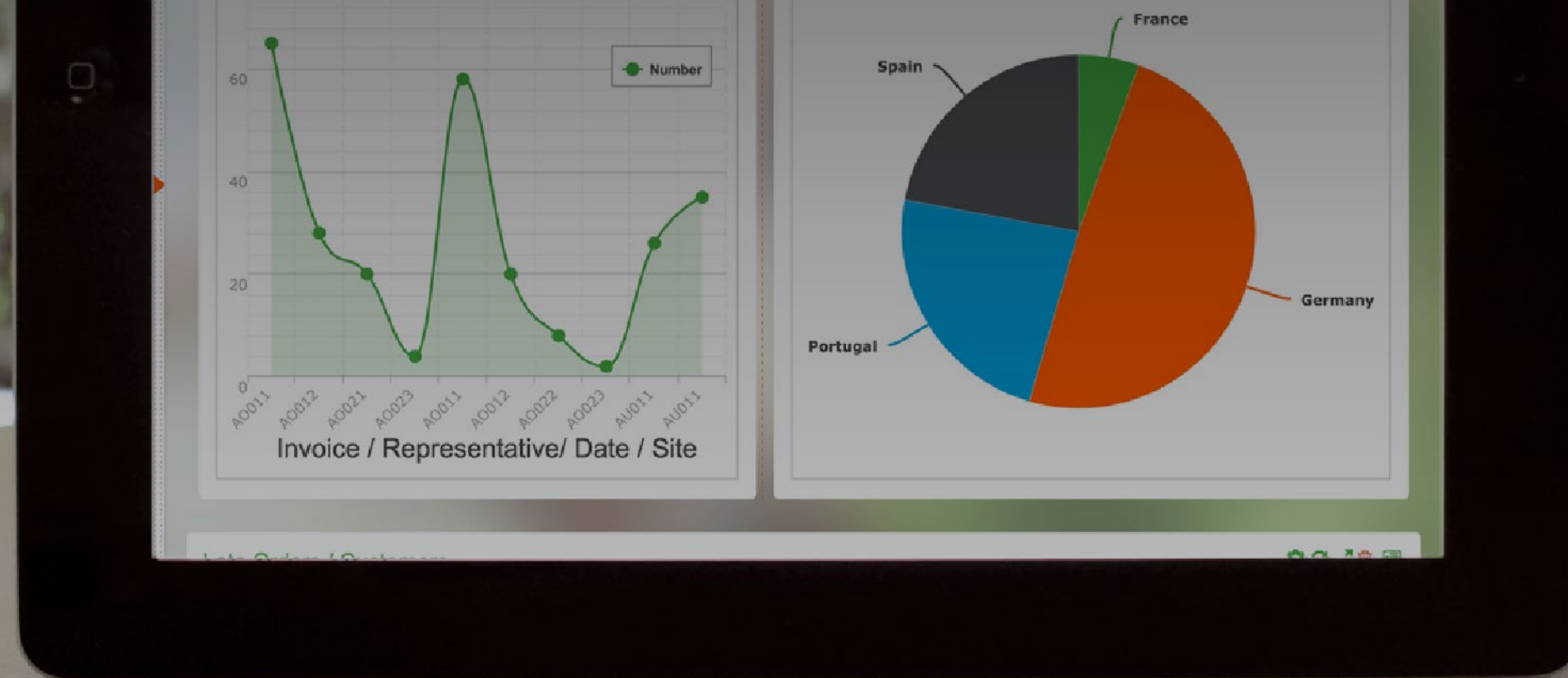
Expedient helps personal care/cosmetics manufacturers address complex industry requirements driven by standardization, globalization, and distributed supply chains.

### Lascom PLM

Lascom cost-effectively manages all the data, requirements, certifications, specifications, ideas, documents, and other information associated with product development, quality management, and regulatory compliance.

### Procession

Procession integrates into Sage X3 to ensure your regulatory, formulation, manufacturing, inventory, QC, safety, shipping and handling, and order data is all stored in a single database and can be accessed through a single user interface.



## SWK and the Sage X3 Nutraceutical bundle: the pain-free approach to FDA compliance

SWK is a Sage Software Authorized Business Partner, Sage Certified Gold Development Partner, Sage Certified X3 Partner, Sage Extended Solutions Preferred Development Partner, and Sage Authorized Training Center. We have invested considerable time and resources into identifying and combining the right products to create a comprehensive solution that best meets the demands of the dietary, vitamin and nutritional supplements industry. Our software development, consulting, and project management teams have carefully chosen each component because of their ability to serve our customers who face FDA regulatory challenges.

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### Next steps

If you'd like to learn more about how SWK and Sage X3 can help you comply with FDA regulations in the dietary, vitamin and nutritional supplements industry, please contact us to schedule a **free demo**.

### Contact:

Email us at [sales@swktech.com](mailto:sales@swktech.com) or call 973.758.6100.