

# Don't let the FDA personal care product regulations become a headache

FIND OUT MORE

**With ERx3P  
Cosmetic bundle from  
SWK Technologies,  
your compliance  
concerns are over.**

Sometimes it seems as if the word **“pain”** should be required after every mention of the term **“regulatory compliance.”** In truth, regulatory compliance is a pain only if you don’t have the preparation, tools, or resources to successfully meet them on time and on budget. When it comes to complying with the Food and Drug Administration’s Drug Supply Chain Security Act (Title II of the Drug Quality and Security Act), make sure the process isn’t a pain.

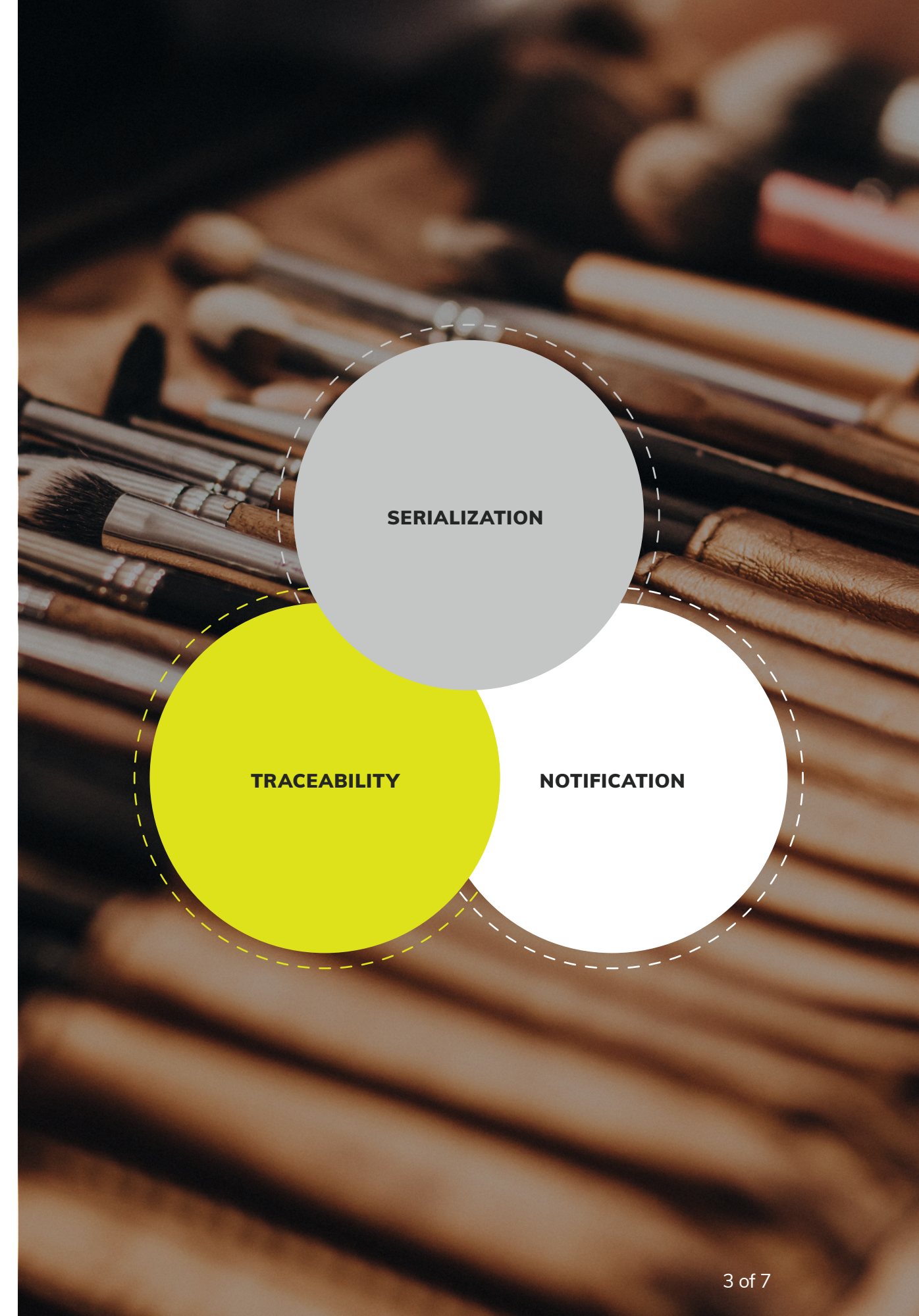


# A major condition of the new regulations could be considered one of those headaches.

Personal care and cosmetics manufacturers will need to trace and track products with a promise of efficacy at the unit level—not at the lot level. This will require many enterprises to upgrade their enterprise resource planning (ERP) software. In fact, you're far from alone if you're currently 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 DSCSA.
- Newer systems that do not have inherent serialization and traceability functionality.
- Older or newer systems that previously used add-on software that might not comply with serialization and traceability.

Cosmetic and personal care products that do not have a promise of efficacy must still comply with those FDA regulations defined in 21 CFR Part 11, which concern electronic records management.





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

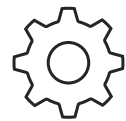
Anticipating that pain, SWK Technologies assembled a fully integrated, end-to-end bundled solution specifically designed for cosmetics and personal care manufacturers that need to comply with FDA electronic system requirements internally and across the supply chain.

The ERx3P bundle combines the power of the Sage X3 business management solution with electronic data interchange (EDI), warehouse management automation, and shipping management automation software to satisfy DSCSA mandates for:

- Prescription drug identification, achieved through serialization.
- Product tracing (which now must be conducted at the unit level—further emphasizing the importance of serialization).
- Product verification.
- 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.

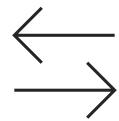


## How to manage and automate the critical FDA regulatory components:



### Business management solution requirements

- Solution captures data around serialized products
- 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 serialized 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 ERx3P cosmetic 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

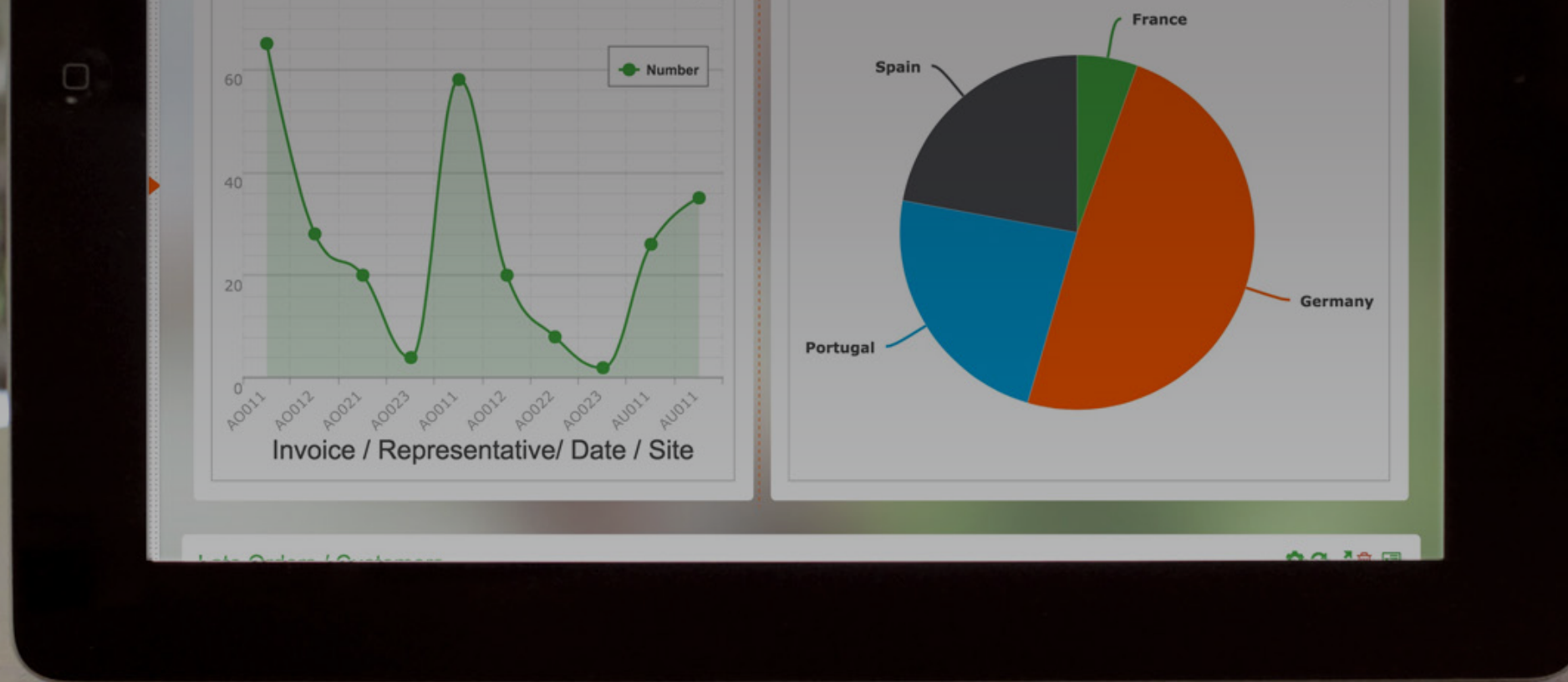
Expedient helps personal care/cosmetics manufacturers address complex industry requirements driven by standardization, globalization, and distributed supply chains.

### 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 ERx3P cosmetic bundle: the pain-free approach to achieving 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 bundled solution that best meets the demands of the personal care and cosmetics 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 upcoming FDA regulations in the personal care and cosmetics industry, please contact us to schedule a **free demo**.

### Contact:

Email us at [erx3p@swktech.com](mailto:erx3p@swktech.com) or call 973.758.6100.