Visante Consulting Services

Sterile compounding

Visante
A vision for *moving healthcare forward*

Safe handling of compounded medications becomes more complex as regulatory standards evolve. Consider all your options to provide critical medicines safely and cost-effectively.

Providing high quality compounded medications is critical to patient care. Hospitals will need to evaluate the best way to optimize care and meet regulatory and safety requirements while managing the costs of these important medicines. We can assist you in evaluating external sources or insourcing sterile compounding functions.

USP 797 compliance is essential

Safe handling of compounded medications is a critically important core competency that hospitals must provide to protect patients, staff and the environment. Unfortunate situations that have occurred in the US in recent years underscore the need for more robust compounding practices and facilities. We help hospitals provide safe, quality compounding practices that meet or exceed USP 797 requirements.

Our experts prepare you for USP 800 compliance

Visante consultants have been monitoring and providing input to USP for the proposed USP 800 guidelines. Our knowledge, coupled with our extensive experience in design, development and management of sterile compounding facilities will help your organization to identify gaps and quickly prepare your organization for compliance.

Manage cost and quality through insourcing

There are many benefits to in-sourcing sterile compounding activities. Visante consultants can conduct a cost/benefit analysis of your current operations and show you how you can optimize current processes, gain control over quality and reduce costs through insourcing. Whether expanding an existing operation or developing a new compounding capability, many hospitals have discovered this can have a very positive ROI and increased control of medication quality and availability.

Consider how USP 800 will impact your facility:

- ✓ Separate storage for hazardous drugs
- ✓ Designated areas for receiving hazardous drugs
- ✓ Separate refrigeration for hazardous drugs
- ✓ Compounding “glove boxes“ no longer acceptable by themselves
- ✓ Removal of the “low volume” exemption of USP 797
- ✓ Integration of closed-system transfer devices

Be prepared.

“Our team helps clients to quickly identify and fill major gaps in sterile compounding performance that can impact compounded drug quality and manage production costs.”

- Fred Massoomi, PharmD, FASHP, Senior Consultant, Visante

Achieving excellence in sterile compounding —
Visante takes you to the next level of safety and efficiency

» USP 797 Compliance Program

Visante consultants provide a swift, yet thorough, assessment of your current operations relating to USP 797. We provide a report highlighting your risk points and including specific recommendations that will correct problem areas using the most cost-effective means available.

» USP 800 gap analysis and preparation

Visante consultants who are working directly on USP 800 guidelines will conduct an on-site visit to your organization. We will observe and assess the current sterile compounding facilities and processes in light of proposed USP guidelines. Our findings and key recommendations will include analysis of standard operating procedures, formulations, expanded services, facilities, training, equipment and personnel.

» Sterile compounding insourcing opportunity

Further expansion of your sterile compounding operation can be an effective way to manage resources, control quality and drug supply. Visante consultants conduct an analysis of your current operations and provide detailed recommendations outlining the cost/benefit scenario and implications for your existing facilities and staff.

» Sterile compounding facility design and implementation

A comprehensive, detailed analysis of your opportunity to develop new sterile compounding facilities and operations is a key area of expertise for Visante. We provide a thorough business case for your organization to help you determine how sterile compounding services can impact your patients, facilities and overall business objectives. Our team is prepared to help you design, build and manage your facility, operations, technology and staff so you can make the most of your sterile compounding services.

"Hospitals are often surprised at the excellent return on investment they can obtain by expanding sterile compounding capabilities. The key is a sound, practical business strategy with advanced clinical protocols."

– Ken Latta, RPh, FIACP, FACA, Senior Consultant, Visante

» Smart business decision

» cGMP consideration

For organizations considering operations at cGMP standards under the 503B requirements of the Drug Quality and Security Act, Visante subject matter experts have worked in the design, build and operation of compounding facilities operating under cGMP. Visante consultants can advise on immediate of transitional plans for a 503B operation.

» To find out more about Visante, please visit visanteinc.com or call (866) 388-7583.

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