How-to Guide for Insourcing I.V. Sterile Compounding

Making the Most of the ASHP Insourcing Sterile Compounding Services Toolkit

The ASHP Insourcing Sterile Compounding Services Toolkit was designed by a steering committee of experienced pharmacy managers and experts in i.v. sterile compounding to help you navigate the insourcing decision-making process and provide tools for implementation. This guide is designed to take you through the evaluation phase as you determine whether or not insourcing is a good option for your hospital or health-system and, if so, to what degree. Once you determine that your organization is going to pursue insourcing, use the resources in the implementation section to move forward.

Many of the tools are available in PowerPoint, Excel, or Word format. Each format is downloadable and can easily be modified to your specific needs.

- The PowerPoint format will be useful for developing presentations and training for stakeholders and other personnel.
- The Excel format will be useful for financial analysis purposes.
- The Word format will be useful if you prefer to work from documents. Materials in these formats were designed for you to copy and repurpose as needed.

Background and Organization of the Insourcing Sterile Compounding Services Toolkit

The decision to "insource" i.v. sterile preparations involves a great deal of consideration from stakeholders throughout the organization. Similar to outsourcing, there are pros and cons to this decision and each variable should be weighed carefully. There are many ways to arrive at the decision to insource or not to insource and just as many ways to implement a new program if you decide to move forward with insourcing. This toolkit is divided into two main sections: The Evaluation Process and Implementation.

Within these two sections you will find categories to help organize the decision-making process and tools to assist with implementation. You might find that some of the items listed in the implementation phase are necessary for you to consider in the decision-making phase and vice versa.

If you are getting started with evaluating the feasibility of insourcing, start with the Evaluation section which focuses on evaluating the following variables:

- Strategic Planning
- Risk
- Quality
- Regulatory Considerations
- Making the Business Case
- Facility and Cleanroom Design

If you have decided to move forward with insourcing you can progress to the Implementation section which includes the following considerations:

- Personnel/Training
- Policies and Procedures
- Workflow
- Cleanroom Design
- End Product Testing
- Product Line Evaluation

Overview of the Evaluation Section

STRATEGIC PLANNING

This step should be the overarching fact-finding portion of the evaluation that sets the stage for why this project is being considered and establishes which stakeholders need to be involved. Some organizations may include items such as conducting a SWOT analysis, reviewing what other organizations have done in similar situations, undergoing a needs assessment, and examining resources that outline the pros and cons of insourcing in the strategic evaluation phase.

Additionally, the decision to insource is further reaching than just the pharmacy and should involve stakeholders from throughout the organization. Below is a list of potential questions to ask to ensure that the appropriate individuals are involved early in the process.

- Which pharmacy personnel should be involved?
- Which physician specialties need to be involved in the decision-making process?
- Which hospital or health system administrators need to be involved?
- Are there other disciplines (e.g., nursing, laboratory, risk management, infection control) that need to be involved in the decision-making process?
- Does central supply need to be involved?
- If building a new space is an option, who needs to be involved from a facilities standpoint?
- Does legal counsel need to be involved?

Visit the Strategic Planning section of the toolkit for SWOT analysis tools, best practices in sterile compounding, and more.

REGULATORY EVALUATION

State rules and regulations for i.v. sterile compounding vary widely and must be considered when determining the feasibility of insourcing. Regulations exist that outline which personnel are allowed to compound, where a sterile compounding facility can be located, and whether or not a "central fill" model is allowed.

Federal regulations also exist and represent an area that has seen many changes in recent years, with additional major changes to be finalized in 2019.

Visit the Regulatory section of the toolkit for links to state and federal regulations applicable to i.v. sterile compounding.

RISK EVALUATION

When evaluating the risk for insourcing vs. outsourcing, an organization must be sure to analyze many types of risk:

- Risks to patient safety
- Financial risks
- Regulatory risks
- Public relations risk—internal and external
- Risks associated with drug shortages
- Systems and technology risks

Visit the Risk section of the toolkit for links to articles and tools to assist in risk assessment.

FACILITY EVALUATION

Where sterile i.v. compounding will occur is a critical part of any service expansion. The following are a sample of the types of considerations to be made regarding real estate, facility, or space needs.

- Will a new space be acquired or will an existing space be modified or retrofitted?
- How much space is needed for compounding, storage, quarantine, administrative space, etc.?
- Are there any controlled substances security considerations needed for the space?
- Will capital equipment acquisitions will be needed? If so, what is needed?
- Are there space requirements for refrigeration, technology or automation, etc.?
- What are the plumbing, HVAC, electricity, and filtration needs of the space?

Visit the Facility section of the toolkit for resources specific to facility or real estate needs.

QUALITY EVALUATION

Quality assurance touches every aspect of sterile compounding from environmental monitoring to personnel competency to certification of the compounding space and beyond. Compounding i.v. sterile products

requires elements of quality to be met. The Quality Evaluation section goes beyond regulatory standards and provides access to best practices documents and examples.

MAKING THE BUSINESS CASE

Cost is a critical element of any service expansion, and the Business Case section of the toolkit provides resources and tools to assist with making the business case. Financial analysis tools can be found in this section and repurposed for use in making the business case for your organization. Business plans come in many forms and must be tailored to fit the needs of the project and the organization. Sample business plans are posted in the toolkit and represent various models that organizations may be faced with.

Overview of the Implementation Section

For organizations that have undergone a thorough evaluation of insourcing and opted to expand current i.v. sterile compounding services, the next steps are planning and implementation. This section of the toolkit provides tools and resources focused on assisting with implementing an insourcing program.

PERSONNEL

Pharmacy personnel involved in i.v. sterile compounding must be well trained and competent to work in this area. Use tools and resources in this area to develop training materials and revise job descriptions.

END PRODUCT TESTING

End product testing is an area that has not traditionally been conducted by pharmacy personnel. Sterility, stability, endotoxin testing, and others have been part of the outsourcing process for many facilities. As organizations transition products with extended beyond-use dates back in house, end product testing needs must be considered.

Reviewing resources on how testing is conducted and the regulatory requirements is a natural place to start. Some specific considerations might include:

- Will end product testing be brought in house or outsourced?
- If outsourced, which lab will conduct the testing?
    - How will external vendors for end product testing be validated?
    - Who will be responsible for tracking items sent out for testing and determining the proper amounts to be tested?
- If brought in house, where will testing be conducted within the organization?
    - Who will be responsible for the testing and how will those individuals be trained and competency tested?
    - What types of devices will be needed to complete in-house testing and how much space will be required?

  - Where will quarantined items be stored and who will monitor the products?
  - What is the release process and the notification process if positive results are reported?
- Which stakeholders outside of pharmacy need to be involved in the end product testing decision-making process?

Visit the End Product Testing section of the toolkit for additional resources and tools.

CLEANROOM DESIGN

If a cleanroom will be modified or built to accommodate insourcing of i.v. sterile compounding services, the organization will need to determine the proper design for the project. Many organizations utilize cleanroom designers or architects to assist with designing a sterile products space. As the end users of this space, it is important to be aware of the unique needs of your facility and know the types of questions to ask of designers and architects. Consider which stakeholders should be involved in any design process and visit the Cleanroom Design section of the toolkit for tools and examples from other facilities to assist you.

PRODUCT LINE EVALUATION

Most hospitals and health systems will not be able to insource all products that were previously outsourced all at once. Product line evaluations can assist in determining which products to insource first and how the process will flow. Specific product line considerations may include:

- Will all products that are currently outsourced be brought back in house or only a few?
- For insourced products, will there be a standard formulation offered to prescribers or will customization be possible?
- Is this an opportunity to streamline to standard concentrations for some products?
- What efforts will be needed to minimize waste?
- What are the implications of drug shortages on certain product lines?
- What is the current utilization data for each product?

Visit the Product Line section of the toolkit for additional tools and resources for implementing specific product lines.

WORKFLOW

New service offerings and extensions usually mean new or modified workflow. The earlier in the process a workflow evaluation can occur, the more efficient implementation will be. Workflow can impact everything from cleanroom design, to training, to policies and procedures to the number of product lines that are insourced.

Visit the Workflow section of the toolkit.

POLICIES AND PROCEDURES

Implementation of a new service offering or modification of existing operations requires harmonizing policies and procedures with the processes. Depending on the extent of insourcing your facility will experience, you may only need to update policies and procedures or you may need to write an entire new manual, especially if tasks, such as end product testing, are brand new to your organization. Visit the Policies and Procedures section of the toolkit for sample policies and procedures, many of which are available in Word format for ease of editing.