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Ensuring the production of accurate and safe sterile compounded medications for our patients spurred our investigation to identify the ideal approach for creating a centralized compounding pharmacy. To create a cutting edge facility that consistently and efficiently delivers safe and effective medications required us to embrace automation. It became clear as we investigated our options that establishing a centralized production facility to provide medications throughout our health system would allow us to justify the purchase of innovative technologies and construct a facility that would operate under an advanced workflow.

Creating a Centralized Compounding Pharmacy within a Health System

Scripps Health System consists of five, commonly owned hospitals, all located within a 50-mile radius. These facilities are of various sizes, ranging from 170 beds up to 400+ beds. A notable difference among the facilities was the different approaches taken to compounding. Much of this variability resulted from the variety of equipment and cleanrooms that had been installed at different points in time. As a result, each of our hospitals had achieved various levels of USP <797> compliance; we did not have consistent compounding practices or facilities.

Drivers for Creating a Centralized Compounding Pharmacy

Three years ago, we began the process of creating a new, centralized facility to provide sterile compounded and repackaged medications to the five hospitals in our health system. Our goal was to create a single facility to centrally produce sterile IV products for all of our facilities in an efficient and cost-effective manner.

Having made the commitment to implement BCMA in our health system, it was obvious that our compounded and repackaged products also required a comprehensive bar coding process. An intrinsic component of the automation in our central compounding pharmacy is the software that consistently creates bar code labeled products to support BCMA. Our final product bar codes ultimately provide the batch lot number for each product, allowing us to retrieve the necessary information for each component used in a given product.

Building a new, USP <797>- compliant facility gave us the opportunity to ensure that both the facility and standard operating procedures (SOPs) would meet or exceed standards. By centralizing operations we also were able to take advantage of economies of scale to justify the purchase of cutting edge technology. This allowed us to create efficiency and safety through automation while avoiding the problems inherent with space constraints in our existing facilities. For example, we have sufficient space within the new cleanroom for three IV compounding robots, a refrigerated

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carousel connected to the cleanroom for product transfer and storage, as well as a high-speed oral solid packager and a liquid packaging machine.

After reviewing various locations to house the central compounding facility, we ultimately chose to locate it in a standalone space centrally located between our multiple hospitals; approximately 3500 square feet are dedicated to the operation including a 1570 square foot cleanroom. One unexpected benefit of the standalone space is the ease of shipping and receiving activities, as we are not constrained by a busy hospital shipping dock. Utilizing batch production in this centralized facility will help us create economies of scale in our compounding processes, which will positively impact pharmacy's bottom line.

Meeting Regulatory Requirements

At the time that we began exploring the possibility of creating a centralized compounding pharmacy, the state regulations in California did not permit batch compounding from a central location even within facilities under the same ownership. As such, we approached the state board of pharmacy and worked with them to develop the necessary state legislation that was eventually enacted (Assembly Bill 377) to permit a centralized pharmacy to provide medications to commonly owned facilities within a 70-mile radius. Key to the success of this legislation was emphasizing the improved safety we could provide our patients via robotic equipment and compounding automation—technology that might prove unaffordable for a single hospital. Under the new legislation, a central compounding facility must pass a state board of pharmacy inspection prior to opening, and undergo regular inspections thereafter.

During our planning process uncertainty continued to define the interpretation of federal regulations as applied to centralized hospital pharmacy operations. Thus, we chose to create SOPs that would meet the strictest regulatory guidelines; the design of our SOPs is based on FDA's current good manufacturing practices (cGMPs) to ensure that our practice will deliver products defined by safety and that we will be prepared to meet new regulations as they develop. For example, in addition to providing in depth training on our SOPs and requiring meticulous process documentation, we will ensure our procedures are followed through consistent, routine auditing. Should a discrepancy be identified, a Corrective Action/Preventive Action (CAPA) approach is undertaken as prescribed in the cGMPs. Discrepancies are documented, root causes are investigated, and the corrective action to prevent a recurrence of the problem is implemented along with a plan for follow-up. This rigorous approach helps avert the risk of developing poor practices.

Designing the New Space

Advanced technology drives the efficiency that makes a centralized compounding pharmacy practical. Therefore, robotic compounding will facilitate much of our compounding production. Two IV robots as well as a robot for preparing sterile syringes complement our modular cleanroom. In addition, IV workflow and inventory management software programs support the process, while a refrigerated carousel

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Robot production takes place within the Misterium modular cleanroom and the pass-through refrigerator improves product accessibility.

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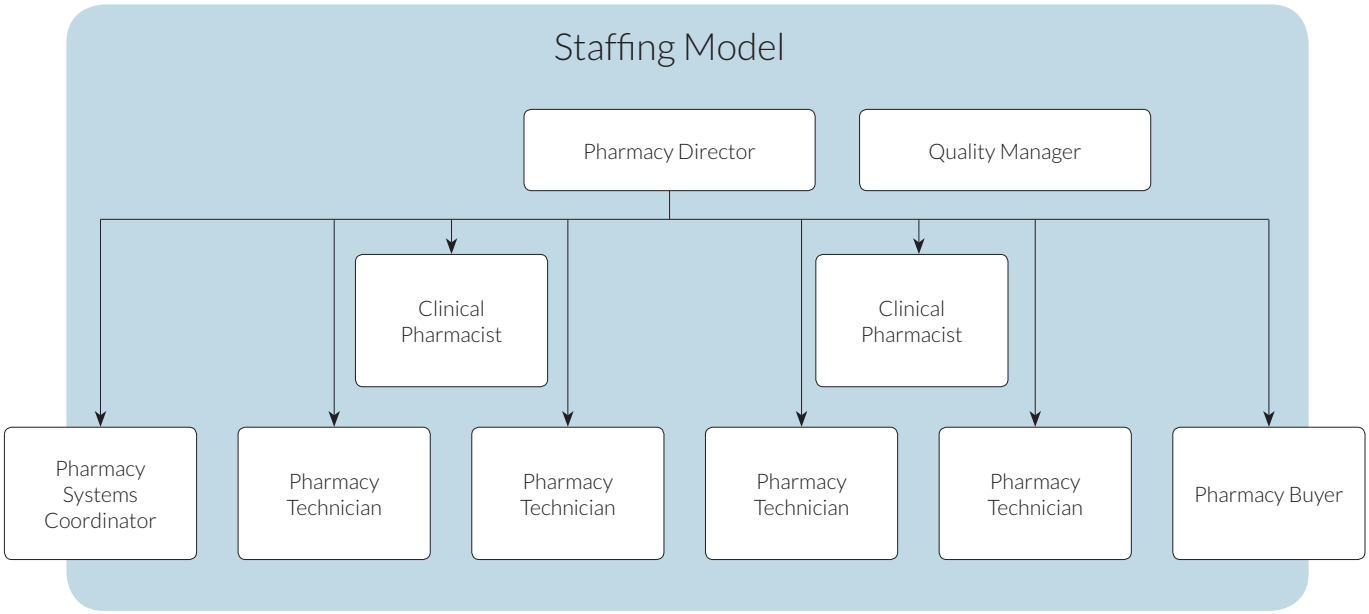

The initial staffing model will support a single shift, 5 day a week compounding program. All staff reports to the Pharmacy Director, with the exception of the Quality Manager. While the Quality Manager works closely with the Pharmacy Director, this role reports to the Executive Director of Pharmacy Services to ensure the independence of this position. The Pharmacy Systems Coordinator is a technician position that manages the automated equipment and interfaces with the IS department and the technology vendors.

ensures appropriate product management and storage. A high-speed oral solid packager and liquid packager round out the automation. The first decisions in the build process revolved around the cleanroom. Rather than have our contractor build the cleanroom, we chose to install a modular cleanroom built by experts who specialize exclusively in cleanroom construction. The decision to go with Grifols was obvious as they not only provided a highly detailed proposal that included cleanroom design and workflow diagrams, but they also have extensive experience designing and building cleanrooms for their own manufacturing facilities. The storage and inventory management system for all compounded products is also automated and includes hardware tools such as our Grifols-SencorpWhite Clean-Room Connect carousel. The refrigerated carousel offers a pass-through design with automatic, interlocked doors to prevent cross contamination when moving products into and out of the cleanroom. We also chose to install our robots and oral solid packaging equipment within the cleanroom. While it is not required that this equipment be located within an ISO-controlled area, we felt this placement would ensure the highest levels of cleanliness and sterility for our operation.

Planning the layout required significant expertise. We benefitted from Grifols' extensive experience in cleanroom design and construction, and also worked with an expert consultant to fill in our knowledge gaps. Taking a team approach to the design and construction phases allows you to take full advantage of in-house expertise. Our facilities department managed the construction phase, which freed pharmacy to work on SOPs and workflow design. It is important to engage the facilities department early in the process and to support the allocation of adequate resources to oversee construction.

The IS department was equally integral to our success. In any highly automated operation, all of the new systems and devices need to be vetted to ensure interoperability and network compatibility. Keep in mind, the technology vetting process can take as long as the construction process, so advanced planning is required. Finally, during the actual installations, the IS department is invaluable to the complex configuration and testing processes.

Workflow

By design, our centralized compounding pharmacy will only produce products from FDA approved sterile ingredients; no high risk or hazardous compounding will be conducted in this facility in the interests of product safety. Our plan is to begin on a small scale, develop expertise, and then expand our practice. The first products we compound will be those that are commonly used throughout our facilities and often outsourced to outside, large-scale sterile compounding pharmacies. An important component of our layout and workflow design is to prevent any process overlap between raw ingredients and final products. As such, the complete production process for each product is mapped out as part of our SOPs.

Just as the centralized approach allows us to take advantage of cutting edge cleanroom equipment, we also enjoy the benefits of process standardization that are only possible on this larger scale. For example, we have a dedicated validation area where all pharmacist checks are completed. Our automated workflow technology tracks and documents each production stage including compounding, pharmacist check, sterility testing, and product releases (ie, sterility testing passed), which provides significant peace of mind. The software also allows for batch number and expiration date management, making it easier to manage out of date or recalled products. Additional control is delivered through the cleanroom carousel's inventory management system, which allows or denies access to products based on their current status (eg, sterility testing, product release). Another area that benefits from standardization is sterility testing. As we conduct batch production, every batch assigned a beyond use date (BUD) exceeding USP <797> microbial contamination risk levels will undergo a USP <71> sterility test.

Because compounded products are only as good as the environment in which they are prepared, environmental monitoring becomes a key component of the process.

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We installed the Grifols/CIMScan environmental monitoring system, which includes sensors to monitor temperature, humidity, differential pressure, and particle counts. CIMScan monitors these parameters and alerts designated individuals if pre-established alert values are exceeded. By automating the environmental monitoring, data is collected regularly and reliably, while staff is free to focus on other areas. Because the data is collected continuously, it is easy to document our compliance.

Quality Control Drives Long-term Success

The key building blocks of a centralized pharmacy operation are creating an environment that is capable of consistently providing USP <797>-compliant compounded products for multiple facilities and establishing SOPs that ensure consistency. However, ongoing quality control measures are imperative to ensuring that the benefits of those initial efforts are maintained over time.

Comprehensive training is the first step to ensuring high proficiency among staff members. Initial efforts should focus on training a limited number of staff members and expand only when the core group has demonstrated sustained proficiency through regular practice. Because our initial operations will commence with just one shift, we will utilize 10 employees at the outset (see the grpah in page 38). Given the realities of vacations and unexpected absences, appropriately trained back-up staff must be available to step in, possibly on short notice. Again, our training will focus on a core group of inpatient pharmacy staff to serve in back-up roles. By keeping this number small we will be able to provide the extensive training that is necessary to develop expertise among both groups. Considering how easy it is for the best of intentions to be lost in practice drift, or the gradual shift away from precise practices into bad habits, establishing a dedicated quality control position underscores management's commitment to the consistent application of quality as well as affords a bulwark against this inevitable drift. Providing a separate reporting structure for this position is necessary to maintain independence. Key responsibilities for this role include scheduling regular times to observe staff in action, paying particular attention to aseptic technique, cleaning and disinfecting, hand hygiene and garbing, equipment operation, policy and procedure adherence, and environmental sampling competency. In addition to keeping a record of training conducted, quality management requires that deviations and incidents be tracked, and corrective actions documented. Implementing quality management software simplifies this process and makes survey preparation and data trend reporting painless.

The automated workflow software tracks and documents each stage in the compounding process.

Conclusion

As the centralized compounding pharmacy project has developed, additional opportunities for delivering cost-effective, safe, efficient centralized services have also evolved. We began with a plan at the outset to provide certain high volume compounded products to our health system facilities, but we now plan to expand to providing centralized automated dispensing cabinet (ADC) and code cart drug tray replenishment as well. Once the safety, efficiency, and cost effectiveness of the centralized model are established, the opportunities for expanding the utility of such a progressive operation abound ⏮

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