Drug Delivery: Minimizing Risks and Enhancing Regulatory Compliance

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Why is this Important?

https://www.youtube.com/watch?v=ipSMvJlw7Rs

Why is this Important?

- Patients expect safe care
- Your reputation is at stake
- Significant cost implications
- The issues are complex

Agenda

- Discuss regulatory risks surrounding drug delivery options
- Importance of direct pharmacy engagement
- Provide real examples of successful implementation

Drug Sourcing Options

- In-house compounded
- Centralized (owned) compounding
- Original manufacturer purchased
- **Outsourced compounding**

Table 3.
Consensus Panel Rankings of I.V. Drug Delivery Systems[a]

Domain	Manufacturer Ready To Use	Outsourced Ready To Use	Point-of-Care Activated	Pharmacy Compounded	Nonpharmacy Compounded at Point of Care
Applicability	4.0	5.4	3.6	6.7	5.8
Ease of use	6.2	5.5	4.9	3.7	3.6
Regulatory compliance	6.5	5.2	6.0	3.5	1.8
Cost	4.0	3.4	4.1	3.8	4.9
Safety	6.0	4.5	4.6	4.2	1.8
Implementation	6.0	4.9	4.7	3.6	2.6
Total	32.7	28.9	27.9	25.5	20.5

[a]Mean scores of rankings based on the Likert scale ranging from 1 = very weak to 7 = very strong.

Outsourced Vendors

- Big difference from national manufacturer compounding
- More common due to frequent manufacturer issues, raw material shortages, or general availability
- Specialty formulations of existing products
- May or may not be regulated by the FDA
- Published guidelines by ASHP

Inherent Risk in Outsourced Compounding

BECKER'S ASC REVIEW

60 patients sue Guardian Pharmacy & 2 Dallas surgery centers that used its drug: 5 insights

Written by Angie Stewart | February 14, 2019 | Print | Email

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Sixty patients are suing Dallas-based Guardian Pharmacy and two Dallas-area surgery centers that administered the company's compounded solution in 2016 and 2017, *WFAA* reports.

What you should know:

1. The lawsuits allege Guardian's solution caused vision damage within weeks after it was injected during procedures at Medical City Surgery Park Central, formerly Park Central Surgical Center, and Key-Whitman Eye Center. Key-Whitman Eye Center spokesperson declined to comment on the pending litigation. *Becker's ASC Review* was unable to reach a Park Central representative at the time of publication.

2. In May 2017, Park Central Surgical Center Administrator Rick Coffman, RN, signed a letter republished by Van Wey Law, which informed patients that some had developed vision impairment after undergoing cataract surgery at the ASC.

"We now believe the underlying cause of this issue may be an antibiotic medication used during surgery. The medication was prepared by an FDA-inspected laboratory here in Dallas and provided to Park Central Surgical Center," the letter said.

3. Van Wey Law identified the solution in question as triamcinolone/moxifloxacin. The law firm is representing cataract patients who reported eye injuries.

4. Jeffrey Whitman, MD, previously told WFAA, "The medication was not made to specifications and that is what most likely affected the retina."

5. Guardian voluntarily stopped compounding the drug. However, Guardian Pharmacy President Jack Munn said in a statement to WFAA, "No scientific connection has been established by any entity between the drug Guardian Pharmacy Services compounded and the illnesses that have been reported."

You want to avoid this

January 31, 2018: New England Compounding Center Pharmacist Sentenced for Role in Nationwide Fungal Meningitis Outbreak

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Food and Drug Administration
Office of Criminal Investigations

U.S. Department of Justice Press Release

For Immediate Release
January 31, 2019

United States Department of Justice
District of Massachusetts

Boston -- The former supervisory pharmacist of New England Compounding Center (NECC) was sentenced today in connection with the 2012 nationwide fungal meningitis outbreak that killed 64 and caused infections in 793 patients.

Glenn Chin, 49, of Canton, Mass., was sentenced by U.S. District Court Judge Richard G. Stearns to eight years in prison, two years of supervised release, and forfeiture and restitution in an amount to be determined later. In October 2017, Chin was convicted by a federal jury in Boston of 77 counts, including racketeering, racketeering conspiracy, mail fraud and introduction of misbranded drugs into interstate commerce with the intent to defraud and mislead.

"Mr. Chin was a pharmacist, but again and again he acted with complete disregard for the health and safety of patients," said United States Attorney Andrew E. Lelling. "Mr. Chin will now be held responsible for producing contaminated drugs that killed dozens and grievously harmed over 750 people across the country. No patient should suffer harm at the hands of a medical professional, and we will continue to work with our law enforcement partners to combat fraud and abuse in the health care system."

"A key aspect of the FDA's mission is to ensure that drugs are made under high quality conditions so that no patient is at risk of harm due to poorly compounded products."

- FDA Commissioner Scott Gottlieb, M.D.

Published Guidelines Help

- Consider an RFP process that appropriately vets the compounder
  - FDA registration, inspection history, financial stability, etc.
  - Processes, testing,
- Contracts with performance requirements
- How to handle performance and contracting issues
- Performance must still adhere/surpass state and regulatory requirements

American Society of Health System Pharmacists® (ASHP)

ASHP Guidelines on Outsourcing Sterile Compounding Services Am J Health-Syst Pharm. 2015; 72:1664-75

Pharmacy Engagement is Key

- As the individual legally responsible, you need to know:
  - That your patients will not be harmed
  - That you are minimizing risk associated with products brought into the organization
  - There is cost/benefit associated with your IV delivery decisions
  - That appropriate safeguards are in place to prevent and immediately detect problems
- Goal: Avoid bad surprises

CPO PERSPECTIVE

The Joint Commission to focus on 4 high-risk areas during surveys – 3 points

Written by Angie Stewart | July 05, 2018 | Print | Email

The Joint Commission plans to increase attention on four high-risk areas and is launching an online educational series called "4-1-1 on Survey Enhancements" to help organizations prepare.

Here's what you should know:

1. The Joint Commission surveyors will focus on evaluating these four areas during onsite surveys:

- Sterile medication compounding
- Suicide prevention
- High-level disinfection and sterilization
- Hemodialysis

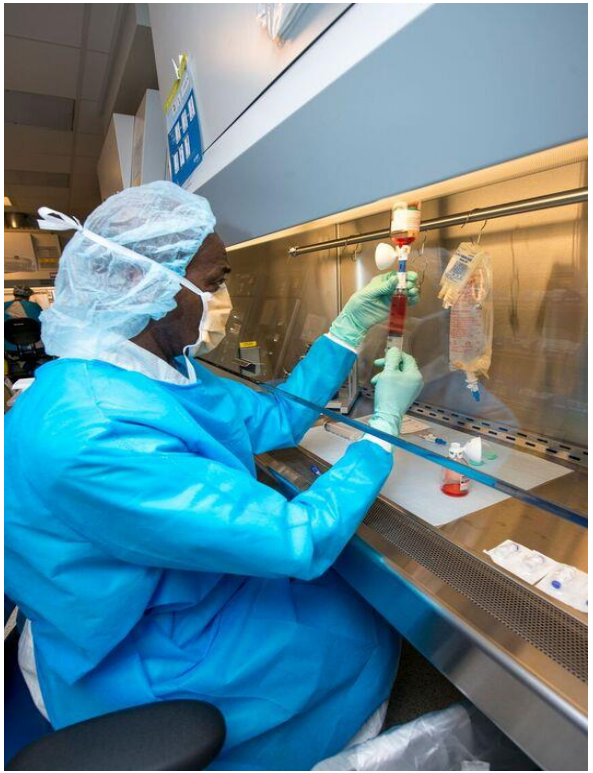

IN-HOUSE
COMPOUNDED

In-House Compounded

Regulatory	• Joint commission, USP 797/800, CMS, Board of Pharmacy
Quality	• Direct control over quality assurance • Control over personnel hiring to ensure staff is competent
Safety	• Pediatrics, oncology • Drug shortages • High risk compounding • Automation – IV workflow, robotics, smart pumps
Operations	• Complexity of preparations • Space limitations • USP non-compliance • Hazardous drugs, CSTD • Live viruses, nano-technology
Staffing	• Staffing shortages • Pharmacist expertise – clinically focused • Ongoing staff training, USP competencies/testing

Role of the Pharmacy Technician

- National technician shortage
- National certification
- Compensation
- Career advancement opportunities




OUTSOURCED

Outsourcing of Medication Preparation Activities

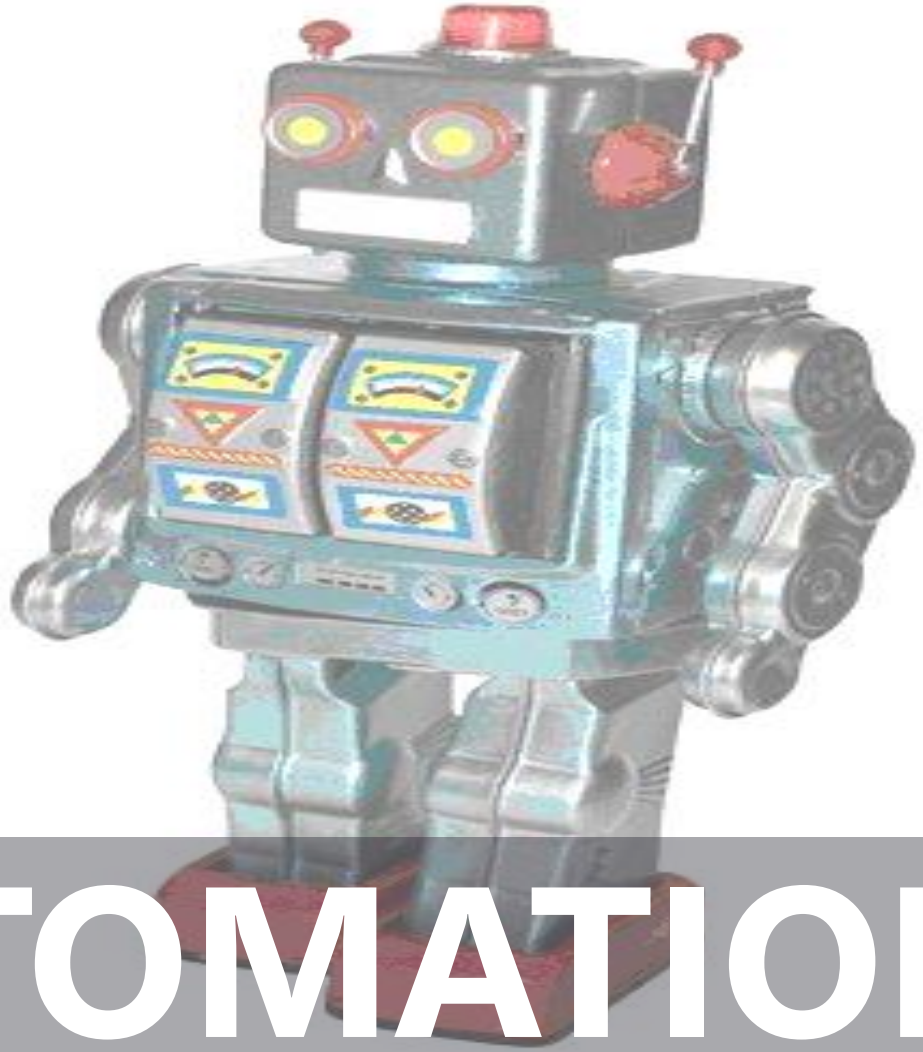
	2017 (*n* = 674)
Outsourced Activity	
Any preparation activities	79.6
Types of preparations or activities[a]	
Total parenteral nutrition solutions	32.4
I.V. admixtures and "piggybacks"	33.6
Patient-controlled and/or epidural analgesia	76.7
Cardioplegic preparations	14.0
Oxytocin preparations	60.5
Syringe-based anesthesia medications	62.3
High-risk compounded sterile products from nonsterile sources	15.9
Other	6.7

[a]Among respondents reporting outsourcing of preparation activities.
[b]Not surveyed.

Schneider P, Pedersen C, Scheckelhoff D. ASHP national survey of pharmacy practice in hospital settings: Dispensing and administration – 2017. Am J Health Syst. 2018: 16; 1203-1226

Outsourced Ready to Use

Regulatory	• FDA 503b registration/inspection, State Board of Pharmacy, Joint Commission • Hospitals responsibility to inspect
Quality	• Consistent and high-quality pharmacy and sterile compounding services, including extended beyond-use-dating • Drug shortages • FDA 483? • cGMP
Safety	• Medications in a dose-specific, ready-to-administer form • Labeling, coloring, bar code
Operations	• Limited available physical or technological resources • Interruptions in service • Beyond use dating • Decrease waste • Inability to perform in-house testing
Staffing	• Enable the organization to reallocate resources • Training



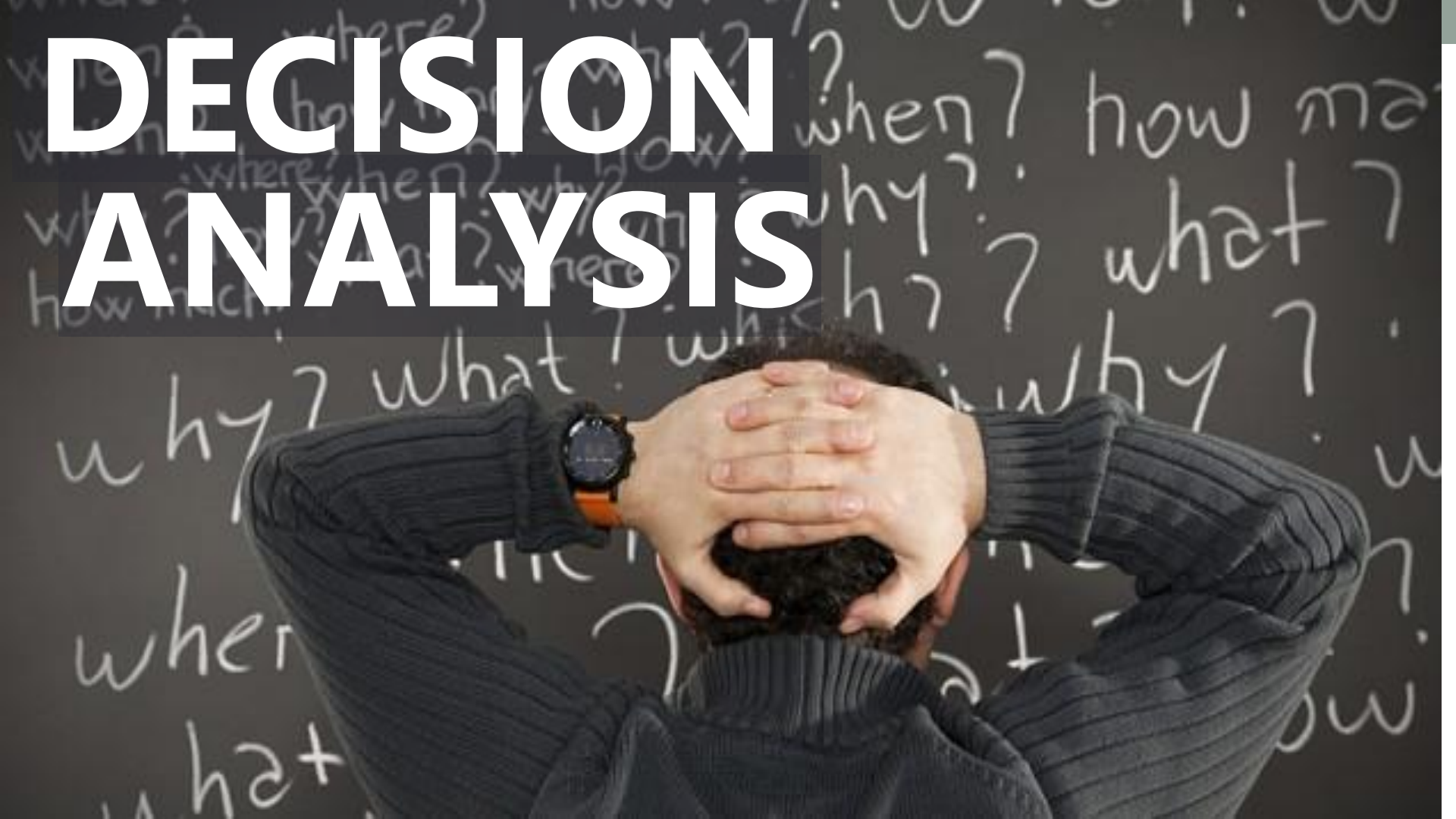
IV AUTOMATION

Automation and Technology Used During Sterile Product Preparation - 2017

Prevalence of Use and Types of Technology Used	Percent
No technologies used for sterile product preparation	64.0%
Barcode scanning to verify ingredients	29.6%
Gravimetric to verify dose, amount, and/or volume	5.5%
Robotic IV compounding device for non-hazardous agents	2.3%
Robotic IV compounding for hazardous agents	0.9%
IV workflow management software	12.8%
Pictures or video of compounding process	12.5%

Schneider P, Pedersen C, Scheckelhoff D. ASHP national survey of pharmacy practice in hospital settings: Dispensing and administration – 2017. Am J Health Syst. 2018: 16; 1203-1226

DECISION ANALYSIS



Decision Analysis

- Financial
- Operational efficiencies
- Drug shortages
- Staffing impact
- Regulatory
- Medication safety
- Construction
- Geographic limitations


MASS
GENERAL
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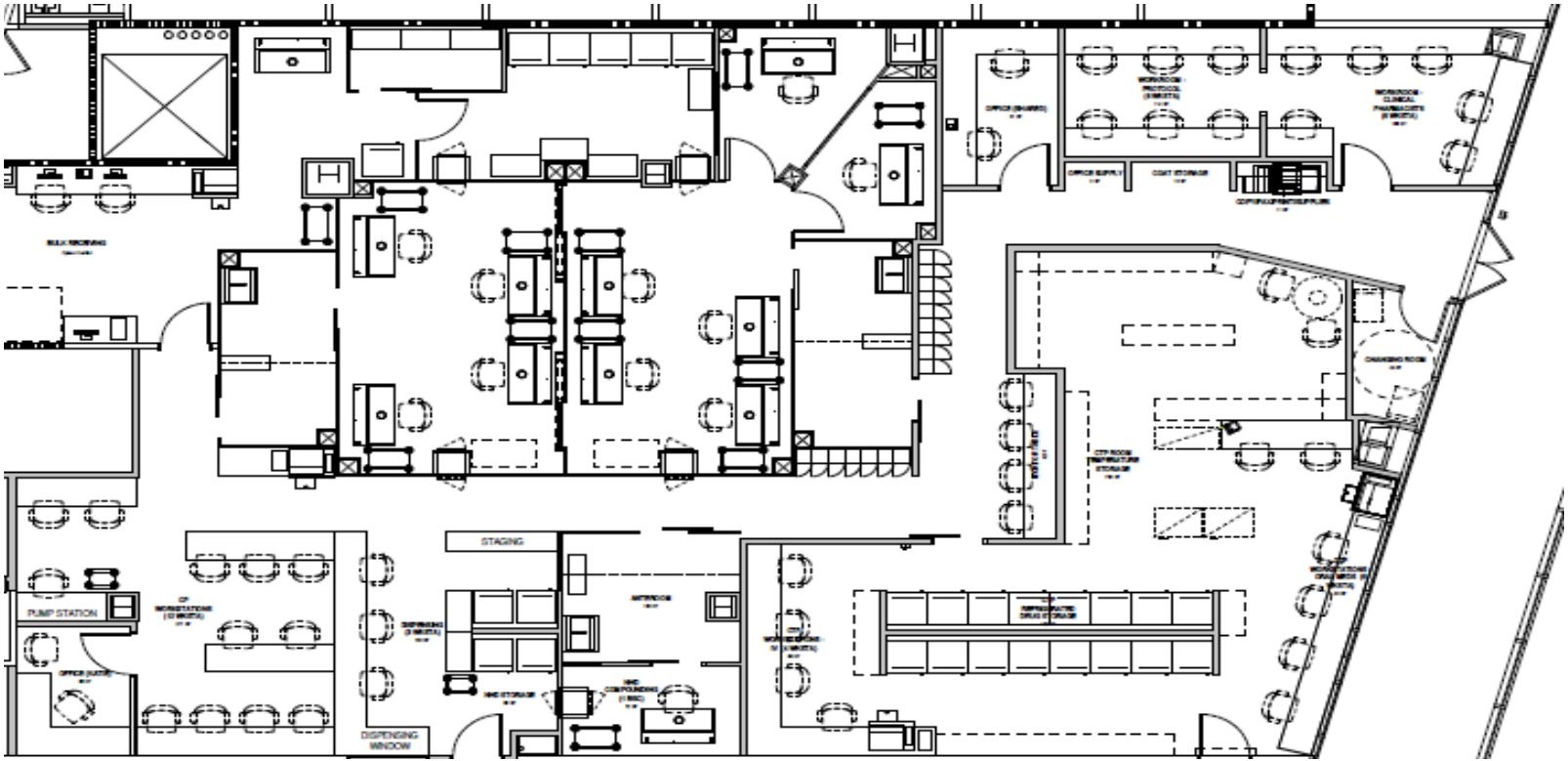
ENTRANCE
ENTRANCE
EMERGENCY

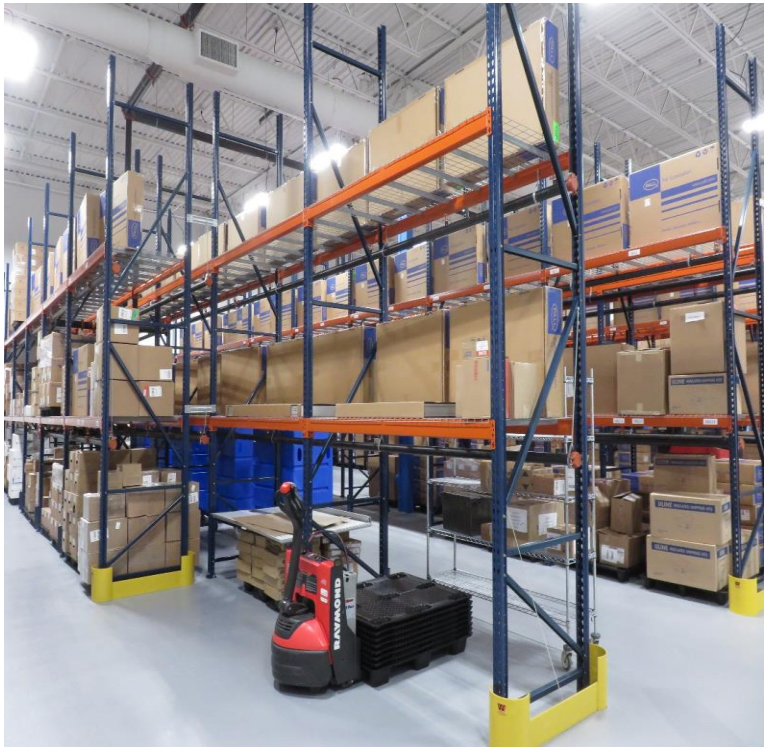
In-House Compounding



Automation and RTU

Centralized Compounding

Centralized Compounding



Summary

- Decision analysis
- Regulatory compliance
- Patient/provider/staff impact and safety
- Strategic priority of Department of Pharmacy

QUESTIONS?