

Leveraging IV Robotics and IV Workflow to Optimize Sterile Compounding Practices to Improve Safety

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This activity is jointly provided by Partners for Advancing Clinical Education (PACE)
and the Institute for Safe Medication Practices (ISMP)

This activity is supported by an independent educational grant from Omnicell

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Objectives

- Describe the role of robotics and workflow in the advancement of safety during sterile compounding operations
- Review the necessary changes in workflows and processes required prior to and after the implementation of IV robotics and workflow
- Describe the challenges associated with obtaining buy-in from leadership and pharmacy staff for the implementation of IV robotic technologies including steps taken to address perceived barriers
- Review the benefits of leveraging a service model vs. traditional model of purchasing IV robotics

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(Universal Activity Number - JA4008073-9999-24-082-L05-P/T)

Type of Activity: Knowledge

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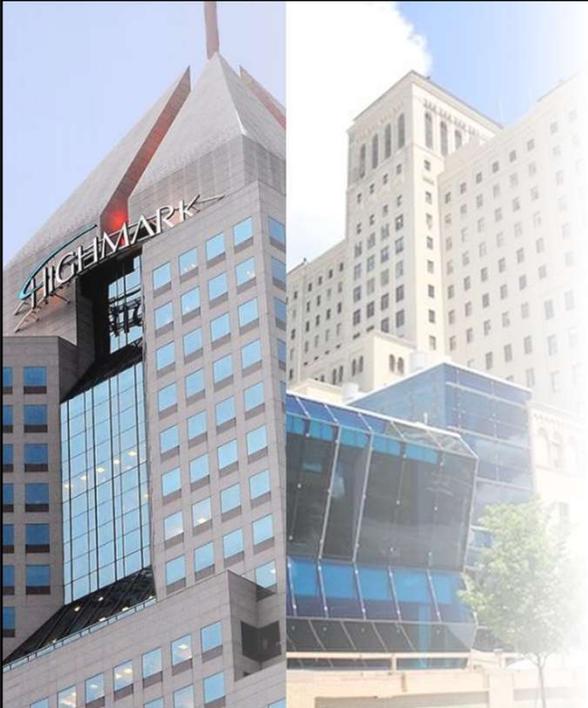
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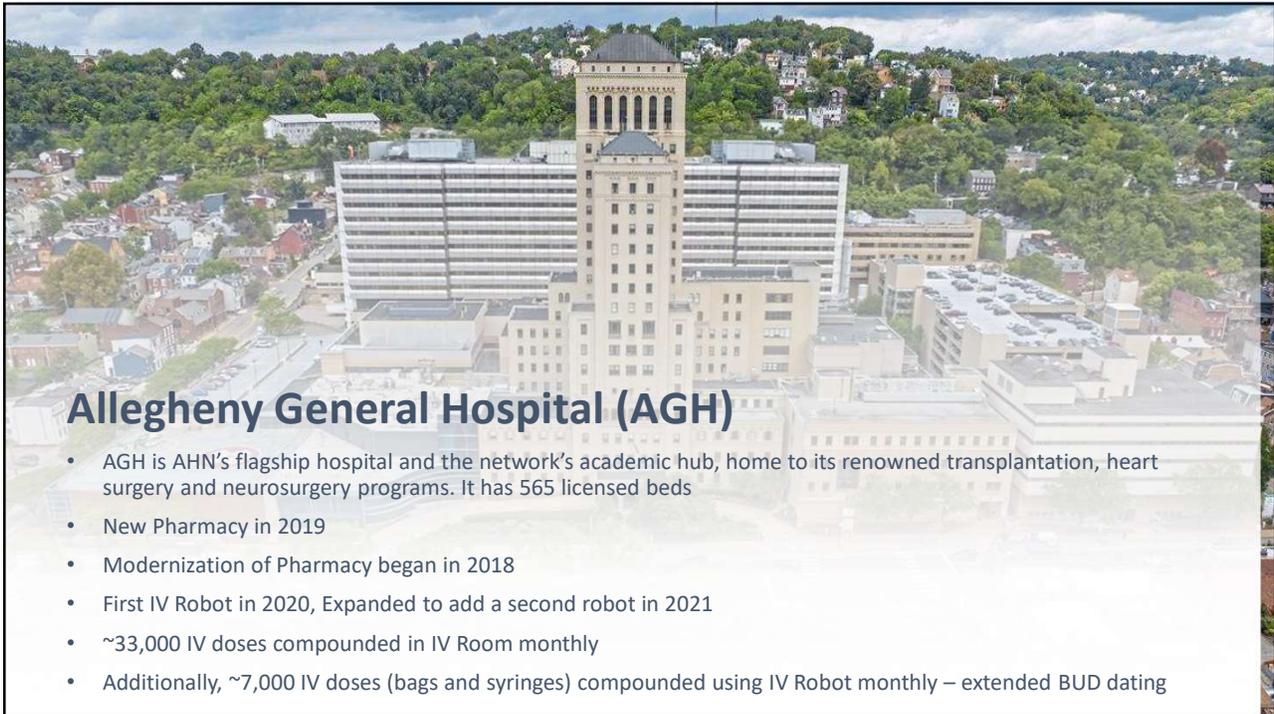
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Allegheny Health Network

- Formed in 2013, AHN, Highmark Inc. and other subsidiaries make up Highmark Health, a \$26B organization and one of the nation's largest integrated payor-provider systems
- AHN is a \$4.3 billion health care delivery system serving Western Pa.
- 14 hospitals, 300 office sites, 2,600 physicians, 22,000 employees
- Full spectrum of advanced medical services: transplantation, cancer care, heart care, neurosciences, obstetrical care, orthopedic surgery, trauma medicine, emergency medicine, and more

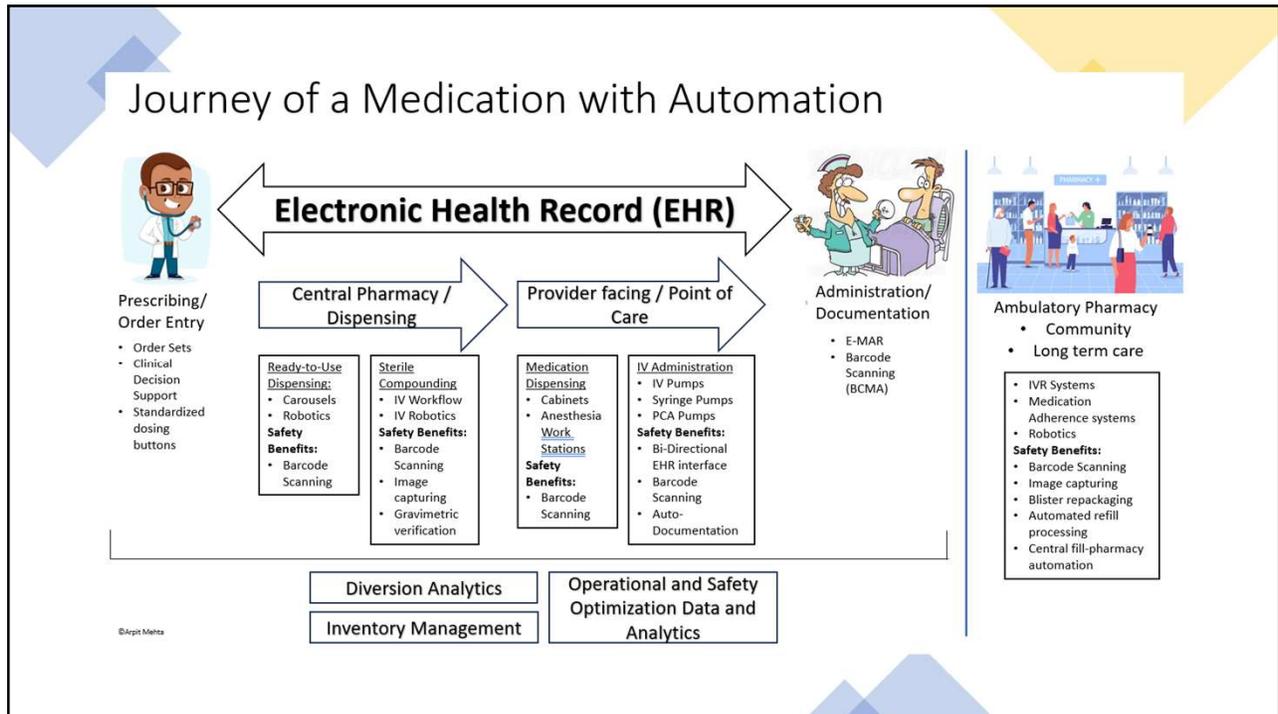
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Allegheny General Hospital (AGH)

- AGH is AHN’s flagship hospital and the network’s academic hub, home to its renowned transplantation, heart surgery and neurosurgery programs. It has 565 licensed beds
- New Pharmacy in 2019
- Modernization of Pharmacy began in 2018
- First IV Robot in 2020, Expanded to add a second robot in 2021
- ~33,000 IV doses compounded in IV Room monthly
- Additionally, ~7,000 IV doses (bags and syringes) compounded using IV Robot monthly – extended BUD dating

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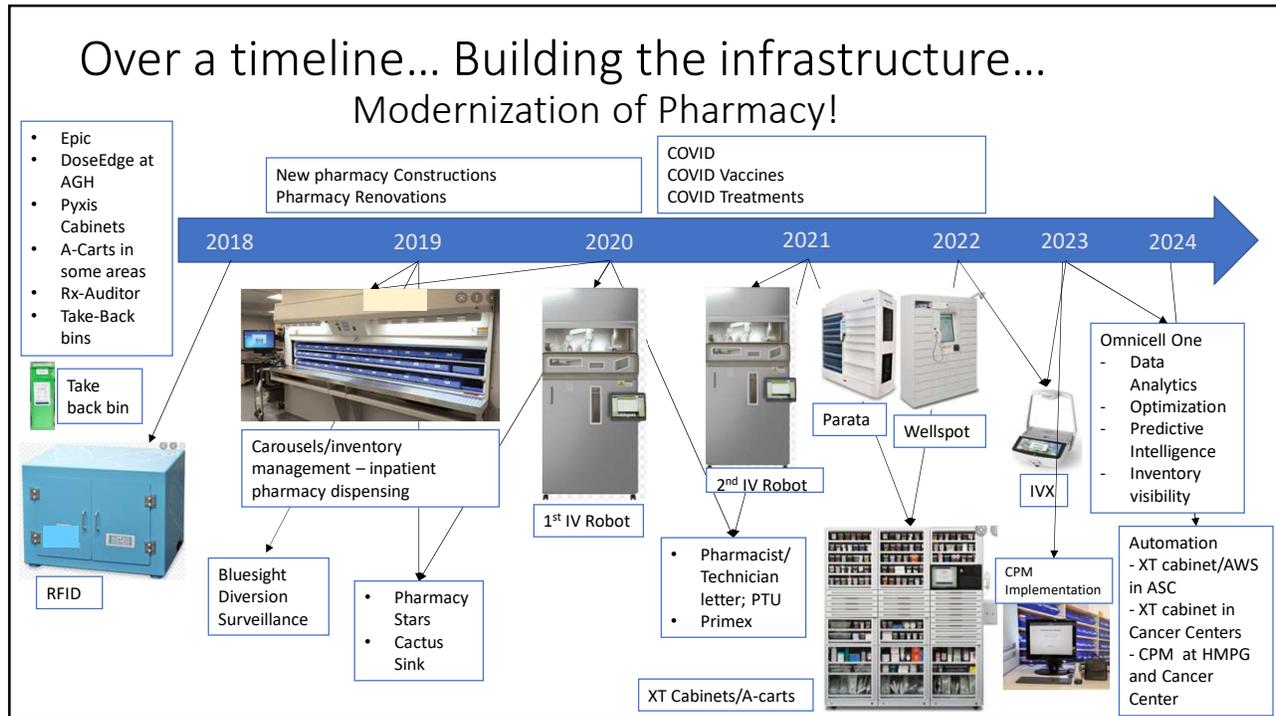


Diversion Analytics

Operational and Safety Optimization Data and Analytics

Inventory Management

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Why IV Robotics



- ~\$2.6 Million spend at AGH on medications from 503B vendor partners for select medications
 - Opportunity to generate savings by insourcing
- Inventory control
- Reliability of medication availability
- We know what we are cooking in our clean room
 - Safety and Sterility
- Perfect timing for us in 2020, as Covid brought significant inventory challenges

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Why IV Robotics



- Fully Automated
- Barcode scanning
- Image recognition – verification
- Image capturing
- Gravimetric Verification
- Non-HD IV bags and syringes preparation
- Batch production – insourcing of 503B
- Extended RT BUD
- Remote verification
- About ~8,000 preps a month



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Why IV Workflow Solution



- Standardization of IV preparation across the network
 - Eliminating human variability and error
- Data/information capturing
- Remote verification
- Gravimetric or Volumetric confirmation for preparation
 - You don't know what you don't measure!



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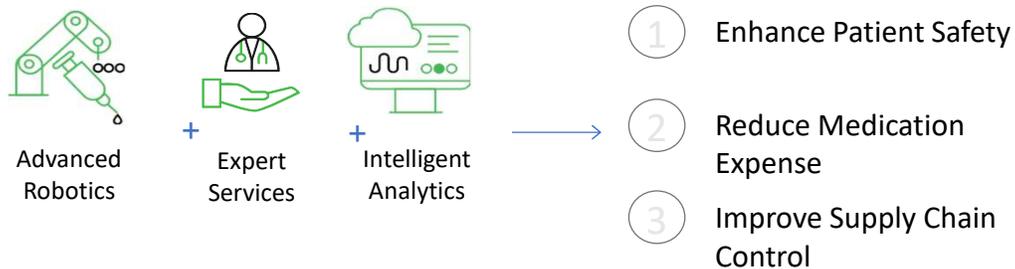
Journey to IV Robotics



- AGH Pharmacy new construction was 2018 – 2019
- Planned for 1 IV Robot at construction
 - Data ports
 - Outlets
 - Weight bearing floor
 - HVAC calculations to account for robot in the buffer room
- Added 2nd Robot during normal operations
 - Added additional weight bearing floor
 - Validated HVAC room balancing
- Had to do over again...
 - Place IV Robots in their own buffer room to allow for Category 3
 - Category 3 was first introduced in the new USP chapter

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Service Model



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Staff buy-in



- ROI and savings
- Shortage mitigation strategy
- Inventory control
- No additional training / need for expertise
 - Except for pharmacists checking
- Adding a pharmacist position as we expand to 2nd Robot

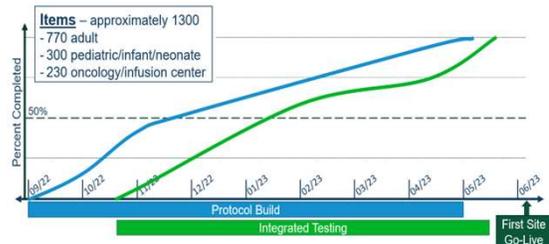


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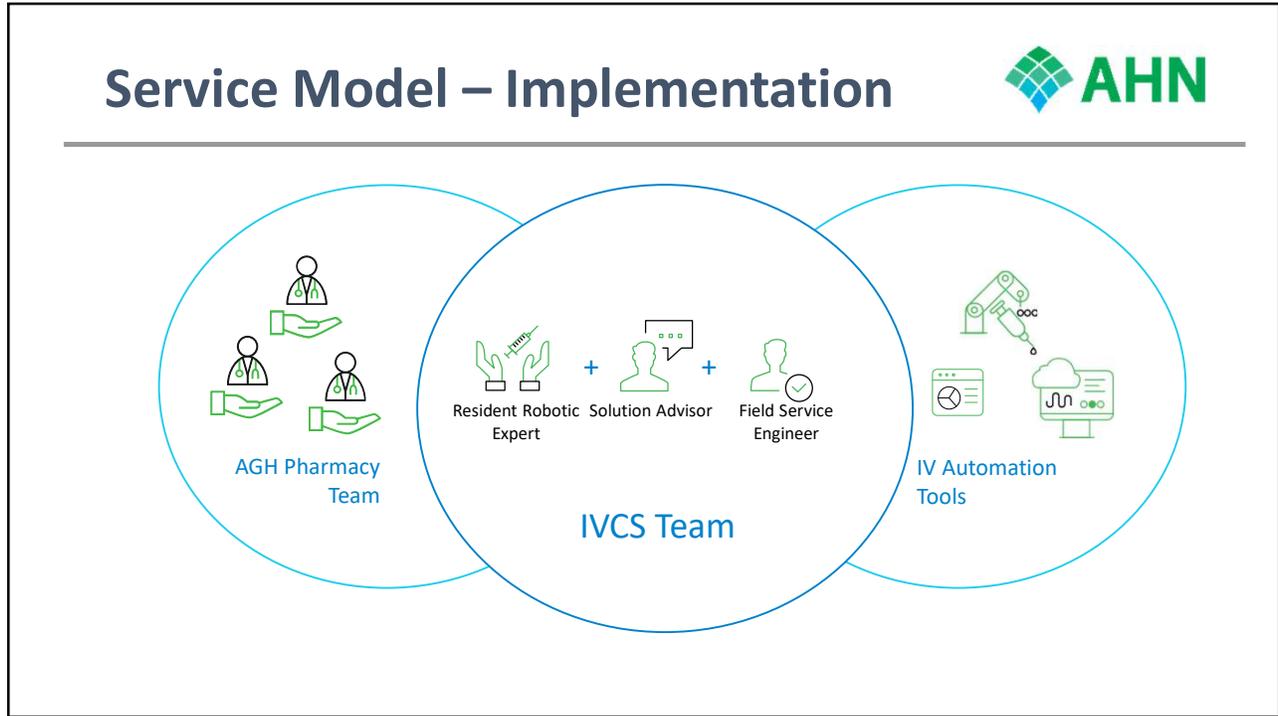
Journey to IV Workflow Solution



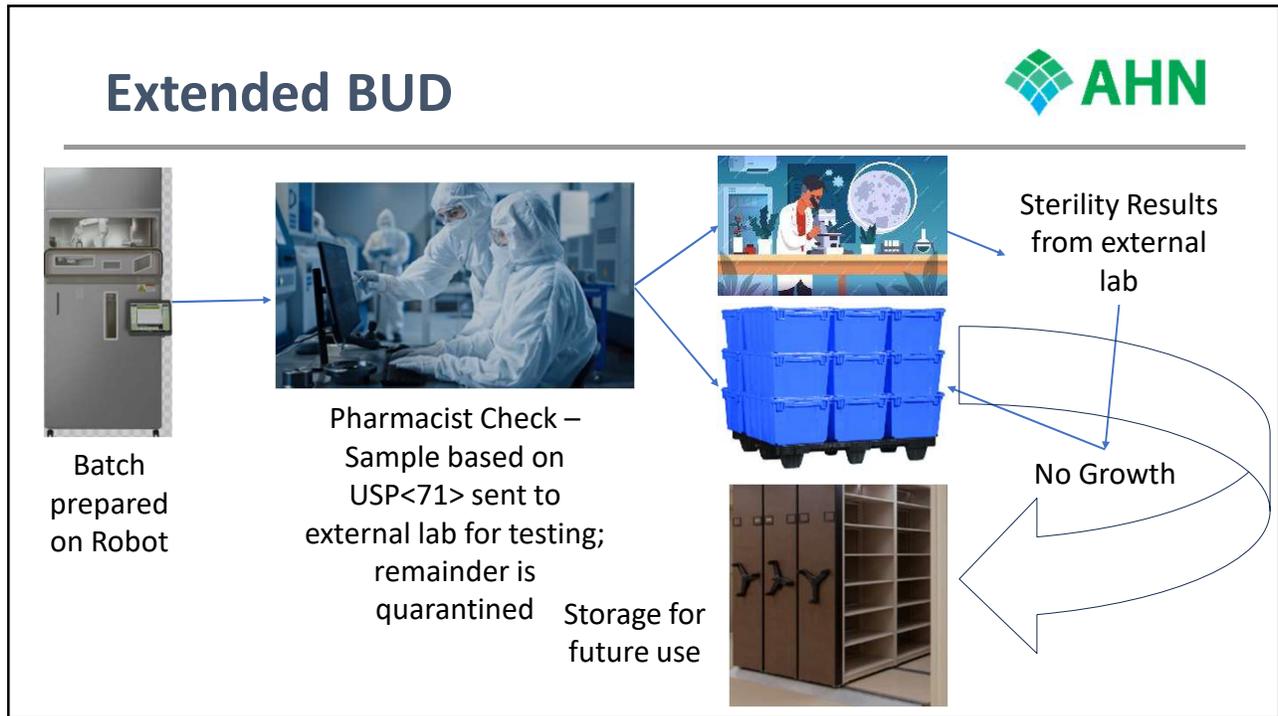
- **Timeline – Protocol build and testing: September 2022 – May 2023**
 - ~1,300 Protocols were built and tested (integration testing with Epic)
 - 95% of protocols are Gravimetric Verification
 - 770 adult, 300 pediatric and 230 oncology
- **Timeline – Go-live: June – December 2023**
 - First site go-live: June 2023 – AGH
 - Phased roll-out across the network, hospital and oncology infusion center pharmacies – last site go-live: December 2023
- **Time Commitment:**
 - Protocol build time: 300 man-hours
 - Prep standardization meeting time: 1,200 man-hours
 - 25 attendees from across the network
 - Integrated testing: 1,000 man-hours
 - Administrative oversight: 324 man-hours
 - **Total: 2,824 man-hours**



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What do we compound – then to now

- What we compounded on the robot has evolved over time
- Initial focus was ROI and savings from insourcing
- Current focus is inventory control and shortage mitigation

2020 and 2021	2022	2023
Vasopressin Bags	Heparin Bags (shortage of premix)	Fentanyl 100 and 250 mL Bags
Fentanyl 100mL Bags	Fentanyl 100 mL Bags	Succinylcholine Syringes
Ephedrine Syringes	Succinylcholine Syringes	Hydromorphone 100 and 250 mL Bags
Norepinephrine Bags	Hydromorphone 100 mL Bags	Norepinephrine Bags
Hydromorphone 100 mL Bags	Norepinephrine Bags	Phenylephrine Bags
Phenylephrine Bags	Phenylephrine Bags	Sugammadex 100mg/1mL Syringes
Neostigmine Bags	Ephedrine Syringes (shortage of premix)	Ephedrine Syringes (shortage of premix)
Ketamine Syringes		

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Benefits of leveraging Service Model

- Shortage Mitigation
- Inventory Control
 - Need extra 100 bags to get through the peak
 - Could be a month prior to receiving it if outsourced
- Compounding new medications
 - Sugammadex
 - Vasopressin



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Benefits of IV Robotics, especially Service model



Tornado damages Pfizer plant in North Carolina, will "likely lead to long-term shortages" of medicine

U.S. | UPDATED ON: JULY 30, 2023 / 11:41 PM / CBS/AP

Shortages

Uncertainties

Compounding pharmacy CAPS recalls 13K bags

Nephron recalls 2.1M drug doses, devices on sterility concerns

MANUFACTURING

Knowing exactly what is in the bag we compound – Diversion

Flexibility in compounding new products – Sugammadex

Compounding: Inspections, Recalls, and other Actions

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USP changes and impact



USP <797> Compounding Category	Environment	Compounding Method	Sterility Test	Ingredients	Storage Conditions	BUD
Category 2	Cleanroom Suite	Aseptic	USP<71>	Sterile to Sterile	Room Temp	30 Days
					Refrigerator	45 Days
Category 3	Cleanroom Suite	Aseptic	USP<71>	Sterile to Sterile	Room Temp	60 Days
					Refrigerator	90 Days

- This is where the location of IV Robots may matter
- Ideally, having IV Robot in its "own IV Buffer room" would allow for Category 3 compounding for IV Robot

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Other regulatory challenges



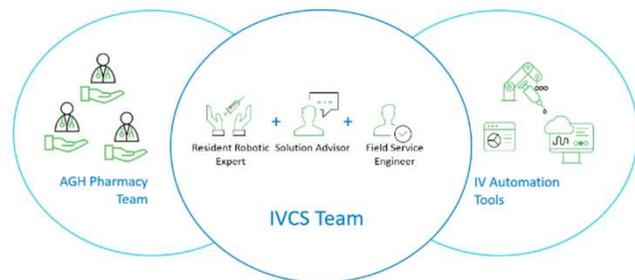
- Engage local regulatory bodies early on to address any concerns
 - BOP
 - DOH
- FDA **Draft** Guidance Document

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Lessons learned during go-live



- Service Model (IVCS)
- Minimal direct impact
- IT challenges and engaging team early on
- Engaging regulatory teams early on – prior to go-live
- Knowledge and understanding of USP
 - USP<71>, USP<797>

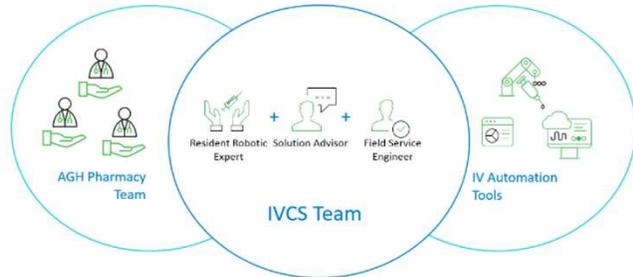


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Ongoing maintenance and Education needs – IV Robotics



- None, really!
- USP changes
- Just FYI for teams on products being compounded
- All maintenance and training by IVCS vendor partner to their teams



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Ongoing maintenance and Education needs – IV Workflow Solution



- NDC/barcode maintenance
- Protocol maintenance in coordination with EHR and other hospitals – standardization
- Data and analytics

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Future of IV Compounding



- Increased Production Capacity for IV Robotics
- All batched / ready to use medication doses would be compounded on IV Robotics
- All patient specific medication doses would be compounded on IV Workflow Solution – gravimetric verification when possible
- IV Robotics for patient specific Hazardous medications – avoid human exposure to hazardous chemicals

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Questions?



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