Beth Israel Lahey Health
Beth Israel Deaconess Medical Center

Keeping Up With Sterile Preparations & USP <797>

Patricia Gerrin CPhT CSPT, Denise Arena Raphe Clinical Pharmacist Supervisor, Julie F Lanza CPhT CSPT

TAP TO GO BACK TO KIOSK MENU

Introduction/Problem

USP <797> requires the skill of personnel that aseptically prepare CSPs (Compounded Sterile preparations) be evaluated using sterile fluid bacterial culture media fill verification. Media fill test represent the most challenging or stressful conditions encountered by personnel being evaluated when they prepare all risk level CSPs.

Media fill test verification are done annually or biannually depending on risk level.

At BIDMC, in order to comply with this regulation – we were faced with the challenge of coordinating media fill test verification of all risk levels for approximately 160 employees for a total of 400 tests (knowing these numbers would increase each year with staffing levels).

Aim/Goal

- Aim: trying to coordinate 400 different tests in an organized fashion while not disrupting existing work flow or interrupting the attention to patient care that our employees are providing.
- Goal: Develop a system that allows us to compete media fill verification for all employees within a short time frame.

The Team

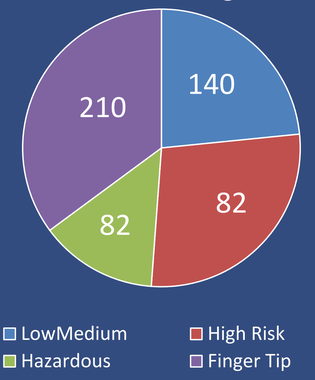
- Denise Arena – RPh Clinical Pharmacist Supervisor
- Patricia Gerrin – CPhT CSPT – Lead Technician Sterile Products
- Bzunesh Abrha CPhT – Lead Technician Scheduling & Training Coordination
- Julie Lanza CPhT CSPT – Pharmacy Compliance Specialist

The Interventions

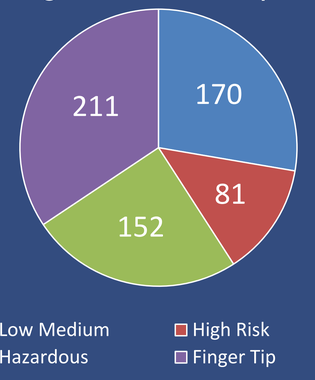
- Train multiple staff to perform media fill verification in order to complete testing in more timely manner
- Working with pharmacy supervisors and the scheduler(s) for both Pharmacist & Technicians as well as the Sterile Products team to develop a timeline of events that wouldn't effect the day today operations of the Pharmacy Department.
- Creating a spreadsheet of materials. times, places, staff & verifications processes that need to happen for the total number of staff to be tested
- Data (including time it takes for each test) in monitored throughout the time frame to maintain the timeline & improve processes for next testing session.

Results/Progress to Date

Media Fill Verification 2017
June 9th thru August 8th



Media Fill Verification 2018
August 2nd thru Sept 13th



2017 time lapse of testing was 60 days. Upon implementation of new processes, 2018 testing was decreased to 42 days with an increase number of staff tested. Through new processes, we were able to decrease testing by 18 days.

For more information, contact:
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More Results/Progress to Date

Both USP <797> & the MA Board of Registration in Pharmacy are due to release new standards for media fill test verification in 2019. We have already begun to develop ideas by which these proposed changes will affect our current testing processes.

Test	Old Regulation	New <USP> regulations	New board of Pharmacy Regulations
Low/Medium	Annually	*Biannually*	*Biannually*
High Risk	Biannually	*Biannually*	*Quarterly*
Chemo/Hazardous	Annually	*Biannually*	*Biannually*
Finger-Tip	Annually	*Biannually*	*Biannually*

Based on the changes to regulations proposed above, we will be tasked with having to revise our testing processes & invest exponentially more to purchase testing supplies

In addition to the Media Fill Verification Testing, all BIDMC Pharmacy employees who compound Sterile Products are required to complete & pass three didactic exams as well as attend an Annual Lecture on the updates/changes of <USP> 797. This allows us to maintain competency & compliance in regards to the laws/regulations.

In addition to USP & MA Board of Pharmacy regulations, The Pharmacy Technician Certification Board (PTCB) has launched an optional certification for Advanced Sterile Products (CSPT) technicians in 2018.

BIDMC has six technicians who have taken this certification exam which has allowed us the flexibility and ability to have more advanced trained sterile products employees performing these verification tests to ensure compliance with national standards.

Lessons Learned

- Pertaining to the world of Sterile Products and USP <797>; lessons are continually evolving as the regulations and parameters set around compounding and patient safety are constantly changing.
- Our lessons involve continuous education around the best way to maintain our quality assurance & performance standards here at BIDMC.

Next Steps

- Maintain monitoring of our current processes & use metrics to implement measures that will improve processes.
- Keeping up with all the changing regulations that are published by the USP
- Promote current and future pharmacy technician staff to sit for CSPT exam allowing for a more comprehensive group of sterile products employees

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