COMMONWEALTH OF MASSACHUSETTS
BOARD OF REGISTRATION IN PHARMACY

Pharmacy Advisory Committee
Meeting held via remote WebEx.
Boston, Massachusetts, 02114
November 4, 2021

Advisory Committee Members Present
Antoinette Lavino, RPh, BCOP (Expert in USP<797>)
Sami Ahmed, PharmD, RPh, BCPS, BCSCP (Expert in USP<71>)
John Walczyk, RPh, PharmD (Expert in USP<795>)
Francis McAteer (Expert in Microbiology)
Michael J. Gonyeau, RPh, PharmD, Med, BCPS, FNAP, FCCP (Expert in Clinical Pharmacology)
Judith Barr, MEd, ScD, FASHAP (Expert in Pharmacoeconomics)
David H. Farb, PhD (Expert in Clinical Pharmacology
Karen B. Byers, MS, RBP, CBSP (Expert in Microbiology)
Keith B. Thomasset, BS, PharmD, MBA, BCPS (Pharmacoeconomics)
John P. Mistler, Pharm. D, RPh, MBA, BCSCP, CPH (Expert in cGMP)
Patrick Gannon, RPh, MSM, FABC additional expert member

Board of Pharmacy Member Present
Caryn Belisle, RPh, MBA

Advisory Committee Members Not Present
James Lavery, JD BHPL Director (chair)
Sylvia B. Bartel, RPh (Expert in USP<797>)

Board Staff Present
David Sencabaugh, RPh, Executive Director
Heather Engman, JD, Board Counsel
William Frisch, RPh Director of Pharmacy Compliance
Michelle Chan, RPh Quality Assurance Pharmacist
Joanne Trifone, RPh, Director of Investigator
Sam Penta, RPh Senior Investigator
Nathan Van Allen, PharmD, RPh Pharmacy Investigator
Ed Taglieri, MSM, NHA, RPh, PSUD Supervisor

TOPIC I. Attendance by roll call: **Time: 9:00 AM**
Call to Order, by: Ed Taglieri and announces meeting is being recorded.

Roll call attendance: A. Lavino; S. Ahmed; M. Gonyeau; J. Barr; F. McAteer; K. Byers; K. Thomasset; J. Mistler; P. Gannon

Not Present: James Lavery; Sylvia Bartel

Join meeting once started: J. Walczyk 9:05 AM; D. Farb 9:12 AM

TOPIC II. **Approval of Agenda** **TIME: 9:10 AM**
Agenda: 11/4/21
Changes: None

Motion by M. Gonyeau, seconded by P. Gannon and voted unanimously by those present to approve the agenda no noted changes by roll call vote.

Topic III **Approval of Board Minutes**
1. Minutes **Time: 9:03 AM**
Draft 5/4/21

Changes: None

Motion by P. Gannon, seconded by A. Lavino and voted unanimously by those present to approve the 5/4/21 minutes no noted changes by roll call vote.

TOPIC IV: Discussion on Media-Fill Testing (Best Practice Recommendation) **Time: 9:04 AM**
Recused:
Presented: Bill/Michelle
Discussion:

C. Belisle: Presented request from Board of Pharmacy to discuss advisory on media fill qualification.

J. Walczyk: Joined meeting at 9:05am.

W.Frisch/M.Chan: Reviewed document outline with committee members. Discussed reasons for guidance document including best practice recommendations for compliance to the standard.

Section 1 Discussion: Committee members discussed and provided input regarding verbiage of the document. Members included additional situations that a media fill should be considered.

David Farb: Joined at 9:12am.

Section II Discussion: Committee members discussed and provided input regarding verbiage of the document.

- Members expressed concern with having clear examples of possible worst-case scenarios specific for time of day (end of work shift, end of day, etc.).
- Members discussed complexity of the compounding process with most manipulations being described more, maximum number of personnel in the classified spaces at one time, longest fill time, workflow, and specialized procedures such as lyophilization or filtration.
- Members expressed difference of opinion regarding time of work shift including end of day being described in document.

P. Gannon: To provide recommendation in writing for consideration. Left at 9:30am.

- Members want to ensure that the document aligns with USP 797 to ensure consistency.
- Members expressed concern with ensuring compliance in facilities with many employees (academic medical centers, facilitating 100+ media fills per year).
- Members discussed documentation required including master formulations and compounding logs. Expressed need for procedure but did not agree on method for documenting the action. Agreed that a policy and procedure would be needed. High risk compounders utilizing non-sterile media may require master formulation.
- Members expressed importance of certificate of analysis for media considerations
- Members expressed importance of 14-day incubations at range denoted in USP standards and/or manufacturer recommendations with calibrated monitoring systems (i.e., thermometers). Manual monitoring is sufficient.
- Members noted that laboratory review should not be required for all situations. Review should be done by qualified individual.

Section III Discussion: Committee members discussed and provided input regarding verbiage of the document.
- Members provided additional elements for inclusion in section.
- Members discussed situations when identification would/would not be feasible and/or appropriate.
- Members discussed alternative situations for failures (i.e., coring of vial septum).

Section IV Discussion: Committee members discussed and provided input regarding verbiage of the document.
- Members discussed speciation may be important in this section for employee failures.

V: Closing remarks and Adjournment of Meeting **Time: 10:15 AM**

W.Frisch/M.Chan: Thanked members for their input.

E. Taglieri:
- Remote meeting until April 2022.
- Office moving to 250 Washington St in December.
- Notes that Sami Ahmed has been appointed to Board of Pharmacy.
- Request motion for adjournment.

ACTION: Motion by K. Thomasset seconded by M. Gonyeau, and voted unanimously by those present, to adjourn from meeting by roll call vote.

Attachment: P. Gannon input:

Media Fill Testing – Outline

I. **Frequency**

After initial qualification:

- at least once every six months if prepare (Should these categories be referenced or defined in this document?)
- at least once every three months if prepare Category 3

Immediately following significant changes in the sterile compounding process, such as, but not limited to: changes in personnel, components, equipment, the environment or whenever evidence of a failure to maintain product sterility has been identified.

Additional considerations?

II. Procedural Considerations

Simulate the most difficult and challenging compounding procedures and processing conditions replacing all the components used in the CSPs with growth media

Worst case scenarios:

- end of work shift:
  -environmental conditions – per comments during the mtg
  -operator fatigue

Video recordings? delete

A. Number of Units

Number of media fill units per day over number of day(s) for initial qualification? What is the value of this metric and how would this metric be used?

After initial qualification, prepare (X) media fill units per day for (X) day(s)?

B. Documentation

Policies and procedures to include?

- change control process
- method for tracking media fill results reporting and trends for each operator

Master formulation record needed? Yes

X. Media Selection

Soy casein digest; other media?

Certificate of analysis (COA) for commercial media / growth promotion certificate

Media prepared in-house; growth promotion capability as described in USP <71> *Sterility Tests*

Non-sterile media powder for pharmacies that engage in non-sterile to sterile (i.e., high risk) compounding.

Commercial kits?

Δ. Incubation

7 days at 20°C to 25°C followed by 7 days at 30°C to 35°C to detect a broad spectrum of microorganisms; multiple incubators to run concurrently?

Temperature monitoring? Temperature recording device?

E. **Inspection of Filled Units**

Container examination frequency? Per batch?

Independent monitoring of results (i.e., not the individual who performed the test)

III. **Interpretation of Results**

Failure:

- visible turbidity (cloudiness)
- "strings" or "clumps" or "unexpected particles"
- other?

Send out for identification / specification? Relate to EM results?

Trending analysis for repeat / frequent failures for multiple individuals

IV. **Corrective Action / Follow-up**

An investigation into any failure should survey the possible causes. Root cause analysis?

Retraining and retesting for failed tests

Maintain results of media-fill testing and any corrective action for all compounding personnel in the pharmacy's records.

Anything else?