COMMONWEALTH OF MASSACHUSETTS
BOARD OF REGISTRATION IN PHARMACY

Pharmacy Advisory Committee
Meeting held via remote WebEx.
Boston, Massachusetts, 02114
March 30, 2022

Advisory Committee Members Present
Ed Taglieri, MSM, NHA, RPh (chair designee by James Lavery)
Antoinette Lavino, RPh, BCOP (Expert in USP<797>)
Timothy D Fensky,RPh,DPh,FACA (Expert in USP<71>)
John Walczyk, RPh, PharmD (Expert in USP<795>)
Francis McAteer (Expert in Microbiology)
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)
John P. Mistler, Pharm. D, RPh, MBA, BCSCP, CPH (Expert in cGMP)
Patrick Gannon, RPh, MS, FABC additional expert member

Board of Pharmacy Member Present
Caryn Belisle, RPh, MBA

Advisory Committee Members Not Present
Keith B. Thomasset, BS, PharmD, MBA, BCPS (Pharmacoeconomics)
Sylvia B. Bartel, RPh (Expert in USP<797>)
Michael J. Gonyeau, RPh, PharmD, Med, BCPS, FNAP, FCCP (Expert in Clinical Pharmacology)

Board Staff Present
David Sencabaugh, RPh, Executive Director
Monica Botto, Assistant Executive Director
Heather Engman, JD, General Counsel
Michael Egan, JD, Board Counsel
William Frisch, RPh Director of Pharmacy Compliance
Michelle Chan, RPh Quality Assurance Pharmacist
Joanne Trifone, RPh, Director of Investigator
Nathan Van Allen, PharmD, RPh Pharmacy Investigator

TOPIC I. Attendance by roll call:

Call to Order, by Ed Taglieri at 9:09am and announces the meeting is being recorded. Ed Taglieri notes James Lavery has appointed him as his designee to run the meeting and is authorized to vote.

Roll call attendance: A. Lavino, T. Fensky, J. Walcyzk, J. Barr, D. Farb, K. Byers, J. Mistler, E. Taglieri, P. Gannon

Fran McAteer joined at 9:12am

Not Present: S. Bartel, M. Gonyeau, K. Thomasset, J. Lavery

TOPIC II. **Approval of Agenda** **TIME: 9:11am**
Agenda: 3/30/22
Changes: None

Motion by A. Lavino, 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: 9:11am**
Draft 11/4/21

Changes: None

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

TOPIC IV: Presentation of Recommendation Document 22-01, "Advisory: Environmental Monitoring Best Practices"
Time: 9:13am

E. Taglieri introduces Caryn Belisle, representative from Board of Pharmacy to present topic.

Recused: None
Presented: Caryn Belisle
Discussion:

C. Belisle: Gave brief overview of request from Board in addition to topics to be discussed and included within the advisory.
W. Frisch: Joined at 9:16am

E. Taglieri: Announces that T. Fensky has been appointed as PAC member. S. Ahmed has joined the Board of Registration in Pharmacy.

W. Frisch: Intent of document is to provide helpful information to optimize workflow. Increased requirements in upcoming proposed USP <797> standards.

TOPIC V: Discuss a new draft Advisory on Environmental Monitoring (Best Practice Recommendations

Time: 9:18am

Recused:
Presented: Bill/Michelle
Discussion:

M. Chan: Initiated review of document and described the topics included within.

P. Gannon: Expressed concern with identified discrepancies between third party vendor procedures and consideration provided in advisory.

M. Chan: Explained that this document is meant to be a general advisory and could be utilized to stem conversation between licensees and third-party vendors.

Members: -Expressed that third party vendors are likely to add sampling sites based on licensee requests.
-Advisory is helpful for licensee conducting their own sampling. Cost considerations come into play and may restrict ability to utilize third party vendor for all samplings. Third party vendor could be utilized as a verification of process.

F. McAteer: -Acknowledged attendance 9:27

Members: -Licensee should concentrate on training and education from vendor; a certain level of competency and detail is needed. Recommend a relationship with laboratory or microbiologist on staff.
-Discussion continued regarding development of sampling program based on contamination risk, frequently touched site, water sources, HVAC dead zones, consistent site selections, and also should be flexible enough to incorporate operational changes. Pass throughs should be included as well as PECs
-Risk based approach is best approach.

W.Frisch: **-** Initiated discussion on one-plate vs. two-plate method?

Members: - Expressed preference to have microbiologist determine one or two plates.
-Difference need to be evaluated regarding timing of results, length of incubation, and also cost.
-Concerned with what type of collection devices are being utilized (plates, paddles, swabs)
-Buying or renting impaction air samplers comes with cost. Expressed concern with contamination of sampling heads and subsequent contamination of plates leading to false positive results.

W. Frisch: **-** Initiated discussion about positive and negative controls

Members: - Expressed that negative control is most important. Positive control is less important due to introduction of contamination to sample or classified area. Certificate of Analysis to prove positive control and ability to support growth. Additional cost may not be necessary.
- Expressed that positive and negative controls can be beneficial for laboratory verification

- Growth promotion certificates should be satisfactory

M. Chan: **-** Initiated discussion about frequency of monitoring

Members: - Expressed consideration for pharmacy's that conduct category 1, 2 and 3
- Interested in increased frequencies in advisory do not align with proposed USP <797> and are more stringent. Prefer to wait until new chapter is finalized.

W. Frisch: - Noted that frequencies in advisory are recommended not mandated.

Members: -Expressed concerned with verbiage in the advisory and ensuring that the language is clear as to requirements versus recommendations.
- Risk assessment could be conducted to increase frequencies based on amount and type of compounding. Possibly add description or example of risk-based approach scenario.
- Expressed need for licensee to seek help when questions arise before trying to fix themselves.
- Members partially agree that additional clarification in advisory may be beneficial but concerned with differences between USP<797> and MA best practice recommendations.

M. Chan: - initiated discussion on sampling conditions

Members: - Questioned need for clarification of worst-case scenarios.
- Thought that exceptions could be included in advisory to help licensee (i.e. post certification, post renovation, etc.)

W. Frisch: **-** Described reasons why additional guidance should be provided.

C. Belisle – Recommended that additional information/examples could be provided regarding timing of cleaning versus sampling.

Members: - Additional information could be provided to delineate routine sampling versus situational sampling.

M. Chan: - initiated discussion of incubation section
Members: - Noted that interruptions in operation should be assessed and included.
- Recommend using language from previous advisory (media fill) and chapter – not a lot of detail within current 2008 version.
- recording devices need to calibrate on annual basis. Difference between continuous monitoring, mercury thermometers, and digital units.

C. Belisle: - Asked if reference is available for incubator calibrations

F. McAteer: - ISO standards are available. Discussed temperature mapping of units. Expressed that these are typically GMP level considerations.

M. Chan: -Is there a recommend frequency for checking plates

Members: -48 hours and 5 days – not recommend daily review to minimize human error or human introduction of contamination
-recommend addition ISO doc as reference.
-recommend clean incubators regularly, mold contamination, humidification, etc. Monthly or quarterly basis for cleaning based on use.

M. Chan: – Initiated discussion on reviewing results. Should these be outlined in Policy & Procedures? Should all growth be sent for identification? Should there be alert or action limits for sending identification?

W. Frisch: -Expressed concern with chapters stance on identifying organisms.

Members: - Expressed that way of thinking has changed since 2008 and putting responsibility on licensee is the new approach with guidance to follow.
- Monitoring is only one part of the sterile compounding program and mostly qualitative versus quantitative.

W. Frisch: - Is there any advice that could be provided for alerts level?

Members: - Recommended separate guidance based on in house versus vendor outsource testing. In house may need to be sent automatically, third party automatically identified.
-Concerned about having only one standard of practice

E. Taglieri: – 10:21 time check

Members: -Expertise not present with in house sampling. What guidance to give a new pharmacy for in house sampling plan. Automated mechanisms decrease time, colony morphology, may be beyond the mission of pharmacy.
-Some expressed need for all growth should be identified
-Recommend tying ISO class and identification – based on number of positive CFU, identify all ISO 7 and ISO 5 PEC contamination. Determine ISO 8 identification based on other factors.

W. Frisch: - Initiated discussion on corrective action – already have multiple references to remediation guidance's and other response data available for licensee.

Members: **-**recommend adding critical and consistent information for top 1-2 items for corrective actions

W. Frisch: **-** Initiated quick discussion on trend analysis

Members: **-** Believe trending analysis will be determined based on frequencies (i.e.- q 6 months vs. q month). Simple chart may be beneficial. Electronic allows for analysis.
-Helps to show events within certain time that may be indicative of a problem. Overall goal is to increase data without increased burden on staff and risk to cleanroom.

M. Chan: **-**Initiated discussion on documentation requirement

Members: -Recommend adding equipment to sampling process methodology and ensuring that calibration information is included and available.
-Questioned requirements of certifiers and vendor conducting environmental monitoring. FDA registrations available and ISO certifications, CNBT certifications.

VI: Closing remarks and Adjournment of Meeting **Time: 10:40am**

Comments:

E. Taglieri: -Caryn Belisle will bring this information discussed back to Board of Pharmacy for next steps.

-Next meeting will be end of year and may be virtual or in-person. Members will be updated once known.

Adjournment:

Motion by P. Gannon, seconded by T. Fensky and voted unanimously by those present to close the meeting by roll call vote.