I Opening Remarks

Vice Chairperson Mike Finamore welcomed everyone and called the meeting to order. Brooker read the antitrust statement and completed roll call.

II Review of Agenda

Finamore asked for any additions to the agenda but none were voiced.

Motion: Maxine Fritz motioned to accept the proposed agenda.
Seconded: Tim Parrent
Objections: None
Abstentions: None
Vote by verbal affirmation: None apposed.
Motion passed.

III Membership Review

Brooker informed the group that JC with 5 Industry, 3 Users, and 2 Public Health (PH) members. She noted that the group is critically close falling into a dominance issue with the low amount of users and PH. She noted that it is imperative that this group adds both users and PH. Brooker requested that anyone who knows of any person or company/organization that would be an asset to this JC to please contact her after the meeting.

IV Standard Issue Papers

A. Issue 13 Section 4.2 & 4.3 (gmpOTC-2019-1)

Motion: Tim Parent motioned to go to ballot but to change the “the” back to the original “this”.
Seconded: Maxine Fritz
Objections: None
Abstentions: None
Vote by verbal affirmation: None apposed.
Motion passed.

B. Issue 14 Section 4.2.2 (gmpOTC-2019-2)

Motion: Fritz motioned to go to ballot as it is.
Seconded: Finamore
Objections: None
Abstentions: None
Vote by verbal affirmation: None apposed.
C. Issue 15 Section 4.5 (gmpOTC-2019-3)

**Motion:** Fritz motioned to go to ballot as it is.
**Seconded:** Finamore
**Objections:** None
**Abstentions:** None
**Vote by verbal affirmation:** None apposed.
Motion passed.

D. Issue 16 Section 4.5.1.1 (gmpOTC-2019-4)

**Discussion:** Fritz voiced concerns that while this issue paper was a good idea it is not quantifiable. She stated that it needed more detail and Finamore agreed to Fritz’s comment. Fritz suggested that it might be best to send to a task group (TG) for more discussion.

**Motion:** Fritz motioned to create a TG to discuss how to define and/or quantify this requirement.
**Seconded:** Finamore
**Objections:** None
**Abstentions:** None
**Vote by verbal affirmation:** None apposed.
Motion passed.

E. Issue 17 Section 4.7.15 (gmpOTC-2019-5)

**Discussion:** Multiple attendees raised concerns about the four hour time limit. Brooker informed the group that the GMP for DS JC also had the same concern. The GMP for DS JC supported the four hour time limit for the traceability aspect of the issue paper but opposed that limit for the rest. Brooker explained that both twenty-four and forty-eight hours were discussed but it was decided to move this to a TG. She suggested that if this JC wanted to send this to a TG then it may be a good idea to have that TG meet with the GMP for DS JC’s TG so to make sure both standards remain as harmonized as possible. The group agreed.

F. Issue 18 Section 4.8.2 (gmpOTC-2019-6)

**Discussion:** This was withdrawn as it was a repeat of issue 14.

G. Issue 19 Section 5.2 (gmpOTC-2019-7)

**Discussion:** Fritz questioned if there were any additional documents that the group should reference here. It was suggested to change the issue paper to the edited version below.

**Original:**
- Educate / inform
  - audit preparation;
- Review and understand 21 CFR Part 210 Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; General,
  21 CFR Part 211 Current - Good Manufacturing Practice for Finished
Pharmaceuticals, and ICH, Harmonised Tripartite Guideline, Q10: Pharmaceutical Quality System

— audit types (certification audit, monitoring audit);
— self-assessment of compliance with the Standard;
— selection of a CB; and
— determine the scope of the audit.

Edited version:
a) Educate / inform
— audit preparation shall include but not be limited to;
- A review and understanding of 21 CFR Part 210 Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; General,

— audit types (certification audit, monitoring audit);
— self-assessment of compliance with the Standard;
— selection of a CB; and
— determine the scope of the audit.

Motion: Fritz motioned to ballot the edited version.
Seconded: Parrent
Objections: None
Abstentions: None
Vote by verbal affirmation: None apposed.
Motion passed.

H. Issue 20 Section 5.3.3 (gmpOTC-2019-8)

Brooker announced that this was an editorial change and did not need to be discussed.

I. Issue 21 Table of Contents (gmpOTC-2019-9)

Brooker announced that this was an editorial change and did not need to be discussed.

V ARG Issue Papers

A. Issue 1 Section 4.2.2 – 4.8.2 (gmpOTC-ARG-2019-1)

Motion: Parrent motioned to open the issue paper for ballot.
Seconded: Fritz
Objections: None
Abstentions: None
Vote by verbal affirmation: None apposed.
Motion passed.

B. Issue 2 Section 4.2 & 4.3 (gmpOTC-ARG-2019-2)

Brooker announced that this was an editorial change and did not need to be discussed.

C. Issue 3 Section 4.5 (gmpOTC-ARG-2019-3)

Brooker announced that this was an editorial change and did not need to be discussed.
VI Tri-JC Issue Papers

Brooker informed the new attendees that there are sections within this standard that are identical in all 455 standards and that if there are any changes proposed to those sections that change must be discussed and balloted by all 455 JCs. She explained that anything that is discussed at this meeting will then be brought up to the other JC meetings this week. If they agree to the same things that this JC agrees to we can move forward but if there are any comment, concerns, or changes then there will have to be a tri-JC teleconference to discuss.

A. Issue 1 Section 5.7.3 Scenario 1 (455MJC-2019-1)

**Discussion:** Brooker reported that the JC on GMP for dietary supplements already discussed this issue paper and agreed to go to ballot with the change of “…auditor’s submitted objective…” to “…client’s submitted objective…”

**Motion:** Fritz motioned to ballot the issue paper with the above edit.

**Seconded:** Finamore

**Objections:** None

**Abstentions:** None

**Vote by verbal affirmation:** None apposed.

Motion passed.

Brooker reminded the group that the JC on GMP for cosmetics still needed to discuss this.

***The JC on GMP for cosmetics also agreed to this change.***

B. Issue 2 Section 5.7.3 Scenario 2 (455MJC-2019-2)

**Discussion:** Raiji officially withdrew this issue paper since it was only created if the JC did not approve of issue 1.

C. Issue 3 Section 5.3.3 (455MJC-2019-3)

**Discussion:** Raiji also officially withdrew this issue paper since it was only created if the JC did not approve of issue 1 but did approve of issue 2.

D. Issue 4 Renumbering (455MJC-2019-4)

**Motion:** Bolar motioned to ballot the issue paper as it is.

**Seconded:** Bagchi

**Objections:** None

**Abstentions:** None

**Vote by verbal affirmation:** None apposed.

Motion passed.

Brooker reminded the group that she will have to discuss these motions with the OTC and Cosmetics JCs as well.

***Update: The Cosmetics JC had some objections to this change stating that the reason the standards were structured the way they are is because all three JCs agreed to follow the structure of ISO 9001:2015. Raiji justified her proposed change because it was more logical on how an auditor would actually conduct an audit but Casey Coy countered that the standards should stay in the same format and that the auditor always has his/her own
checklist that he/she can order in any way he/she sees fit. Brooker noted that she will organize a tri JC meeting to discuss this.***

**VII**  **New Business & Next Meeting**

Finamore asked if there was any new business, but no one voiced anything. Brooker laid out the plan for the task groups. She explained that she will send out a survey where members and observers can check if they want to be in either of the new TGs. Once that is complete she will open a straw ballot to the whole JC to make comments on the issue papers that were sent to TG. She noted that she will only open a couple at a time as to not overload the JC all at once.

This group has a standing date of the first full week of August. There has been no objection to this date so it continues to stand.

**VIII**  **Adjournment**

**Motion:** Parrent motioned to adjourn the meeting.
**Seconded:** Riggs
**Objections:** None
**Abstentions:** None
**Vote by verbal affirmation:** None apposed.
Motion Passed
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<td>Mike Finamore</td>
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