I Opening Remarks

Chairperson Brian Zamora welcomed everyone and called the meeting to order. Brooker read the antitrust statement and completed roll call.

II Review of Agenda

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

**Motion:** Mark Jost motioned to accept the proposed agenda.
**Seconded:** Lisa Lattimore
**Objections:** None
**Abstentions:** None
**Vote by verbal affirmation:** None apposed.
Motion passed.

III Membership Review

Brooker informed the group that JC with 6 Industry, 4 Users, and 4 Public Health (PH) members. This group is deficient in PH and User stakeholders, and 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 2 Grade Rule (gmpDS-2019-1)

**Motion:** Lattimore motioned to open this issue paper for ballot.
**Seconded:** Paul Bolar
**Objections:** None
**Abstentions:** None
**Vote by verbal affirmation:** None apposed.
Motion passed.

B. Issue 3 Section 4.6.1 (gmpDS-2019-2)

**Motion:** Jost motioned to open this issue paper for ballot.
**Seconded:** Christine Summers
**Objections:** None
**Abstentions:** None
**Vote by verbal affirmation:** None apposed.
Motion passed.
C. Issue 4 Section 4.5.47 (gmpDS-2019-3)

**Discussion:** There was some concern that the submitted language required the whole list of detection methods. After some discussion the language was changed to the language below.

**Original:**

4.5.47 Manufacturing operations shall include controls in manufacturing steps to prevent contamination, including metal detection. Manufacturing operations include controls to prevent contamination from foreign matter including, but not limited to magnets, sieves, metal detectors, x-ray and other devices. [21 CFR § 111.365(h), (i)]

**New:**

4.5.47 Manufacturing operations shall include controls in manufacturing steps to prevent contamination, including metal detection. Manufacturing operations shall include controls to prevent contamination from foreign matter some examples of this include, but are not limited to magnets, sieves, metal detectors, x-ray or other devices as appropriate. [21 CFR § 111.365(h), (i)]

**Motion:** Bolar motioned to open the new language for ballot.
**Seconded:** Jost
**Objections:** None
**Abstentions:** None
**Vote by verbal affirmation:** None apposed.
Motion passed.

D. Issue 5 Environmental Monitoring (gmpDS-2019-4)

**Discussion:** Raiji summarized the issue paper but Jost had a questioned the definition of “indicator organisms”. Raiji stated that it could be addressed in the ARG but the JC decided it would be better to address it in the standard. Since this required more discussion than time allowed Zamora informed the JC that they could open a task group (TG) to give more detail to the issue paper.

**Motion:** Jost motioned to create a new TG to discuss this issue paper further.
**Seconded:** Summers
**Objections:** None
**Abstentions:** None
**Vote by verbal affirmation:** None apposed.
Motion passed.

E. Issue 6 Mock Recall Criteria (gmpDS-2019-5)

**Discussion:** Bolar raised concerns about the four hour time limit. He supported the four hour time limit for the traceability aspect of the issue paper but opposed that limit for the rest. Both twenty-four and forty-eight hours were discussed but it was decided to move this to the same TG that Jost moved to create for the above issue.
Motion: Jost motioned to move to the TG created by the motion above.
Seconded: Lattimore
Objections: None
Abstentions: None
Vote by verbal affirmation: None apposed.
Motion passed.

***This requirement was also proposed in the OTC JC. They too agreed that four hours was not acceptable for a mock recall. They agreed to send this to a TG and also agreed that it needed to meet with the DS TG to discuss this requirement to make sure the two standards remain as harmonized as possible.***

V ARG Issue Papers

A. Issue 1 Section 4.4.16 – 4.4.17 (gmpDS-ARG-2019-1)

Motion: Jost motioned to create a new TG to discuss this ARG issue paper.
Seconded: Lattimore
Objections: None
Abstentions: None
Vote by verbal affirmation: None apposed.
Motion passed.

B. Issue 6 Section 4.4.16 – 4.4.17 (gmpDS-ARG-2019-6)

Discussion: Raiji explained that she only opened this issue paper as an alternative to ARG issue 1. Since the JC decided to discuss issue 1 in a TG she officially withdrew this issue paper.

C. Issue 2 Section 4.1 (gmpDS-ARG-2019-2)

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

D. Issue 3 Section 4.2 (gmpDS-ARG-2019-3)

Discussion: Zamora decided that the issue paper was needed to be further discussed to nuance the language and therefore he sent it to the ARG TG.

E. Issue 4 Section 4.3 (gmpDS-ARG-2019-4)

Discussion: An observer commented that this issue paper is very useful and is a big opportunity for this JC. There was some mention of redundancy in this paper though. Bolar expressed that the redundancy did not bother him, but he felt that there were some points that needed to be addressed. Zamora decided that the issue paper was needed to be further discussed to nuance the language and therefore he sent it to the ARG TG.

F. Issue 5 Section 4.4.2 – 4.4.14 (gmpDS-ARG-2019-5)

Discussion: Zamora decided that the issue paper was needed to be further discussed to nuance the language and therefore he sent it to the ARG TG.
G. Issue 7 Section 4.4.38 – 4.4.46 (gmpDS-ARG-2019-7)

**Discussion:** Bolar stated that he agreed with this issue paper on principle, but he also noted that he wanted to change some language. He added that he was concerned about scope creep siting that 4.4.39.1 was covered in another section. Zamora decided that the issue paper was needed to be further discussed to nuance the language and therefore he sent it to the ARG TG.

H. Issue 8 Section 4.5.1 – 4.5.30 (gmpDS-ARG-2019-8)

**Discussion:** Zamora decided that the issue paper was needed to be further discussed to nuance the language and therefore he sent it to the ARG TG.

I. Issue 9 Section 4.5.31 – 4.5.50 (gmpDS-ARG-2019-9)

**Discussion:** Zamora decided that the issue paper was needed to be further discussed to nuance the language and therefore he sent it to the ARG TG.

J. Issue 10 Section 4.5.51 – 4.5.70 (gmpDS-ARG-2019-10)

**Discussion:** Zamora decided that the issue paper was needed to be further discussed to nuance the language and therefore he sent it to the ARG TG.

K. Issue 11 Section 4.5.73 – 4.5.80 (gmpDS-ARG-2019-11)

**Discussion:** Zamora decided that the issue paper was needed to be further discussed to nuance the language and therefore he sent it to the ARG TG.

L. Issue 12 Section 4.6.1 – 4.6.28 (gmpDS-ARG-2019-12)

**Discussion:** Zamora decided that the issue paper was needed to be further discussed to nuance the language and therefore he sent it to the ARG TG.

M. Issue 13 Section 4.7 (gmpDS-ARG-2019-13)

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

**Seconded:** Debasis Bagchi

**Objections:** None

**Abstentions:** None

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

Motion Passed.

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:** Bolar had a concern with the use of “…auditor’s submitted objective…” He and the rest of the JC present agreed to “…client’s submitted objective…”

**Motion:** Lattimore motioned to ballot the issue paper with the above edit.
**Seconded:** Summers
**Objections:** None
**Abstentions:** None
**Vote by verbal affirmation:** None apposed.
Motion passed.

****The JCs on GMP for OTC and cosmetics also agreed on moving to ballot with this edit.***

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 OTC JC passed to go to ballot with this but 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**

Zamora 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:** Jost motioned to adjourn the meeting.
**Seconded:** Lattimore
**Objections:** None
**Abstentions:** None
**Vote by verbal affirmation:** None apposed.
Motion Passed

Meeting Attendance

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<tr>
<th>Organization</th>
<th>Name</th>
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<th>Role</th>
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<tbody>
<tr>
<td>RFI LLC</td>
<td>Paul Altaffer</td>
<td>Industry</td>
<td>Member</td>
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<tr>
<td>CRN</td>
<td>Gisele Atkinson</td>
<td>Industry</td>
<td>Member</td>
</tr>
<tr>
<td>University of Houston College of Pharmacy</td>
<td>Debasis Bagchi</td>
<td>Public Health / Regulatory</td>
<td>Member</td>
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<tr>
<td>National Institutes of Health (NIH)</td>
<td>Joseph Betz</td>
<td>Public Health / Regulatory</td>
<td>Member</td>
</tr>
<tr>
<td>Pharmavite LLC</td>
<td>Paul Bolar</td>
<td>Industry</td>
<td>Member</td>
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<tr>
<td>NSF International</td>
<td>Rachel Brooker</td>
<td>General Interest</td>
<td>Secretariat</td>
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<td>Gemini Pharmaceuticals, Inc</td>
<td>Mark Jost</td>
<td>Industry</td>
<td>Vice chair</td>
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<tr>
<td>University of Mississippi</td>
<td>Ikhlas Khan</td>
<td>Public Health / Regulatory</td>
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<td>Lisa Lattimore</td>
<td>User</td>
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<td>Costco Wholesale Corporation</td>
<td>Christine Summers</td>
<td>User</td>
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<tr>
<td>County of San Mateo</td>
<td>Brian Zamora</td>
<td>General Interest</td>
<td>Joint Committee Chair</td>
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