

## Appendix 2: Draft Agenda of Expert Circle Meeting, Dec 2<sup>nd</sup>, 2022

### Day 4 Friday Dec 2<sup>nd</sup>, 2022 (9:00am – 4:10pm)

Session No.	Title & Key Description	Time
1	Welcome, Introductions and Aims of the Meeting	9:00am - 9:15am (15min)
2	General discussion on how the training event went over the last three days	9:15am - 9:30am (15min)
3	<p><b>Review of the Current Mandate of the Expert Circle:</b></p> <ul style="list-style-type: none"> <li>✓ What work remains to be completed and how should we plan that work?</li> <li>✓ Should the 2012 PIC/S Risk-based GMP Inspection Planning tool be revised? <ul style="list-style-type: none"> <li>○ What key things might need to be changed in it?</li> <li>○ What improvements would we wish to make?</li> <li>○ Should we include a PQS Effectiveness Rating within the tool to support the implementation of ICH Q12?</li> <li>○ Should it reflect any learnings that have come out of inspecting remotely during the Covid-19 pandemic</li> </ul> </li> </ul>	9:30am - 10:15am (45min)
-	<b>Break</b>	10:15am – 10:30am (15min)
4	<p><b>Strategic discussion on the future work of the Expert Circle:</b></p> <ul style="list-style-type: none"> <li>✓ How should the ICH Q9 Revision inform what the Expert Circle does in the future?</li> <li>✓ What should we think about for future Inspector training activities in light of the Q9 revision?</li> <li>✓ What else should we think about? Are there any lessons from Covid-19 that we should draw upon when designing future QRM training events?</li> </ul>	10:30am – 11:30am (60min)
5	<p><b>Ensuring that our Expert Circle training activities are effective:</b></p> <ul style="list-style-type: none"> <li>✓ Perspectives from a training/education expert</li> </ul>	11:30am – 12:30pm (60min)
-	<b>Lunch</b>	12:30pm – 1:30pm (60min)
6	<p><b>The July 2021 PIC/S Recommendation on How to Evaluate and Demonstrate PQS Effectiveness with regard to Risk-based Change Management:</b></p> <ul style="list-style-type: none"> <li>✓ Overview of the paper and its history</li> <li>✓ How might we as GMP Inspectors use this paper?</li> <li>✓ Presentation on what the Pharmaceutical Industry and the <i>One Voice of Quality</i> group is doing in response to this paper</li> </ul>	1:30pm – 2:30pm (60min)
-	<b>Break</b>	2:30pm – 2:40am (10min)
7	Potential Topic: Still to be decided	2:40pm – 3:15pm (35min)
8	Open Floor Discussion on Misc. QRM Topics	3:15pm – 3:45pm (30min)
9	Closing Remarks & Wrap Up	3:45pm – 4:00pm (15min)
-	Group Photograph	4:00pm – 4:10pm (10min)
-	End of Expert Circle Meeting	-