Appendix 1 – QRM Training Event Draft Programme, Nov 29th-Dec 1st, 2022

Day 1 Tuesday Nov 29th, 2022 (8:15am – 5:25pm), Plenary Room		
Session No.	**Title & Key Description**	**Time**
-	Registration	8:15am - 9:00am (45min)
1	Welcome Remarks	9:00am - 9:15am (15min)
2	Opening Session – Introductory Remarks	9:15am - 9:35am (20min)
3	QRM Refresher Presentation – the basics of QRM	9:35am - 10:15am (40min)
-	Break	10:15am – 10:30am (15min)
4	Interactive Presentation – How Mature Quality Systems use QRM to Assure Lifecycle Process and Facility Improvement	10:30am – 11:30am (60min)
5	Case Study: QRM and the Supply Chain	11:30am – 12:20pm (50min)
-	Lunch	12:20pm – 1:30pm (70min)
6	Plenary Presentation: FMEA – Issues for Inspectors to consider, including Hazard Identification, RPN Numbers, Risk Assessment & Risk Control	1:30pm –2:20pm (50min)
7	Plenary Presentation – Understanding HACCP and its applications in the GMP Environment	2:20pm – 3:00pm (40min)
-	Break	3:00pm – 3:15am (15min)
8	Plenary Presentation - Overview of Various QRM Tools and Common Ways that QRM Can Go Wrong	3:15pm – 4:15pm (60min)
9	Interactive Presentation: Data Integrity - Identifying and Managing Risks	4:15pm – 5:00pm (45min)
-	Open Floor Discussion and Q&A	5:00pm – 5:25pm (25min)
-	Social Event – Dinner	7:30pm – 10:00pm (150min)

Day 2 Wednesday Nov 30th, 2022 (8:45am – 5:30pm) - Interactive Workshops				
Session No.	**Group 1**	**Session No.**	**Group 2**	**Time**
W1	Identifying Risks When Walking Through a Facility	W2	Critique of an FMEA Risk Assessment in a PAT Change Control	8:45am-10:00am (75min)
-		Break		10:15am – 10:30am (15min)
W3	Understanding the Problems of Subjectivity & Uncertainty in QRM – Issues to Consider	W4	Critical points regarding QRM to prevent Cross-contamination in Shared Facilities	8:45am-10:00am (75min)
-		Break		10:30am – 11:45am (15min)
W5	How to inspect QRM in pharmaceutical product development activities	W6	Inspecting a Fishbone Analysis and an FMEA Risk Assessment at a Steriles Site	11:45am-12:35pm (50min)
-		Lunch		12:35pm – 1:45pm (70min)

Session No.	Group 2	Session No.	Group 1	Time
W1	Identifying Risks When Walking Through a Facility	W2	Critique of an FMEA Risk Assessment in a PAT Change Control	1:45pm-3:00am (75min)
-		Break		3:00pm – 3:15pm (15min)
W3	Understanding the Problems of Subjectivity & Uncertainty in QRM – Issues to Consider	W4	Critical points regarding QRM to prevent Cross-contamination in Shared Facilities	3:15pm - 4:30pm (75min)
-		Break		4:30pm – 4:40pm (10min)
W5	How to inspect QRM in pharmaceutical product development activities	W6	Inspecting a Fishbone Analysis and an FMEA Risk Assessment at a Steriles Site	4:40pm-5:30pm (50min)

Day 3 Thursday Dec 1st, 2022 (8:45am – 3:45pm), Plenary Room

Session No.	Title & Key Description	Time
10	Have Your Say! This session will discuss any QRM topics not covered in the first two days. (Topics can be suggested during Days 1 & 2). It will also address what GMP Inspectors may struggle with in relation to inspecting QRM.	8:45am – 10:00am (75min)
-	Break	10:00am – 10:15am (15min)
11	Plenary Presentation: Overview of the PIC/S Risk-based GMP Inspection Planning tool, and how it can be customised to suit local needs	10:15am – 11:15am (60min)
-	Break	11:15am – 11:30am (15min)
12	Plenary Presentation: Risk-based GMP Inspection Planning in Brazil – ANVISA's Experience	11:30am –12:00pm (30min)
13	Interactive Presentation - The 2020-2023 Revision of ICH Q9 – What's changing and what the will revision mean for GMP Inspectors? Followed by open floor discussion	12:00pm – 12:50pm (50min)
-	Lunch	12:50pm – 2:00pm (70min)
14	Interactive Plenary Discussion: The upcoming revised version of the PIC/S QRM Aide Memoire – what's coming?	2:00pm – 2:45pm (45min)
15	Round table: Open Discussion.	2:45pm – 3:15pm (30min)
16	Closing Session - Closing Remarks	3:15pm – 3:30pm (25min)
-	Group Photograph	3:30pm – 3:45pm (25min)
-	End of Training Event	-