

## IAS, USA

### ISO/IEC 17034 for Reference Material Producer (RMP) (PHASE 1 TRAINING)

Day 1 – 22<sup>nd</sup> March 2021

Time (Hrs)	Topics
09.00 – 09.10 A.M.	Inauguration and introduction of Trainees and Trainer
09.10 – 10.00 A.M.	Definitions and terminology used in RM production as given in <b>ISO Guide 30</b>
10.00 – 11.30 A.M.	Production and technical requirements- <b>Clause 7 of ISO 17034:2016 – Part 1</b>
11.30 – 11.45 A.M	<b>TEA BREAK</b>
11.45 – 01.00 P.M.	Production and technical requirements – <b>Clause 7 of ISO 17034:2016 – Part 2</b>
01.00 – 01.30 P.M.	Contents of labels and RM certificates/ documents as per <b>ISO Guide 31</b>
01.30 – 2.15 P.M	<b>LUNCH BREAK</b>
02.15 – 03.00 P.M.	Overview of RM Production - <b>Clause 6 of ISO Guide 35:2017</b>
03.00 – 03.30 P.M.	Resource requirements - <b>Clause 6 of ISO 17034:2016</b>
03.30 – 04..00 P.M	General and Structural requirements - <b>Clause 4 and 5 of ISO 17034:2016</b>

**Day 2 – 23<sup>rd</sup> March 2021**

Time (Hrs)	Topics
09.00 – 09.30 A.M.	Recap on day 1
09.30 – 10.00 A.M.	Assessment of homogeneity – Basic concepts - <b>Clause 7 of ISO Guide 35:2017</b>
10.00 – 10.45 A.M.	Exercise – 1 on Homogeneity assessment – Between unit homogeneity, $U_{bb}$ by Simple randomized design (One Way ANOVA)
10.45 – 11.45 A.M.	Exercise – 2 on Homogeneity assessment – Between unit homogeneity, $U_{bb}$ by Randomized block design (Two Way ANOVA without replicates)
11.45 A.M – 12.00 P.M	TEA BREAK
12.00 – 12.30 P.M.	Exercise – 3 on Homogeneity assessment – Within unit homogeneity, $U_{wb}$ by (One Way ANOVA)- as per figure 5(a) of ISO Guide 35
12.30 – 01.30 P.M.	Exercise – 4 on Homogeneity assessment – Both Between unit homogeneity, $U_{bb}$ & Within unit homogeneity, $U_{wb}$ by (Two Way ANOVA with replicates)- as per figure 5(b) of ISO Guide 35
01.30 – 2.15 P.M	LUNCH BREAK
02.15 – 03.00 P.M.	Assessment of stability – Basic concepts - <b>Clause 8 of ISO Guide 35:2017</b>
03.00 – 03.30 P.M.	Exercise – 5 on Stability assessment – Estimation of slope, intercept and their uncertainties + Estimation of value after certain period
03.30 – 04..00 P.M	Exercise – 6 on Stability assessment – Estimation of property value, $U_{Its}$ and shelf life

**Day 3– 24<sup>th</sup> March 2021**

Time (Hrs)	Topics
09.00 – 10.00 A.M.	Recap on day 2 - Homogeneity and Stability assessment
10.00 – 10.45 A.M.	Assessment of stability monitoring - as per Clause 8.10 of ISO Guide 35
10.45 – 11.15 A.M.	Exercise – 7 on Stability monitoring
11.15 – 11.30 P.M	TEA BREAK
11.30 A.M – 12.15 P.M	Short term stability calculation + Exercise – 8 on Short term stability calculation
12.15 – 1.00 A.M	Characterization and assignment of property values as per Clause 9 of ISO Guide 35
01.00 – 01.30 P.M	Exercise – 9 ILC for assigning value and homogeneity
01.30 – 2.15 P.M	LUNCH BREAK
02.15 – 03.15 P.M.	Exercise – 10 Calculation of weighted mean
03.15 – 03.30 P.M.	Exercise – 11 Calculation of overall MU
03.30 – 04..00 P.M	Management System requirements - Clause 8 of ISO 17034:2016