ANNEXURE-1

Training on ISO 11137 Part-1 & Part-2(Including Risk Analysis of medical devices based on ISO 14971)

Training Schedule

Location: ISOMED SOUTH SITE BARC

Day :One			
Clause No (ISO11137 -1)	Clause Description	Time	Lecture by
4.1 4.2	Introduction Documentation ➢ Change control ➢ Deviation ➢ OOS(Out of Specification) ➢ customer complaint ➢ product recall ➢ Introduction to Risk based evaluation as per cGMP/eu-GMP/WHO-GMP ➢ sharing experiences with MHRA-UK/CDSCO Management Responsibility ➢ Training need identification	10:00 to 11:00	FIC/MR/RSO/LEAD AUDITOR
4.3 4.4	Role of RA in changing environment-Medical Devices act -2017 Product Realisation Measurement Analysis Improvement	11:00 to 12:00	QA/QC OFFICER/RSO/LEAD AUDITOR
5.0	Sterilising agent characterisation (sterilising agent, microbicidal effectiveness, material effect, environmental consideration)	12:00 to 13:00	QA/QC OFFICER/RSO/LEAD AUDITOR

Lunch break (13:00 to 13:30)			
6.0	Process and equipment characterisation	13:30 to 14:30	QA/QC OFFICER/RSO/LEAD AUDITOR
7.0	Product definition Process definition Establishing maximum acceptable dose	14:30 to 15:30	QA/QC OFFICER/RSO/LEAD AUDITOR
Tea break (15:30 to 16:00)			
8.0	Establishing sterilisation dose Specifying maximum acceptable	16:00 to 17:00	QA/QC OFFICER/RSO/LEAD AUDITOR
8.1	Specifying sterilisation dose	17:00 to 18:00	QA/QC OFFICER/RSO/LEAD AUDITOR

Day :Two			
Clause No (ISO 11137-1)	Clause Description	Time	Lecture by
9.0 9.1 9.2	Validation Installation Qualification Operational Qualification	10:00 to 11:00	RSO/LEAD AUDITOR
9.3	Performance Qualification	11:00 to 12:00	QA/QC OFFICER/RSO/LEAD AUDITOR
9.4	Review and approval of validation	12:00 to 13:00	QA/QC OFFICER/RSO/LEAD AUDITOR
Lunch break (13:00 to 13:30)			
10.0	Routine monitoring and control	13:30 to 14:30	QA/QC OFFICER/RSO/LEAD AUDITOR

11.0	Product realisation from sterilisation	14:30 to 15:30	QA/QC OFFICER/RSO/LEAD AUDITOR
Tea break (15:30 to 16:00)			
9.0 (ISO 11137-2)	Method VDmax (substantiation of 25kGy dose)	16:00 to 17:00	QA/QC OFFICER/RSO/LEAD AUDITOR
10.0 (ISO11137-2)	Auditing sterilisation dose	17:00 to 18:00	QA/QC OFFICER/RSO/LEAD AUDITOR

Day :Three			
Clause No (ISO 11137-1)	Clause Description	Time	Lecture by
12.0 12.4	Maintaining process effectiveness Demonstration of continued effectiveness Re-qualification	10:00 to 11:00	QA/QC OFFICER/RSO/LEAD AUDITOR
ISO 14971	Risk Analysis (Medical Devices)	11:00 to 12:00	QA/QC OFFICER/RSO/LEAD AUDITOR
ISO 14971	Risk Analysis (Medical Devices)	12:00 to 13:00	QA/QC OFFICER/RSO/LEAD AUDITOR
Lunch break (13:00 to 13:30)			
	Site Visit of ISOMED (Field training)	13:30 to 14:30	RSO/PLANT ENGR
	Site Visit of ISOMED (Field training)	14:30 to 15:30	RSO/PLANT ENGR

Tea break (15:30 to 16:00)			
	Training & Training in Evaluation Method with ISOTRAIN	16:00 to 17:00	RSO/PLANT ENGR
	Training & Training Evaluation Method with ISOTRAIN	17:00 to 18:00	RSO/PLANT ENGR

Day: Four	Time
Written exam (in ISOTRAIN)	10:00 to 11:00
Viva	11:00 to 12:00
Discussion and Feed- back session	12:00 to 13:00