ESCCA
European Society
for Clinical Cell Analysis

ESCCA 2022

WEDNESDAY 21 SEPTEMBER 2022

09.00-12.30 Training course 4: Validation and ISO Accreditation of FCM Assays

In the first part of the course participants will receive a comprehensive review of the Regulation (EU) 2017/746 on in vitro diagnostic medical devices. During the second part participants will learn the approaches for preanalytical, analytical and postanalytical validation procedures for in-house FCM methods. In the last part participants will gain understanding of the requirements for ISO 5189 accreditation.

Level: Advanced
Organisers: Iuri Marinov (Prague, CZ) and Frank Preijers (Nijmegen, NL)

09.00-09.10	Welcome	Iuri Marinov (Prague, CZ)
09.10-09.40	EU Regulatory requirements Regulation (EU) 2017/746 of the European Parliament and the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU	Iuri Marinov (Prague, CZ)
09.40-10.10	Validation of FCM assays - preanalytical phase - Specimen requirements: storage, transportation, stability, processed stability - Reagent requirements: clone/flurochrome selection, SI, SR, Ab titration, controls, panel Design	Frank Preijers/Willemijn Hobo (Nijmegen , NL)
10.10-10.40	Validation of FCM assays - analytical phase - Instrument qualification: optical alignment, calibration, compensation, standardization, Carryover - Advanced software for clinical data analysis	Frank Preijers/Willemijn Hobo (Nijmegen , NL)
10.40-11.15	Coffee break	
11.15-11.45	Validation of FCM assays - postanalytical phase - Assay accuracy, analytical specificity, clinical specificity, analytical sensitivity, functional sensitivity, clinical sensitivity, repeatability, reproducibility, linearity - EQC	Iuri Marinov (Prague, CZ)
11.45-12.15	ISO 15189 accreditation	Iuri Marinov (Prague, CZ)
12.15-12.30	Discussion	

Lunch on your own
14.00