

2nd European Training Course on Quality Management for Tissue Establishments

26 September 2022 to 9 November 2022

ONLINE



PROGRAMME

2nd European Training Course on Quality Management for Tissue Establishments

Programme

26 September to 3 October 2022

Module 1: General concepts on quality management

Pre-recorded lectures:

Introduction to the course	Jaime Marco
Quality Management in EU legislation: Current and future perspectives	Deirdre Fehily
Quality Management System: An overview	Johan Guns
The guide to the quality and safety of tissues and cells for human application. Good Practice Guidelines in Tissue Banking	Richard Lomas
Validation and qualification	Jaime Tabera
Specificities of validation and qualification in MAR	María José de los Santos

Live session Monday 3 October 2022 (14-16.30h)

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3 October to 14 October 2022

Module 2: Personnel, auditing & biovigilance

Pre-recorded lectures:

Personnel, training and competency assessment	Renza Monteleone
Training and competency assessment in the medically assisted reproduction field	Borut Kovacic
Self inspections	Mona Hansson
Biovigilance: General approach	Jacinto Sánchez
Specificities of biovigilance in medically assisted reproduction	Borut Kovacic
Specificities of biovigilance in haematopoietic progenitor cells	Mona Hansson

Live session Friday 14 October 2022 (14-16.30h)

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14 October to 19 October 2022

Module 3: Risk assessment

Pre-recorded lectures:

Risk assessment in replacement tissues	Jaime Tabera
Risk assessment in haematopoietic progenitor cells	Mona Hansson
Risk assessment in medically assisted reproduction	Kelly Tilleman
Risk assessment tool Euro GTP II	Jaime Tabera
EDQM Risk of Contamination Assessment tool (ERICA)	Johan Guns

Live session Wednesday 19 October 2022 (14-16.30h)

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19 October to 26 October 2022

Module 4: Change control, improvement & traceability

Pre-recorded lectures:

Change control management

Jaime Tabera

Corrective and preventive actions (CAPA)

Johan Guns

Traceability and coding systems

Jacinto Sánchez

Witnessing 2.0: from manual to electronic approaches

Kelly Tilleman

Live session Wednesday 26 October 2022 (14-16.30h)

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26 October to 2 November 2022

***Module 5: Outsourced activity management,
qualification of suppliers & quality indicators***

Pre-recorded lectures:

Supplier qualification, batch acceptance and contractual agreements

Renza Monteleone

Quality indicators in replacement tissues

Richard Lomas

Quality indicators in haematopoietic progenitor cells

Mona Hansson

Statistical process control (SPC) in MAR

Kelly Tilleman

Live session Wednesday 2 November 2022 (14-16.30h)

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2 November to 9 November 2022

***Module 6: Microbiological testing and environmental
monitoring***

Pre-recorded lectures:

Environmental monitoring

Johan Guns

Microbiological testing

Johan Guns

**Microbiological testing and air quality in medically
assisted reproduction**

María José de los Santos

Live session Wednesday 9 November 2022 (14-16.30h)