

# 1<sup>st</sup> European Training Course on Quality Management for Tissue Establishments

20 October 2021 to 25 November 2021

ONLINE



## PROGRAMME

## 1<sup>st</sup> European Training Course on Quality Management for Tissue Establishments

# Programme

*20 to 27 October 2021*

## ***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

Deidre Fehily

Quality Management System: An overview

Sinéad Masterson  
and Johan Guns

Good Practice Guidelines in Tissue Banking

Richard Lomas  
and Jacinto Sánchez

Validation and qualification

Jaime Tabera  
and Richard Lomas

### **Live session Wednesday 27 October 2021 (14-16.30h)**

- Practical workshop
- Q&A

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*27 October to 3 November 2021*

***Module 2: Personnel, auditing & biovigilance***

Pre-recorded lectures:

**Personnel, training and competency assessment**

**Richard Lomas and  
Sinéad Masterson**

**Personnel training in medically assisted reproduction**

**Kelly Tilleman**

**Internal audits**

**Mona Hansson and  
Nina Worel**

**Biovigilance: General approach**

**Jacinto Sanchez,  
Kelly Tilleman and  
Nina Worel**

**Example of biovigilance in medically assisted reproduction**

**Kelly Tilleman**

**Example of biovigilance in haematopoietic progenitor cells**

**Nina Worel**

**Live session Wednesday 3 November 2021 (14-16.30h)**

- Practical workshop
- Q&A

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*3 to 10 November 2021*

***Module 3: Risk assessment & environmental  
monitoring***

Pre-recorded lectures:

Risk assessment in replacement tissues	Jaime Tabera and Jacinto Sánchez
Risk assessment in haematopoietic progenitor cells	Nina Worel and Mona Hansson
Risk assessment in medically assisted reproduction	Kelly Tilleman and Johan Guns
Risk assessment tool Euro GTP II	Jaime Tabera and Richard Lomas
Environmental monitoring	Johan Guns and Jacinto Sánchez

**Live session Wednesday 10 November 2021 (14-16.30h)**

- Practical workshop
- Q&A

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*10 to 17 November 2021*

***Module 4: Change control, improvement & traceability***

Pre-recorded lectures:

**Change control management**

**Jaime Tabera and  
Sinéad Masterson**

**Corrective and preventive actions (CAPA)**

**Johan Guns and  
Jacinto Sánchez**

**Traceability**

**Nina Worel and  
Mona Hansson**

**Witnessing**

**Kelly Tilleman**

**Live session Wednesday 17 November 2021 (14-16.30h)**

- Practical workshop
- Q&A

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*17 to 24 November 2021*

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

**Pre-recorded lectures:**

**Supplier qualification, batch acceptance and contractual agreements**

**Sinéad Masterson,  
Mona Hansson and  
Richard Lomas**

**Quality indicators in replacement tissues**

**Richard Lomas and  
Jacinto Sánchez**

**Quality indicators in haematopoietic progenitor cells**

**Nina Worel**

**Quality indicators in medically assisted reproduction**

**Kelly Tilleman**

**Live session Wednesday 24 November 2021 (14-16.30h)**

- Practical workshop
- Q&A
- Concluding remarks and take home messages