

BASICS OF PHARMACEUTICAL GRADE MANUFACTURING OF iPSC FOR CLINICAL TRANSLATION

Barcelona, Spain

This event focuses on giving a first grasp of the steps needed for clinical translation of iPSC-based products to members of haploIPS COST Action. Researchers working on iPSC-based therapeutics may benefit from attending this workshop sessions including GMP basics and requirements to regulatory issues and the industry viewpoint, given by experts in the development, manufacturing, quality control and clinical translation of ATMP.

The workshop will take place in Barcelona, on March 6-8 2024, at Banc de Sang I Teixits (BST).

Organizing Committee:

- Joaquim Vives, PhD, *Banc de Sang i Teixits*, *local organiser*
- Sergi Querol, MD, PhD, *Banc de Sang i Teixits*, *co-chair*

DAY 1: March 6th, 2024

Location: Banc de Sang i Teixits, Barcelona & online

14:30-15:00h. Registration

15:00-15:10h. OPENING (AUTHORITIES, COST ACTION COORDINATION, LOCAL ORGANISER)

15:00-15:10h. BRIEF INTRODUCTION OF FACULTY AND ALUMNI

15:30-17:00h. SESSION 1: iPSC-BASED THERAPY DEVELOPMENT FOR CLINICAL APPLICATION

1.1. CURRENT LANDSCAPE OF CLINICAL APPLICATIONS OF hiPSC-BASED THERAPIES AND BANKING INITIATIVES OF GMP-GRADE hiPSC

Ana Belén Álvarez-Palomo (30 min)

1.2. iPS-PANIA: A PUBLIC BANK OF GMP-GRADE hiPSC HAPLOLINES

Sergi Querol (30 min)

1.3. BST TOUR

Joaquim Vives & Margarita Codinach (60 min)

DAY 2: March 7th, 2024

Location: Banc de Sang i Teixits, Barcelona & online

09:00-13:00h. SESSION 2: REGULATORY AND QUALITY REQUIREMENTS IN iPSC-BASED THERAPY DEVELOPMENT FOR CLINICAL APPLICATION**2.1. REGULATION APPLICABLE TO ATMP IN EUROPE**

Joaquín A. Delgado (60 min)

2.2. THE MEANING, THE SENSE AND THE SIGNIFICANCE OF GMP

Joaquim Vives (60 min)

11:00-11:30h. COFFEE BREAK

2.3. HOW TO IMPLEMENT GMP IN AN EUROPEAN PUBLIC INSTITUTION

Ana Mendoza (60 min)

2.4. DESCRIPTION OF TASKS AND DUTIES IN GMP LABS

Alba López & Helena Pasamar (60 min)

13:30-15:00h. LUNCH

15:00-17:00h. SESSION 3: PRACTICAL SESSION**3.1. CLEANROOM GOWNING PROCEDURES**

Laura Reales, Andrea Juarez, Maribel Coca (60 min)

3.2. ASEPTIC PROCEDURES

Sara Martínez, Beatriz Perdigón, Ana Yakimer Meneses (60 min)

DAY 3: March 8th, 2024

Location: Banc de Sang i Teixits, Barcelona & online

09:00-13:00h. SESSION 4: QUALITY CONTROL IN COMPLIANCE TO GMP**4.1. QUALITY TARGET PRODUCT PROFILE *(includes a practical case)***

Margarita Codinach & Joaquim Vives (60 min)

4.2. VALIDATION OF ANALYTICAL TECHNIQUES

Margarita Codinach (60 min)

11:00-11:30h. COFFEE BREAK

11:30-12:30h. SESSION 5: PRACTICAL SESSION**5.1. ACCEPTANCE OF STARTING MATERIALS AND BATCH RELEASE**

Jara Palomero & Cristina Prat-Vidal (60 min)

12:30-13:30h. WRAP UP SESSION, FINAL Q&A AND CERTIFICATES