



3rd INTERNATIONAL
WORKSHOP ON

ADVANCED THERAPIES

Overcoming Challenges in Multi-Product
Manufacturing Facilities

29-30 MAY 2025

Instituto de Salud Carlos III

Campus of Majadahonda
Carretera Majadahonda-Pozuelo Km 2
Majadahonda (Madrid)



MINISTERIO
DE CIENCIA, INNOVACIÓN
Y UNIVERSIDADES



Instituto
de Salud
Carlos III



Sociedad Española
Terapia Génica y Celular



Cátedra UAM-FOI
Oncohematología Pediátrica y
de la Adolescencia

THURSDAY, MAY 29TH

09:30–10:00 Registration

10:00–10:30 Welcome & workshop introduction

Isabel Jado (SG de Servicios Aplicados, Formación e Investigación)

Manuel Juan Otero (Coordinador de la Red TERA+ Hospital Clinic de Barcelona)

Javier García Castro (Director del Departamento de Desarrollo de Medicamentos de TA)

Luis Mariñas Pardo (Director de la Unidad de Terapias Celulares).

10:30–10:50 Introduction to validation of aseptic processes in advanced therapies using media fill. Konexio Biotech

10:50–11:40 Considerations in open manufacturing systems.

- Practical example 1. **Carlos Julia Figueras**. Plataforma de Teràpies Avançades - Banc de Sang i Teixits. Barcelona. TERA+ y TERA+ ISCIII. (20min)
- Practical example 2. **Marta Español Rego**. Hospital Clinic de Barcelona. TERA+ y TERA+ ISCIII. (20min)
- Roundtable (10 min)

11:40–12:20 Coffee break and visit to the sponsors booths

12:20–13:15 Considerations in closed manufacturing systems.

- Practical example 1. **Isabel Mirones Aguilar**. Unidad de Producción Medicamentos de Terapia Avanzada. Hospital Universitario La Paz. Madrid. TERA+ y TERA+ ISCIII. (20 min)
- Practical example 2. **Ana Bonora**. Unidad de Terapias Avanzadas. Instituto de Investigación Sanitaria . Hospital La Fé. Valencia. TERA+ ISCIII. (20min)
- Roundtable (10 min)

13:15–13:35 The revolution of ATMP in manufacturing: challenges and opportunities for the future. **Maria Luisa Nolli**. CEO NCNCNbio - Member of the Board Assobiotec. Member of the Board Europabio. Member of the Board AFI

13:35–14:00 New isocell by IWT: pioneering the future of ATMP manufacturing Enhancing Safety and Quality in ATMP Production, Improving Sustainability of Your Cell Factory **C. Zanini, F. Severina, P. Bosi**. IWT PHARMA

14:00–15:30 Lunch and visit to the Sponsors Booth

15:30–16:40 General considerations on validation of analytical methods: sterility. Biomerieux (20 min)

- Practical example 1. **Julio Castaño Cardoso**. Plataforma de Terapias Avanzadas. Hospital Sant Joan de Déu. Barcelona. TERA+ ISCIII. (20 min)
- Practical example 2. **Oscar M. Pello**. Unidad de Terapias Avanzadas. Fundación Marqués de Valdecilla. Santander. TERA+ ISCIII. (20min)
- Roundtable (10 min)

16:40–17:10 Coffee break and visit to the sponsors booths

17:10–18:20 General considerations on validation of analytical methods: endotoxins. Charles River (20 min)

- Practical example 1. **Blanca Arribas Arribas** - Unidad de Producción y Reprogramación Celular de Sevilla. Red Andaluza de diseño y traslación de Terapias Avanzadas (Radytta). TERA y TERA+ ISCIII. (20min)
- Practical example 2. **Rosa Yañez González** - División de Terapias Innovadoras en el sistema hematopoyético. Unidad de Innovación Biomédica. CIEMAT/CIBERER/IIS-FJD. TERA y TERA+ ISCIII. (20min).
- Roundtable (10 min)

19:30 Guided historic tour of downtown Madrid

20:30 Gala dinner

FRIDAY, MAY 30TH

09:00–09:30 Research support to advanced therapies in Spain by ISCIII. **Luis Mariñas Pardo**. Director de la Unidad de Terapias Celulares. TERA+ Instituto de Salud Carlos III.

09:30–10:00 State of the art in advanced therapies in Italy and the “NOTA” as association experience. **Massimiliano Petrini**. President NOTA, Italy. (20 min+10 min questions)

10:00–10:30 Opening the way to innovation: the Romanian dream of a cellular GMP laboratory. **Alina Tănase, Cristina Gociman, Anca Colita**. Institutul Clinic Fundeni, Bucharest, Romania. (20 min + 10 min questions)

10:30–11:00 Sponsor talks

10:30–10:45 Advancing Research in Advanced Therapies through Specialized Facilities. **Miguel Ángel Sánchez**. Albion

10:45–11:00 Optimized workflows for cell manufacturing and quality control of ATMPs. **Jose Luis Mateos Sanz**. Clinical Business Manager, Miltenyi Biotec

11:00–11:45 Coffee break and visit to the sponsors booths

11:45–13:00 Design and operation of multiproduct and multicategory cleanrooms. Gradocell - Advanther (20 min).

- Practical example 1. **Enrique J. Andreu Oltra**. Laboratorio de GMP de Terapia Celular.. Clínica Universitaria de Navarra. TERA+ y TERA+ ISCIII. (20 min)
- Practical example 2. **Antonio Alarcón Mínguez**. Unidad de Fabricación de Medicamentos de Terapias Avanzadas. Hospital Universitario Niño Jesús. TERA+ y TERA+ ISCIII (20 min)
- Roundtable (15 min)

13:00–13:50 Quality requirements for clinical trials with advanced therapies. **Pablo de Felipe**. AEMPS (30 min + 20 min questions)

13:50–14:00 Workshop wrap up and conclusions.

Cristina Zanini, Luis Mariñas Pardo

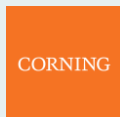
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