

## EATRIS & ISS PRESENT

# INTRODUCTORY ATMP DEVELOPMENT REGULATORY COURSE

**September 14-15, 2015 - Rome Italy**

### Who should participate?

The course is designed for professionals working on new gene and cell therapies or tissue engineering approaches who are in need of an introduction to the regulatory issues associated with ATMP development. The course is open to participants from academia, SMEs, and related industries.

### Why should I participate?

The course provides participants with a sound understanding of pre-clinical and clinical requirements for ATMP development, which ultimately supports meeting ATMP regulatory requirements in a timely & cost effective manner.

This course is structured to provide a unique interactive discussion platform, which offers participants ample opportunities to discuss ATMP development with European regulators, industry representatives, and other ATMP experts.

### What will I learn?

- Knowledge of the European ATMP regulatory landscape;
- Understanding of the major regulatory differences between ATMP and classical drugs of a chemical or biological nature;
- Ability to identify regulatory pathways applicable in the translational development of ATMP; and
- Ability to correctly apply regulatory requirements in ATMP translational development.

### Course providers

EATRIS will provide this course in cooperation with the Italian Institute of Health Istituto Superiore di Sanità (ISS).

### Course dates

September 14-15, 2015

### Teaching Methods

Lectures, case studies, and discussions

### Language

English

### Location

Rome

### Costs

700 Euro  
600 Euro until June 30, 2015

Discounts for EATRIS institutes:  
600 Euro  
500 Euro until June 30, 2015

**Further info & registration**  
[training@eatris.eu](mailto:training@eatris.eu)

## Day 1: September 14, 2015

08.00 Registration

### Module 1: Regulatory framework for investigational ATMP

*Advanced therapy medicinal products pose specific regulatory challenges as compared to other medicines throughout development. Knowledge of European regulatory landscape for ATMP is critical to efficiently drive translation into clinical trials. These aspects will be reviewed and discussed.*

- 08.15 EU Regulatory frame for ATMP (basic elements of Regulation 1394/2007, definitions and classification of ATMP as compared to vaccines or other biologics, centralised procedure, clinical trial directive/Regulation, ERA) (Giovanni Migliaccio, EATRIS, confirmed)
- 09.15 ATMP production (basic elements of GMP, requirements and criticalities for aseptic production and for investigational ATMP) (M.C.Galli, ISS, confirmed)
- 10.15 Coffee break
- 10.30 Preclinical Studies and GLP (basic elements of GLP, requirements and criticalities for investigational ATMP) (G.Ferrari, HSR, confirmed)
- 11.30 Clinical Studies and GCP (basic elements of GCP, requirements and criticalities for investigational ATMP) (Marit Hystad, CAT/EMA, confirmed)
- 12.30 Multiple choice test (30 minutes +15 correction/discussion)
- 13.15 Lunch break

### Module 2: Quality, Safety and Efficacy assessment

*Scientific requirements for obtaining a safe investigational ATMP to be translated into clinical trial will be reviewed and discussed.*

- 14.15 Flow cytometry applications under a quality system (quality management of FC for characterising and controlling investigational ATMP) (M.Sanchez, ISS, tbc)
- 15.15 GTMP (Q,S,E requirements) (M.C.Galli, ISS, confirmed)
- 16.15 Coffee break
- 16.30 CTMP and TEMP (Q,S,E requirements) (E.Flory, PEI, confirmed)
- 17.30 Multiple choice test
- 18.15 Closing of first day

## Day 2: September 15, 2015

### Module 3: case studies

*Practical cases from real life will be reviewed and discussed, aiming at showing examples of a general development plan for ATMP*

09.00 GTMP (criticalities and issues in development) (A.Aiuti, HSR, confirmed)

10.00 CTP (criticalities and issues in development) (G.Cossu, Manchester Univ., confirmed)

11.00 Coffee break

11.15 TEP (criticalities and issues in development) (A.Chiesi, Chiesi Farmaceutici, confirmed)

12.15 Multiple choice test

13.15 Course closing