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EDUCATIONAL PROGRAM **ON ADVANCED THERAPY MANUFACTURING**

ANDALUSIAN NETWORK FOR THE DESIGN & TRANSLATION OF ADVANCED THERAPIES
INTERNATIONAL SOCIETY FOR CELL & GENE THERAPY

ORGANIZERS:

Junta de Andalucía
Consejería de Salud y Familias
FUNDACIÓN PROGRESO Y SALUD

andalusian network
for the design & translation of
advanced therapies

International Society
ISCT
Cell & Gene Therapy®

WITH THE COLLABORATION OF:

International Society
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Junta de Andalucía
Consejería de Salud y Familias
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IAVANTE
Formación y Evaluación de Competencias Profesionales

EDUCATIONAL PROGRAM
ON ADVANCED THERAPY MANUFACTURING

WELCOME

Dear ISCT Member,

Welcome to the Educational Program on Advanced Therapy Manufacturing offered by ISCT and developed by the Andalusian Network for the design and translation of Advanced Therapies (ANd&tAT). We are thrilled to offer this Educational Program exclusively to ISCT Members at no cost.

This Educational Program arose from the partnership between ISCT and the ANd&tAT to foster the training of professionals in the fundamentals of ATMP regulation and the specific knowledge necessary for the development of medicinal products for cell therapy, gene therapy, and tissue engineering.

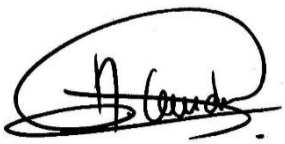
The complete program consists of 6 individual online courses of which contents stem from sections offered in the Master in Manufacturing of Advanced Therapy Medicinal products, University of Granada degrees (www.atmp-masterinmanufacturing.com), organised by ANd&tAT since 2010.

You are invited to complete the whole Educational Program, or the course(s) of your interests or professional scope.

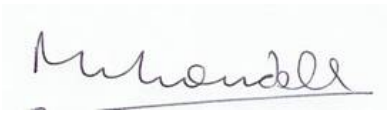
We hope this Educational Program will provide an interesting and informative educational experience for you and proves beneficial towards your professional development and career ambitions.

Thank you very much for your participation in the ISCT global cell & gene therapy community.

Yours sincerely,



Natividad Cuende, MD, MPH, PhD
Past Chair, Europe Legal and Regulatory Affairs Committee
ISCT, International Society for Cell & Gene Therapy



Mark Lowdell, PhD, FRCPath, FRSB
Past Regional Vice-President, Europe
ISCT, International Society for Cell & Gene Therapy

Bruce Levine, PhD
President
June 2020 - June 2022
ISCT, International Society for Cell & Gene Therapy

Junta de Andalucía
Consejería de Salud y Familias
Fundación Progreso y Salud

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METHODOLOGY

Once you click in the course of your choice, you will be able to complete the whole course at your convenience through the e-learning platform that is available on a 24/7 basis.

Tuition:

There will be no dedicated tuition to this program but the ANd&tAT will monitor the platform and in case you need to, you can write an email at:

terapias.avanzadas@juntadeandalucia.es,

an answer will be sent to you as soon as a member of the faculty, expert in that matter, is available.

Certification:

This online educational program includes the possibility to obtain a "Certificate of completion" for each course upon completion of a self-evaluation test that will be available at the end of each course.

CONTENT

COURSE 1:

Course 1 will provide students with the theoretical basis to understand conditions for ATMP production, with an emphasis on the importance of culture media, equipment, facility design, etc. Basic knowledge of cell identity, sterility, virus safety and detection of replicant competent virus will be discussed among quality control in manufacturing cell and gene therapy products.

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COURSE 2:

Course 2 will provide the knowledge of guaranteeing that all the processes are organised and carried out with the objective of ensuring that medicinal products are of the quality required for their intended use (clinical grade).

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COURSE 3:

This course 3 will help students to develop their abilities and show a roadmap to bring basic laboratory results to the bedside. It reviews intellectual property and industry right management in advanced therapies adopting a worldwide perspective. Finally, some speculation is provided on next generation ATMPs (iPSC? transdifferentiated cells? targeted mutation replacement?) and future perspectives in advanced therapies will be summarized so that the student may foresee alternatives that might impact their product development strategy in the not-so-distant future.

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COURSE 4:

Course 4 describes Good Manufacturing Practice (GMP) as applied to ATMPs. While the generic GMP regulations is common knowledge that is easily accessible to anyone, we expect this section to explain this to the students in a very clear manner by making use of specific examples.

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COURSE 5:

Course 5 summarizes the structure of an investigational medicinal product dossier (IMPD). The IMPD is required to start a clinical trial. During this course, it is described as applied to ATMPs using specific examples not only related to this purpose but also to the difficulties usually encountered by independent researchers.

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COURSE 6:

Course 6 examines biosafety issues related to donor selection, cell and tissue manipulation as considered specifically under transplant and pharmaceutical legislation. Regulatory requirements for gene therapy products (GMO) and pharmacovigilance are also discussed.

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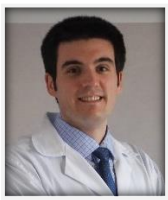
FACULTY

DR. ELISABET AGUILAR BOHÓRQUEZ
Process and Quality Manager.
Andalusian Network for the design and translation of Advanced Therapies. Seville. Spain.

Elisabet Aguilar *is PhD in biomedical research with extensive experience in cell and gene therapies. She is the process and quality manager at the ANd&tAT since 2016 and supervises GMP and GDP compliance in the ANd&tAT GMP facilities network. Broad knowledge in identifying and implementing process improvements, market research in bioreactors, cost analysis, and medicinal product translation from basic research to the GMP facility according Agency requirements.*

DR. ANTONIA ÁLVAREZ MÁRQUEZ
Andalusian Transplant Coordination. Seville. Spain

Antonia Álvarez *is Doctor in Medicine specialist in Immunology. Since 2008, she works as adviser technician in the Andalusian Transplant Coordination. Seville. Spain*



DR. SALVADOR ARIAS SANTIAGO
Cell Production and Tissue Engineering Unit. Hospital Virgen de las Nieves. Granada. Spain

Salvador Arias *is Head of tissue Engineering and Cell Production Unit and Head of Dermatology Department. Virgen de las Nieves University Hospital. Spain. Professor of Dermatology. Granada University. Spain*

MS. GLORIA CARMONA SÁNCHEZ
Quality Assessment and GMP Facilities Coordinator. Andalusian Network for the design and translation of Advanced Therapies. Sevilla. Qualified Person. Production and Reprogramming Cell Unit. Seville. Spain

Gloria Carmona *is Head of Quality Assessment and GMP facilities in the Andalusian Network for the Design and Translation of Advanced Therapies, organization in which she has been working since 2008. She coordinates a GMP network of 10 ATMP facilities. She has more than 15 years of expertise in training people and coordinates an international Master in Manufacturing of Advanced Therapy Medicinal Products. She has been involved in many national and international specialized congresses in the biotechnological sector and ATMPs. She is a Pharmacist Graduate and has a Master in Pharmaceutical and Parapharmaceutical Industry.*

DR. NATIVIDAD CUENDE MELERO
Deputy Director of the Andalusian Transplant Coordination. Seville. Spain

Natividad Cuende*, degree of MD and PhD, is specialist on Family and Community Medicine as well as on Preventive Medicine and Public Health. She is the Deputy Director of the Andalusian Transplant Coordination since 2005 and previously she worked at the National Transplant Organization for over 7 years. Dr. Cuende was the Former Executive Director of the Andalusian Initiative for Advanced Therapies and Former Director of the Master in "Manufacturing of Advanced Therapy Medicinal Products" of the University of Granada (since its creation in 2010 until 2020) and the Former Chair of the European Legal and Regulatory Affairs Committee of the International Society for Cell and Gene Therapy from 2014 to 2019.*

MS. MAR MACÍAS SÁNCHEZ
Pharmacovigilance Technician.
Andalusian Network for the design and translation of Advanced Therapies. Seville. Spain

Mª del Mar Macías *is a pharmacist graduated from the University of Granada. She specializes in pharmacovigilance and regulatory affairs, she has a postgraduate diploma of pharmaceutical regulatory affairs from the University of Barcelona and a Master Degree in Health Economics, Health Management, and Rational Use of Medicines from the University of Málaga. Currently, is the pharmacovigilance officer of the Andalusian Network for the design and translation of Advanced Therapies.*

MR. ROKE IÑAKI ORUEZABAL GUIJARRO
Head of Development and Innovation. Andalusian Network for the Design and Translation of Advanced Therapies. Seville. Spain.

Roke Iñaki Oruezabal *MSci MHEcon and Head of Innovation & Development at AND&TAT gathers proven performance in entrepreneurship and business development with participation in several entrepreneurial and business development initiatives. Proven experience in intellectual property, patents and technology transfer, participating in the creation of public-private agreements. Coordination in areas of technology transfer, application of research projects, as well as knowledge dissemination & consortia set up. Expert knowledge of the regulatory frame in advanced therapies as well as its business environment.*

MS ALBA PEÑA HERNÁNDEZ
Quality Assessment and GMP Facilities Technician.
Andalusian Network for the design and translation of Advanced Therapies. Seville. Spain.

Alba Peña *is graduated in Biotechnology and got Master degree in Evaluation and Development of Medicines. She has been working in the Pharmaceutical Industry for four years regarding injectable products, solid tablets, powder and sprays, in different positions regarding manufacturing and validation and qualification.*

MS. ÁNGELA PONCE POLO
Development and Translation Technician.
Andalusian Network for the design and translation of Advanced Therapies. Seville. Spain.

Ángela Ponce *is graduated in Biotechnology and got Master degrees in Bio enterprises and Quality Assurance for manufacturing of ATMPs, both from University of Granada. As a Development and Translation Technician at the Andalusian Network for the design and translation of Advanced Therapies, she has expertise in technology transfer and business development. She also participates in research projects on technology maturation and health economics.*

DR. ISIDORA RANCHAL ILLESCAS
Preclinical Research Management Technician.
Andalusian Network for the Design and Translation of Advanced Therapies. Seville. Spain.

Isidora Ranchal *is graduated in Biology and completed her PhD from University of Córdoba. Her professional career has mainly focused on translational medical research. She entered the field of advanced therapy medicinal products through a Master's in Manufacturing of Advanced Therapy Medicinal Products. Currently she works as Preclinical Research Management Technician at the Andalusian Network for the design and translation of Advanced Therapies in Seville, Spain.*

MR. ÁLVARO RITORÉ HIDALGO
Innovation and Development Technician.
Andalusian Network for the Design and Translation of Advanced Therapies. Seville. Spain.

Álvaro Ritoré *is graduated in Biotechnology and expanded his knowledge on Biomedical Research and Quality Assurance for Manufacturing of ATMPs. Currently he works as Innovation and Development Technician at the Andalusian Network for the design and translation of Advanced Therapies, covering areas such as supply chain and business models, valorisation and maturation of ATMPs, market analysis and technology surveillance.*

DR. ANTONIO RODRÍGUEZ-ACOSTA
Qualified Person. GMP Laboratory Hospital Regional Málaga. Málaga. Spain

Antonio Rodriguez *received his Bachelor of Science in Biology from the University of Granada (Spain) and started his career as a clinical analyst and microbiologist responsible in clinical laboratories, exerting as Technical Director for over 10 years. He joined the Andalusian Initiative for Advanced Therapies in 2012 and served as Quality Manager in the Cell Manufacturing Unit at the Regional University Hospital (Málaga, Spain), where he currently holds a position as Qualified Person.*

MR. ANTONIO RUIZ GARCÍA
Head of Quality Vithas. Almería. Spain

Antonio Ruiz *is graduated in Pharmacy by the university of Seville. He got a Master degree in Pharmaceutical industry and from 2008 to March 2021, he worked as Head of Quality and Deputy Qualified person in the Cell Production and Tissue Engineering Unit. Hospital Virgen de las Nieves. Granada and currently he is Head of Quality in Vithas. Almería*

DR. ROSARIO SÁNCHEZ PERNAUTE
Scientific Director. Andalusian Network for the Design and Translation of Advanced Therapies. Seville. Spain.

Rosario Sanchez-Pernaute *MD, PhD is a neurologist and stem cell scientist with broad expertise in cellular reprogramming, preclinical in vitro and in vivo models and clinical translation of gene and cell therapies for degenerative disorders. Since mid-2016 she is the scientific director at the Andalusian Network of Advanced Therapies and supervises basic and preclinical regulatory studies and related training. She is a Member of the Spanish Advisory Committee for Human Tissue and Cell Donation and Use, and participates in national and international expert panel*

COORDINATION

Dr. Rosario Sánchez-Pernaute
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Ms. Gloria Carmona
Quality Assessment and GMP Facilities Coordinator. Andalusian Network for the design and translation of Advanced Therapies. Sevilla. Qualified Person. Production and Reprogramming Cell Unit. Sevilla

Ms. Meagan Pasternak
ISCT Manager,
Regional Development and Member Engagement

Ms. Amaya García
Technical secretariat. Training Department. Andalusian Network for the design and translation of Advanced Therapies. Sevilla

HOW TO REGISTER

*You need to be an **ISCT member** to register in this Educational Program*.

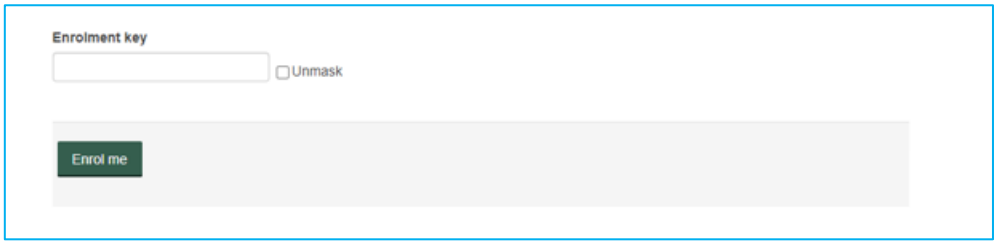
Once you are logged in at the ISCT website, click at the URL that you will find at the Educational Program page, to create your own account to enter at the ANd&tAT e-learning platform.

You will be asked for your name/ surname, e-mail address, country as well as a username and password of your choice to enter from now on.

Note that this information (name and surname) will be used later to generate the certificates, so it is important that you use your full name.

Then, you will receive an e-mail of confirmation and, at this point, you will have access to the Educational program platform and to the list of the 6 courses.

Click at the course of your choice and the following window will appear. Enter the ISCT password (Enrolment Key) previously given or sent to you and enjoy the course!



CONTACT DETAILS

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