PEC PHARMA EDUCATION CENTER

EUROPEAN PHARMACOVIGILANCE CONGRESS 2021

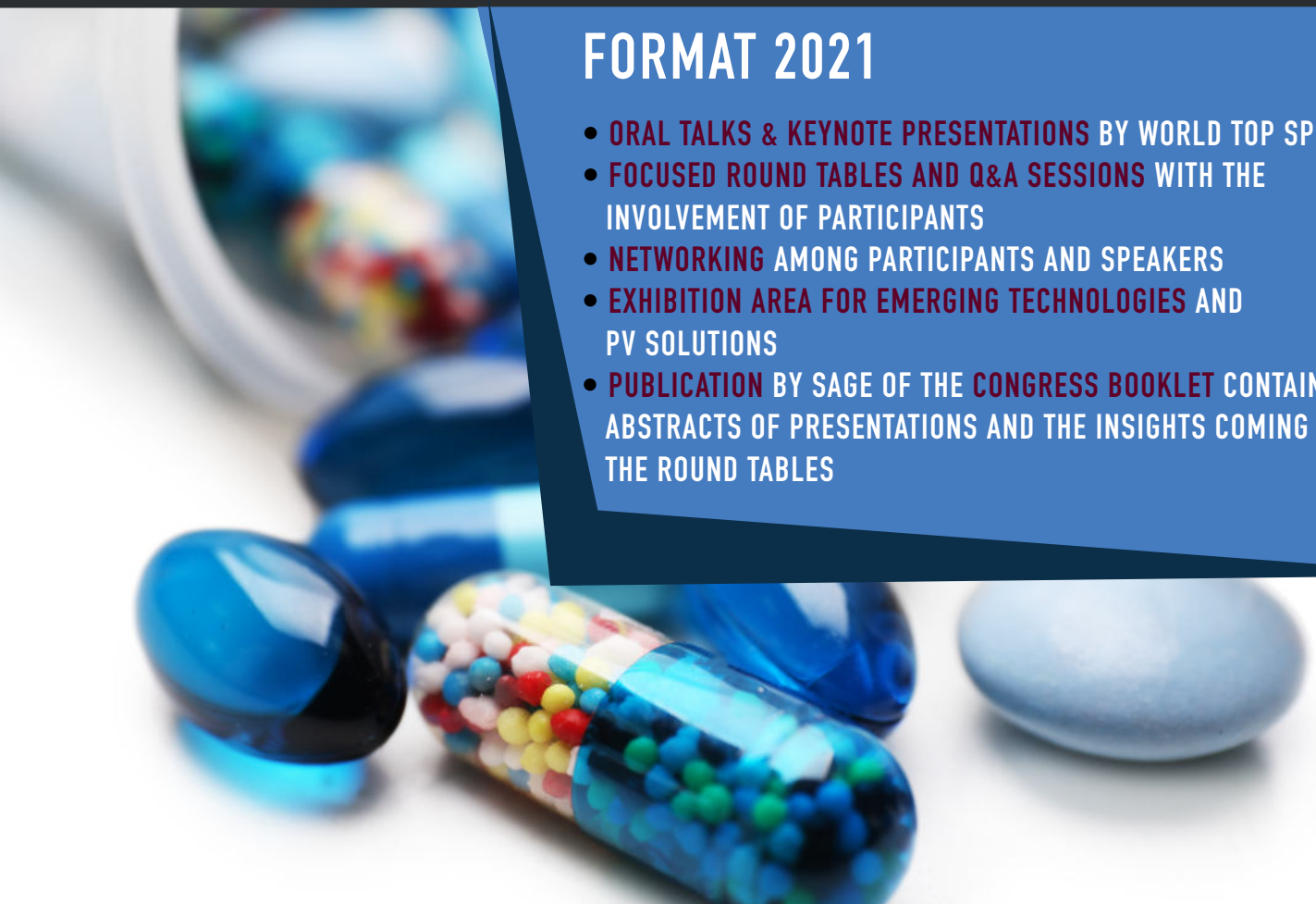
DECEMBER 1 – 3 | ONLINE

#EUPV2021

The European Pharmacovigilance Congress organized by Pharma Education Center has become one of most appreciated international PV meeting.
Last year, the virtual edition of the congress reached a great success with an exceptional participation of PV delegates from all over the world.
International top speakers from marketing authorization holders, competent authorities, international pharmacovigilance organizations, European expert patient organizations and independent consultants animated the three days of conference with fruitful discussions in interactives sessions of Q&A and in focused round tables.
The congress, now at its fifth edition, is a unique opportunity to get the sight of different international stakeholders, to learn more about the new requirements, the new emerging challenges in pharmacovigilance and to discuss the possible strategies and solutions to address them.

The European Pharmacovigilance Congress…

Is more than a traditional conference, it is a great opportunity to learn, to develop your professional skills, to get in touch with international renowned experts and colleagues. Discuss and share the strategies and the main trends in the international pharmacovigilance scenario: be part of the community!



FORMAT 2021

- ORAL TALKS & KEYNOTE PRESENTATIONS BY WORLD TOP SPEAKERS
- FOCUSED ROUND TABLES AND Q&A SESSIONS WITH THE INVOLVEMENT OF PARTICIPANTS
- NETWORKING AMONG PARTICIPANTS AND SPEAKERS
- EXHIBITION AREA FOR EMERGING TECHNOLOGIES AND PV SOLUTIONS
- PUBLICATION BY SAGE OF THE CONGRESS BOOKLET CONTAINING THE ABSTRACTS OF PRESENTATIONS AND THE INSIGHTS COMING FROM THE ROUND TABLES

AGENDA

Time	DECEMBER 1st	Speaker
09.00 am	Welcome by the Chairperson of the congress	**Marco Sardella,** *Chief Pharmacovigilance Officer & EU QPPV - ADIENNE Pharma & Biotech*
09.10	A word from the Editor-in-Chief of Therapeutic Advances in Drug Safety - Eu PV Congress Media Partner	**Arduino Mangoni,** *Strategic Professor in Clinical Pharmacology, School of Medicine, Flinders University, Australia*
SESSION 1. UPDATE FROM INTERNATIONAL PV ORGANIZATIONS		
09.15	Introduction - Chairperson of the Session	**Hervé Le Louët,** *CEO of the UMC, President of CIOMS, Past President of ISoP, Past Member of PRAC*
09.20	Updates from the UMC: New organization, roles and opportunities	**Christian Rausch,** *Global Health, Special Advisor - Uppsala Monitoring Centre*
09.35	Updates from CIOMS	**Rägo Lembit,** *Secretary-General at Council for International Organizations of Medical Sciences (CIOMS)*
09.50	Updates from PIPA	**Sarah Hall,** *HonFPIPA, Managing Director - MIPSOL*
10.05	Updates from ICH	**Rägo Lembit,** *Secretary-General at Council for International Organizations of Medical Sciences (CIOMS)*
10.20	Q&A TIME (20') AND COFFEE BREAK (30')	
SESSION 2. SIGNAL DETECTION & EVALUATION		
11.10	Introduction - Chairperson of the Session	**Mircea Ciuca,** *Global Therapeutic Area Head in Global Clinical Safety and Pharmacovigilance - CSL Behring*
11.15	Required Competence of Signal Management Team	**Jan Petracek,** Director Institute of Pharmacovigilance, Advisory Board International Society of Pharmacovigilance
11.30	Strategies to improve Signal Detection: quality of information and causality assessment	**Fabio De Gregorio,** *Vice President, Head of Drug Safety Europe - Shionogi Europe*
11.45	Tips and guidance on EVDAS use	**Calin Lungu,** *Eudravigilance and XEVMPD-EMA, CEO-DDCS*
12.00 pm	Signal detection in post-marketing studies in the older patient population: the role of machine learning	**Arduino Mangoni,** *Strategic Professor in Clinical Pharmacology, School of Medicine, Flinders University, Australia*
12.15	What signal management system works best for your company and its products	**Glyn Belcher,** *CEO of PV Consultancy Ltd*
12.30	Round Table & Q&A Time	**Moderator: M. Ciuca** **Participants: F. De Gregorio, G.Furlan-** *Pfizer,* **C. Lungu, A. Mangoni, J. Petracek**

AGENDA

01.00	**LUNCH & NETWORKING**	
SESSION 3. PV IN COVID-19 VACCINES		
02.00	**Introduction - Chairperson of the Session**	**Hervé Le Louët,** *CEO of the UMC, President of CIOMS, Past President of ISoP, Past Member of PRAC*
02.05	**Global Drug Safety: The role of the UMC in times of the COVID-19 vaccines**	**Christian Rausch,** *Global Health, Special Advisor - Uppsala Monitoring Centre*
02.20	**Safety of a COVID-19 vaccine**	**Maddalena Lino,** *Neurologist, Safety Risk Lead Director - Pfizer*
02.35	**Communicating vaccines safety in the age of COVID-19**	**Marco Tuccori,** *Unit of Adverse Drug Reactions Monitoring - University Hospital of Pisa*
02.50	**How has ISoP helped tackle Covid-19 vaccine errors?**	**Brian Edwards,** *Managing Director - Husoteria Ltd*
03.05	**Round Table & Q&A Time**	**Moderator: H. Le Louët** **Participants: B. Edwards, M. Lino, C. Rausch, M. Tuccori**
03.35	**COFFEE BREAK AND NETWORKING**	
SESSION 4. DIGITAL HEALTH TECHNOLOGY & PV		
03.50	**Introduction - Chairperson of the Session**	**Margherita D'Antuono,** *Corporate PV Director, EU/UK QPPV - Italfarmaco*
03.55	**The growing area of Telehealth and Pharmacovigilance**	**Hadir Rostom,** *Lecturer MSA university & President of ISoP Egypt Chapter*
04.10	**Application of Digital Health Technology in PV**	**Rish Chopra,** *Senior Director, Head of International Pharmacovigilance, Deputy EU QPPV at Biogen*
04.25	**Round Table & Q&A Time**	**Moderator: M. D'Antuono** **Participants: R.Chopra, P. Kruger-** *EUPATI*, **V. Mancini, H. Rostom**
04.55	**Closing Remarks by the Chairperson of the congress**	**M. Sardella,** *Chief Pharmacovigilance Officer & EU QPPV - ADIENNE Pharma & Biotech*
05.00	**Greetings by Pharma Education Center**	

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Time	DECEMBER 2nd	Speaker
09.00 am	Welcome by the Chairperson of the congress	**Marco Sardella**, *Chief Pharmacovigilance Officer & EU QPPV - ADIENNE Pharma & Biotech*
09.05	A word from the Editor-in-Chief of Therapeutic Advances in Drug Safety - Eu PV Congress Media Partner	**Arduino Mangoni**, *Strategic Professor in Clinical Pharmacology, School of Medicine, Flinders University, Australia*
SESSION 5. PV REGULATORY UPDATES: GLOBAL LANDSCAPE		
09.10	Introduction - Chairperson of the Session	**Francoise Dumas Sillan**, *Vice President, TA lead and EU UK QPPV - Ipsen*
09.15	Global Regulatory Updates concerning PV	**Ilaria Grisoni**, *Senior Director, Head of EU/INT PV Office & EEA QPPV - Jazz Pharmaceuticals*
09.30	PV regulations in Uganda and other African countries	**Helen Byomire Ndagije**, *Product Safety Director - Uganda National Drug Authority*
09.45	Life after Brexit: UK PV and the PSMF	**Sarah Hall**, *HonFPIPA, Managing Director - MIPSOL*
10.00	TBD	**Bert Van Leeuwen**, *deputy QPPV - Astellas Pharma Europe*
10.15	Putting the human at the centre of Quality Management	**Brian Edwards**, *Managing Director - Husoteria Ltd*
10.30	Round Table & Q&A Time	**Moderator:** F. D. Sillan **Participants:** R. Chopra-*Biogen*, B. Edwards, S. Hall, I. Grisoni, H. B. Ndagije, B. Van Leeuwen
11.00	COFFEE BREAK AND NETWORKING	
SESSION 6. PHARMACOEPIDEMIOLOGY & RISK MANAGEMENT		
11.30	Introduction - Chairperson of the Session	**Giovanni Furlan**, *Safety Risk Lead, Director - Pfizer*
11.35	Predictive Pharmacovigilance - Towards preventing future outcomes	**Michael Von Forstner** , *Senior Director Pharmacovigilance & Patient Safety - PRA Health Science*
11.50	Overview of proposed changes to GVP Module XVI -Risk Minimization	**Peishan Liu Snyder**, *Pharmacovigilance Scientist - AstraZeneca*
12.05 pm	Update on activities in the Pharmacovigilance Risk Assessment Committee in 2021, with focus on activities targeting the Covid-19 pandemic	**Doris Irene Stenver**, *Indep. PV Adviser Founder of Unique Advice*
12.20	Round Table & Q&A Time	**Moderator:** G. Furlan **Participants:** M.Ciuca-*CSL Behring*, M.Forstner, P. Liu, J. Petracek-*Institute of PV*, D.I. Stenver

AGENDA

12.50	**LUNCH & NETWORKING**	
SESSION 7. CLINICAL TRIALS REGULATION: IMPACT ON PV		
01.50	**Introduction - Chairperson of the Session**	**Alessandra Traversa,** *Senior Manager in PV Global Process*
01.55	**Implementation of CTR: impacts on Pharmacovigilance**	**Elena Prokofyeva,** *Head of the Drug Safety Team, R&D Department, DG PRE, FAMHP*
02.10	**TBD**	**TBD**
02.25	**Round Table & Q&A Time**	**Moderator: A. Traversa** **Participants: Mircea Ciuca-***CSL Behring***, F. De Gregorio-***Shionogi Europe***, E. Prokofyeva**
02.55	**COFFEE BREAK AND NETWORKING**	
SESSION 8. MEDICAL DEVICE & COMBINATION PRODUCTS		
03.30	**Introduction - Chairperson of the Session**	**Fabio De Gregorio,** *Vice President, Head of Drug Safety Europe - Shionogi Europe*
03.35	**An introduction to vigilance of Medical Devices**	**Gian Nicola Castiglione,** *Director Global Pharmacovigilance - Chiesi Farmaceutici*
03.50	**EU Combination Products: Pharmacovigilance or Vigilance?**	**Tina Amini,** *Medical Device Division Director of NDAREG*
04.05	**Managing of PV in products with double registration worldwide as both Devices and Drugs**	**Daniela Marcozzi,** *Head of R&D Quality & Compliance Company Representative for Competent Health Authorities - Fidia Farmaceutici SpA*
04.20	**Patient Support Program and Combination Products**	**Phillip Eichorn,** *Senior Director - Pfizer Pharmaceuticals*
04.35	**Round Table & Q&A Time**	**Moderator: F. De Gregorio** **Participants: T. Amini, G. Belcher-***PV Consultancy Ltd***, G.N. Castiglione, P. Eichorn, D. Marcozzi**
05.05	**Closing Remarks by the Chairperson of the congress**	**M. Sardella,** *Chief Pharmacovigilance Officer & EU QPPV - ADIENNE Pharma & Biotech*
05.10	**Greetings by Pharma Education Center**	

AGENDA

Time	DECEMBER 3rd	Speaker
09.00 am	**Welcome by the Chairperson of the congress**	**Marco Sardella,** *Chief Pharmacovigilance Officer & EU QPPV - ADIENNE Pharma & Biotech*
SESSION 9. PV IN PERSONALIZED MEDICINE		
09.05	**Introduction - Chairperson of the Session**	**Giovanni Furlan,** *Safety Risk Lead, Director - Pfizer*
09.10	**The role of Pharmacogenomics in drug safety**	**Giovanni Furlan,** *Safety Risk Lead, Director - Pfizer*
09.25	**Pharmacogenomics in Pharmacovigilance**	**Qun Ying Yue,** *MD, PhD, Associate professor, Senior Pharmacovigilance Expert - UMC*
09.40	**Prevalence of CYP2C8*2 and 3 among Eritreans and its Potential Impact on Artenusate/Amodiaquine Treatment**	**Mulugeta Russom,** *Head, Eritrean Pharmacovigilance Centre*
10.00	**Round Table & Q&A Time**	**Moderator: G. Furlan** **Participants: A. Mangoni-***Flinders University,* **S. Persiani-***Rottapharm,* **Q.Y.Yue, M. Russom, M. Von Forstner-***PRA Health Science*
10.30	**COFFEE BREAK AND NETWORKING**	
SESSION 10. INTERACTIONS BETWEEN PV (GVP) AND MANUFACTURING (GMP/GDP)		
11.00	**Introduction - Chairperson of the Session**	**Glyn Belcher,** *CEO of PV Consultancy Ltd*
11.05	**GVP & GMP/GDP : Regulatory inspection findings and possible consequences of lack, poor interaction between these areas**	**Terenzio Ignoni,** *SVP Quality and CMC - Gain Therapeutics*
11.20	**MSPR - Manufacturing Site Pharmacovigilance Representative - The interface between manufacturing QA and Pharmacovigilance**	**Christoph Höck,** *Global Manufacturing Site Pharmacovigilance Representative - CLS Behring*
11.35	**Round Table & Q&A Time**	**Moderator: G. Belcher** **Participants: L. Boga-***Dompé Pharmaceuticals S.p.A.,* **B. Edwards-***Husoteria Ltd,* **C. Höck, T. Ignoni, C. Lungu-***DDCS,* **Bert Van Leeuwen-***Astellas Pharma Europe*
12.05 pm	**LUNCH & NETWORKING**	

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SESSION 11. PV INSPECTIONS & AUDIT		
01.45	**Last updates on Inspections**	**Valentina Mancini,** *Pharmacovigilance Director, EU and UK QPPV - Shionogi Europe*
02.00	**PV Inspections from Authorities who have recently started this activity**	**Alberto Gramaccioli,** *Director, Quality Management and Inspections - Pfizer* **Pramod Wable,** *Director Senior Inspection Management Lead - Pfizer*
02.25	**PV Inspections System**	**Raj Bhogal,** *Head of R&D Audits & Inspections - Jazz Pharmaceuticals*
02.40	**Round Table & Q&A Time**	**Moderator: V. Mancini** **Participants: R. Bhogal, G. N. Castiglione**-*Chiesi Farmaceutici* **A. Gramaccioli, D.Marcozzi**-*Fidia Farmaceutici* **P. Wable**
03.10	**Closing Remarks by the Chairperson of the congress**	**M. Sardella,** *Chief Pharmacovigilance Officer & EU QPPV - ADIENNE Pharma & Biotech*
03.15	**Greetings by the European Pharmacovigilance Congress Scientific Board & Pharma Education Center**	

Be part of the Poster Session!

Any participant can submit a poster on their work/research/studies.

The selected posters will be showcased in a dedicated area of the virtual location of the conference.

Contact us to know more at info@pharmaeducationcenter.it

INTERNATIONAL SPEAKERS

Tina Amini
PharmD, PhD, Medical Device Division Director - NDAREGg

Margherita D'Antuono
PharmD, PhD, Corporate PV Director, EU QPPV - Italfarmaco

Glyn Belcher
CEO - PV Consultancy Ltd

Rägo Lembit
MD, PhD, Secretary-General at Council for International Organizations of Medical Sciences (CIOMS)

Raj Bhogal
Sr. Director, R&D Audits & Inspections – Jazz Pharmaceuticals

Françoise Dumas Sillan
MD, Vice President, TA lead and EU UK QPPV - Ipsen

Gian Nicola Castiglione
Director Global Pharmacovigilance - Chiesi Farmaceutici

Fabio De Gregorio
M.D., Vice President, Head of Drug Safety Europe - Shionogi Europe

Mircea Ciuca
MD, Global Therapeutic Area Head in Global Clinical Safety and Pharmacovigilance - CSL Behring Scientific Board EUPV congress

Brian Edwards
Managing Director - Husoteria Ltd

Rishi Chopra
Senior Director, Head of International Pharmacovigilance, Deputy EU QPPV - Biogen

Philip Eichorn
M.D., Senior Director Worldwide Safety & Regulatory – Pfizer Pharmaceuticals

INTERNATIONAL SPEAKERS

Fernanda Ferrazin
Former Head of Pharmacovigilance Dept. – Italian Medicines Agency
Scientific Board EUPV congress

Giovanni Furlan
Pharm.D., Safety Risk Lead, Director - Pfizer
Scientific Board EUPV congress

Alberto Gramaccioli
PharmD, Director, Quality Management and Inspections - Pfizer

Ilaria Grisoni
Sr. Director, EEA QPPV - Jazz Pharmaceutical

Sarah Hall
PhD, HonFPIPA,Managing Director - MIPSOL

Christoph Höck
Global Clinical Safety and Pharmacovigilance - CSL Behring

Terenzio Ignoni
SVP Quality and CMC - Gain Therapeutics

Paola Kruger
Expert Patient - EUPATI (European Patient's Academy for Therapeutic Innovation)

Hervé Le Louët
CEO of the UMC, President of CIOMS, Past President of ISOP, Past Member of PRAC

Qun Ying Yue
MD, PhD, Associate professor, Senior Pharmacovigilance Expert - UMC

Maddalena Lino
MD, PhD, Neurologist, Safety Risk Lead Director - Pfizer

Peishan Liu
Clinical operation expert, PV & Project Management - Astrazeneca

INTERNATIONAL SPEAKERS

Calin A. Lungu
MD, MRQA, BCPM,
Eudravigilance and XEVMPD
Trainer - EMA, CEO – DDCS

Jan Petracek
MD. PhD, ISoP Advisory Board -
International Society of
Pharmacovigilance

Daniela Marcozzi
Head of R&D Quality & Compliance
Company Representative for Com-
petent Health Authorities -
Fidia Farmaceutici SpA

Elena Prokofyeva
MD, MPH, PhD, Head of
Drug Safety Unit – AFMPS

Valentina Mancini
Pharmacovigilance Director, EU
and UK QPPV - Shionogi Europe
Scientific Board EUPV congress

Christian Rausch
MD, PhD, MSc Global Health,
Special Advisor

Arduino Mangoni
MBBS, MD (Hons), PhD, Professor
and Head, Department of Clinical
Pharmacology, School of Medicine,
Flinders University, Australia

Hadir Rostom
President of ISoP Egypt Chapter,
Pharmacovigilance consultant,
PV lecturer & Co-founder of the
Egyptian pharmacovigilance system

Helen Byomire Ndagije
Director Product Safety -
Uganda National Drug Authority

Patrizia Rotunno
PV Consultant
Scientific Board EUPV congress

Stefano Persiani
PhD, Director Translational
Sciences and Pharmacokinetics -
Rottapharm Biotech

Mulugeta Russom
MSc. PhD Candidate, Head -
Eritrean Pharmacovigilance Centre

INTERNATIONAL SPEAKERS

Marco Sardella
Chief Pharmacovigilance Officer, EU QPPV - ADIENNE Pharma & Biotech

Doris Irene Stenver
D.M., MPA, Indep. PV Adviser
Founder of Unique Advice,
former Chief Medical Officer Danish Medicines Agency and
former member of PRAC

Alessandra Traversa
PV Net consulting

Marco Tuccori
PharmD, PhD, Unit of Adverse Drug Reactions Monitoring - University Hospital of Pisa

Bert Van Leeuwen
Deputy Qualified Person for Pharmacovigilance (QPPV) - Astellas Pharma Europe

Michael Von Forstner
PhD, Senior Director, Pharmacovigilance & Patient Safety - PRA Health Science

Pramod Wable
PhD, Director, Senior Inspection Management Lead - Pfizer

Laura Boga
QPPV – Dompé Pharmaceuticals S.p.A.

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PharmaVOICE

MEDIA7

ENTRY FEE

650€ until November 1st

400€ freelance professionals, University & Research Centers

950€ full price

VAT not included

Discounts are not cumulative

For multiple registrations contact: info@pharmaeducationcenter.it

ONLINE

TEL (+39) 055 7224179
(+39) 055 7224076
FAX (+39) 055 7227014

TERMS OF PAYMENT

Advance payment is required with respect to the event date by bank transfer to BANCO BPM Spa – Florence (Italy), IBAN IT81P0503402801000000007431, Bic/SWIFT: BAPPIT21N25 made payable to Pharma Education Center S.r.l., Via dei Pratoni 16, 50018 Scandicci (FI), VAT number 02173670486, specifying event title along with name and surname of the participant enrolling. Attendance to the event will be allowed upon payment received. Invoice of payment will be issued after the second half of the month after the course.

For further information and/or further assistance please contact (+39) 055 7224179 or email: amministrazione@pharmaeducationcenter.it

COURSE/EVENT CANCELLATION

If the minimum number of participants is not reached, Pharma Education Center reserves the right to cancel or schedule the event for another date. Formal communication will be given within 5 days before the event date. In this case Pharma Education Center will refound the registration fee in full and without additional charges. Alternatively, the participant can request a spendable coupon for participating in another PEC event scheduled in the current year.

CANCELLATION TERMS

In order to cancel enrolment to a event, please email info@pharmaeducationcenter.it within 2 weeks before the starting date of the event. Once this term will be expired, the entire fee will be charged.

PARTICIPANT REPLACEMENT

It is possible to replace a participant attendance without additional cost, simply by contacting info@pharmaeducationcenter.it. It is asked to notify the participant replacement request within 5 days before the starting date of the course/event, specifying the full name and surname of the enrolled participant as well as the full name and surname of the substitute.

HOW TO REGISTER

Please, fill the form on the web site https://www.pharmaeducationcenter.it/

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