EMBRYOLAB ACADEMY

Workshop

Total Quality and Risk Management in your IVF laboratories From theory to practice: 2nd edition.

Program

March 18-19, 2016

Leuven, Belgium



Workshop 2016 Course Objectives

Total Quality Control and Risk Management (TQM) in the IVF laboratory plays a very important role in the success of any IVF program. Due to high demand, Embryolab Academy is organising the 2nd edition TQM Workshop.

Delegates will improve knowledge and understanding

- in Total Quality and Risk Management for assisted reproduction technologies (ART) laboratories
- on all processes performed within ART laboratories and how they will be improved by Total Quality Management (TQM)
- on how to organise internal and external quality control for the different departments in an ART Unit
- a rigid risk assessment and risk analysis method for the ART Unit
- on how TQM can be a useful tool to improve efficacy and efficiency, including financial and administrative aspects
- on how quality assessment and TQM will provide patients with the best and safest treatments modalities available
- In how to develop a patient centred treatment plan

Target Audience

This two-day workshop is designed for reproductive scientists, embryologists, quality managers in IVF, clinicians as well as ART Unit managers who desire to improve their knowledge and understanding of all the recent advances in Total Quality and Risk Management for ART laboratories.



Accreditation

The Embryolab Academy Workshop is under the auspices of ASEBIR.



The Embryolab Academy Workshop is compliant to the assessment based on the provisions of the Eucomed Code of Ethical Business Practice.

EthicalMedTech

Certificate of attendance

A Certificate of attendance will be awarded to the delegates after attending the full workshop program. After completing the on-line evaluation form of the workshop, all certificates can be downloaded.

Program

The theoretical session will give an overview of the recent advances in Total Quality and Risk Management for ART laboratories.

In the' Brains-on' sessions, delegates are invited to present a specific problem/trouble/issue they have or are encountering in their laboratories. In an interactive way, the expert team and the participants will investigate the problem and design a route for solving and preventing these (and other) problems in the future.

Workshop Directors

Alexia Chatziparasidou M Clin Embryology, M Sc, Bac Sc, Sr Clinical Embryologist

Martine Nijs PhD, M Sc, Bac Sc, Sr Clinical Embryologist

Nikos Christoforidis MRCOG, DFFP, Gyn & Obstet, Fertility Specialist

Prominent speakers

Embryolab Academy strives to provide evidence-based scientific knowledge presented by an international panel of prominent lecturers. Our speakers are carefully selected on the basis of the importance and weight of their scientific work in the specific domains of interest as well as their excellent educational skills.



Alexia Chatziparasidou M Clin Embryology, M Sc, Bac Sc, ESHRE accredited Sr Clin Embryologist Laboratory Director Embryolab, Thessaloniki, Greece; Co-founder Embryolab Academy, Greece

Mrs. Chatziparasidou obtained her MSC in Clinical Embryology from the University of Leeds and was certified as senior clinical embryologist by ESHRE in 2008. In 2004, Ms Chatziparasidou founded Embryolab, a modern assisted reproduction unit, which she

also directs. Alexia Chatziparasidou has a vast experience of more than 45,000 IVF cycles. Her scientific interest is mainly focused on the application of modern oocyte and embryo cryopreservation methods and treating male infertility and azoospermia. Ms Chatziparasidou is co-founder of Embryolab Academy, an international research and educational non-profit organisation.



Edith Coonen

PhD , MSc, BacSc, Sr Clinical Embryologist Reproductive Medicine and Clinical Genetics, Maastricht University Medical Center, Maastricht, Netherlands

Dr. Edith Coonen is a Senior Clinical Embryologist at the department of Reproductive Medicine and heads cytogenetic based diagnosis in PGD at the department of C linical Genetics, Maastricht University Medical Centre (MUMC), in Maastricht, the Netherlands. Edith graduated from Maastricht University in 1989 with a BSc in Health Sciences and

completed her PhD at the department of Genetics & Cell Biology from the same institute in 1995. Between 1995 and 1997 Edith was a Research Fellow in the department of Reproductive Medicine, MUMC working on the chromosomal constitution of gametes and preimplantation embryos. In 1997 she completed her specialist training in Clinical Embryology at the department of Reproductive Medicine, MUMC and has since worked there as a Clinical Embryologist. Edith has been involved in the PGD activities at MUMC from the start in 1994 and currently oversees PGD for chromosomal indications. Dr. Coonen is presently the Chair of the ESHRE PGD-Consortium.



Emilie Færch Jenssen Bac Biom Sc, Sr Clin Embryologist Lab Manager, Quality Manager Copenhagen Fertility Center, Copenhagen, Denmark

Emilie graduated as a Bachelor in Biomedical Laboratory Science in 2012 from the Metropol University in Copenhagen, Denmark, and received a post graduate training in Clinical embryology at the Copenhagen Fertility Center. She is currently Quality

Manager and Lab Manager at the Copenhagen Fertility Center, ISO 9001:2008. Emilie was member of the organizing committee for ISIVF 2015 Copenhagen, Denmark



Nicolás Garrido Puchalt PhD, MSc, M Res Methods, Bac Sc Director of the Andrology Laboratory and Sperm Bank, IVI Valencia, Spain

Dr. Nicolás Garrido received his Biological Sciences Degree in 1997 from the University of Valencia in Spain. He did a pre-doctoral fellowship at the Frauenklinik, Düsseldorf, Germany and received his Ph.D. Degree in Obstetrics and Gynecology in 2001 from the University of Valencia, Spain, and the Extraordinary Prize for his thesis work in 2002. He

also has a Master degree in Research Methods; Design and Statistics from Universidad Autónoma de Barcelona, Spain. Since 2000, he is the Director of the Andrology Laboratory and Sperm Bank at the Instituto Valenciano de Infertilidad (IVI). Dr. Garrido is a member of several scientific societies and has twice received the research award from the Spanish Society of Fertility, and the Prize Paper of the Spanish Society of Urology. The primary areas of his research are the molecular markers of male infertility and sperm survival after freezing/thawing, assisted reproduction in HIV/VHC sero discordant couples, and sperm banking. Dr. Garrido is the recipient of several grants from public and private organizations in Spain. He has published over 100 articles and 40 reviews or book chapters, made almost 300 presentations at national and international congresses. He is also currently statistics assessor of IVI Valencia the biggest infertility clinic in Spain. Dr. Garrido is the Director of the IVI Learning Center (actually over 30 Infertility clinics worldwide, presenting more than 120 courses and 6 different Master studies) and is Professor, among others, of the post graduate Master in Biotechnology of the Human Reproduction from Instituto Universitario IVI, Valencia University. He is also in charge of IVICO, an IVI group company dedicated to provide with training, consulting and auditing services to assisted reproduction units.



Marjan Happel

BSc

Biovigilance coordinator, TRIP Hemovigilance and Biovigilance office, Leiden, Netherlands

Marjan Happel has been working in the field of biovigilance since 2008 as biovigilance coordinator at TRIP, the hemovigilance and biovigilance office for the Netherlands. TRIP receives and analyses reports of adverse reactions and

events associated with blood transfusion, human tissues or cells and promotes hemovigilance and biovigilance in the widest sense. This throughout the chain from donor to recipient, in order to contribute to improved safety of transfusion and transplantation in the Netherlands. Marjan was actively involved in several EU projects: EUSTITE, SOHO V&S and recently the report on the Economic landscapes of human tissues and cells for clinical application in the EU. Her background is in obstetrics, and assisted reproductive technology is here speciality.



Katleen Hostens PhD, M Sc, Bac Sc Sr Clin Embryologist Academic Hospital St Jan, Brugges, Belgium

Katleen Hostens studied Chemical sciences, specialty Biotechnology) at the Ghent University in Belgium. She obtained her PhD at the Free University of Brussels. She was trained as a clinical embryologist at the IVF Unit of the Catholic University of

Leuven. She started her work in the fertility unit in Roeselare and is currently working as a senior clinical embryologists at the Academic Hospital St Jan in Brugges-Ostende. Dr. Hostens trained as an external auditor for ISO15189 for BELAC, the Belgian Accreditation Organisation. She visited several IVF Unites for inspection. Katleen is a lecturer for the course in Reproductive Medicine at VIVES in Brugges, Belgium.



Martine Nijs

PhD, M Sc, Bac Sc, ESHRE accredited Sr Clin Embryologist Scientific Director Nij Geertgen, Elsendorp; Netherlands; Research and Development Consultant Embryolab, Greece; Co-founder and Director Embryolab Academy, Greece

Martine Nijs has been working in the field of reproductive biology for over 20 years; first as a senior clinical embryologist and later as IVF lab director. She obtained her PhD in Medical Sciences at the Free University of Brussels in Belgium. She is also an

ESHRE certified Senior Clinical Embryologist. Delivering high quality laboratory work as well as research in reproductive medicine have always been one of her passion. Martine is first author of 17 peer reviewed publications, 6 chapters in books and co-author in 75 publications. Martine has presented over a hundred lectures as an invited speaker at national and international meetings. She has been actively involved in organising International Meetings, Workshops and one-on-one Hands-on workshops.

Martine Nijs is member of the Editorial Board Faculty 1000 Research and ad hoc Board member of 9 international Journals in reproductive biology. She is an active member of 8 professional societies. Martine is Scientific Director at Nij Geertgen, a fertility center in the Netherlands and co-founder and Director of Embryolab-Academy, a non-profit foundation in Greece.



Jane Saxton

PhD, Senior Clinical Embryologist Senior Embryologist, Jessop Fertility, Sheffield, UK

Jane Saxton is Senior Embryologist at Jessop Fertility in Sheffield, UK and in 2006 practiced as a locum working in Sydney, Australia. She completed her PhD in Developmental Biology at the University of Warwick in 1999 and has published several papers including work on quality control and sperm DNA fragmentation. Jane

has had an active role at Jessop Fertility for 14 years, during which time she was part of the team that designed and validated the UK's first EUTCD compliant IVF laboratory. Her current interests include sperm/embryo cryopreservation and time lapse culture. Jane has presented work at conferences worldwide and lectures students on the MSc in Reproductive and Developmental Medicine in Sheffield. Jane is a member of the Obstetrics and Gynaecology International Journal editorial board and runs the independent website Embryonews.



Ingrid Segers PhD, M Sc, Bac Sc, Sr Clinical Embryologist Center for Reproductive Medicine, VUB, Brussels, Belgium

Ingrid Segers started her career in reproductive biology in 2002 as a PhD student in the Follicle Biology Laboratory at the Free University of Brussels (Belgium). Research interests are the antral follicle phase, follicle culture, in vitro maturation and in vitro fertilization and cumulus-oocyte interaction in the mouse animal model and in the human.

In 2011, she made the transition to the fertility clinic and started as a clinical embryologist in the IVF laboratory of the Centre for Reproductive Medicine UZ-Brussel Belgium. In her current position as clinical embryologist, she is responsible for the laboratory activities of in vitro maturation and ovarian cortex cryopreservation. She is member of the multidisciplinary oncofertility team at UZ Brussel.



Marieke Schoonenberg MD, Gyn & Obstet, Fertility Specialist Medical Director Nij Geertgen, Elsendorp, Netherlands

Dr. Marieke Schoonenberg is a Consultant Obstetrician and Gynecologist . Marieke subspecialised in Human reproduction and Assisted reproduction techniques at the Department of Reproductive Medicine of the University of Ghent. She is member of

the Nederlandse vereniging voor Obstetrie en Gynecologie. Dr. Schoonenberg is the Medical Director of Nij Geertgen, the largest private fertility center in the Netherlands. Marieke is currently preparing her PhD at the University of Ghent.



Kelly Tilleman PhD, MSc, BacSc Quality Manager Department of Reproductive Medicine of the University of Ghent

Dr Tilleman's obtained her PhD in biomarker research in inflammatory arthritis at the University of Ghent in 2007. At the time, Kelly combined her scientific enthusiasm in research in proteomics with the responsibility of quality manager

for an accredited DNA fingerprinting laboratory. In November 2009, Kelly joined the Department of Reproductive Medicine of the University of Ghent. Her main scientific research interests are in the area of fertility preservation. Dr Tilleman is the Quality Manager of this large University fertility centre in Belgium.



Katherine Whalley BSc, HCPC registered Clinical Scientist Lead Clinical Embryologist Assisted Conception Unit, Ninewells Hospital, Dundee, UK

Katherine Whalley moved into an embryology Unit in 1986 from a molecular genetics background and has essentially developed with the profession. Katherine was appointed Lead embryologists of the Assisted Conception Unit in Dundee, UK in the

mid 1990s when her mentor David Edgar moved to Melbourne. The Clinic was upgraded in 2011 and a new lab was built to meet the requirements of the EU Tissue Directive. The facility has continued to evolve over the last few years with the introduction of blastocyst culture and more recently time-lapse incubation. The clinic has collaborative links with the University of Dundee and teaching of the MSc in Human Clinical Embryology and Assisted Conception. Katherine is also the training scheme lead in Scotland for embryologists working towards HCPC registration.

Program 18 March 2016

8:00-8:30	Registration with coffee and tea.		
8:30-8:40	Welcome by the Director of the Embryolab Academy		
	Martine Nijs, Netherlands		
8:40-9:20	What is quality and why does it matter? What is total quality management - TQM?		
	Edith Coonen, Netherlands		
9:20-10:00	ISO 9001 or ISO 15189 for your ART Unit?		
	A detailed update on both systems and what it all involves for the ART Unit.		
	Alexia Chatziparasidou, Greece		
10:00-10:40	What does a quality manager in ART actually do? Let's hear it from the expert!		
	Katleen Hostens, Belgium		
10:40-11:00	Coffee break		
11:00-11:35	So much data! How to collect, manage and learn from them.		
	Nicolás Garrido Puchalt, Spain		
11:35-12:15	What is validation and how to validate new media, methods and equipment –		
	a challenge or actually so simple?		
	Emilie Jenssen, Denmark & Jane Saxton, UK		
12:15-13:15	Lunch Break		
13:15-13:45	Traceability and witnessing in ART, is so important? Really?		
	Martine Nijs, Netherlands		
13:45-14:15	Audits – why, how and who will do them.		
	Katleen Hostens, Belgium		
14:15-14:45	Setting up a new ART Unit: Planning, building, validating and starting: TQM challenges		
	Katherine Whalley, UK		
14:45-15:15	Transport of fresh and frozen reproductive cells and embryos and TQM: what it all		
	involves.		
	Martine Nijs, Netherlands		
15:15-15:45	Coffee Break		
15:45-16:15	How to assess and minimise risk in ART.		
	Alexia Chatziparasidou, Greece		
16:15-16:45	Serious adverse events and reactions for reproductive tissues and cells: report from		
	Europe - what do we learn from it?		
	Marjan Happel, Netherlands		
16:45-17:15	How does TQM impact your day to day work in the ART laboratories- the embryologists		
	view.		
	Jane Saxton, UK		
17:15-17:30	Summary of the day.		
	Martine Nijs, Netherlands		
19:30	Workshop Reception and Dinner		

Program Morning session 19 March 2016

8:45-12:15	'Brains-on' session		
	Bring your troubles to us and we will 'shoot' them!		
	Chair: All invited speakers will take part of the expert panel		
	This session is always the highlight of our Embryolab Academy workshop. In this interactive session, delegates are invited to present a mini-poster describing a specific problem/trouble/issue they have or are encountering in their laboratories.		
	Collectively, the expert team and the participants will investigate the problem and		
	design a route for solving and preventing this (and other) problems in the future.		
	Mini-poster examples:		
	B We thawed the wrong embryo for the patient. What went wrong? How do I perform		
	a root cause analysis?		
	Since the last two days I am observing repetitive failed fertilisation in IVF but not in		
	ICSI. Nothing changed in my procedures. How can this be?		
	B We are moving to a new operating IVF Unit for our egg collections and embryo		
	transfers. How do I validate this? What do I need to test?		
	I think that one my embryologists is performing poorly? How do I test in an objective way?		
	Session Includes coffee break		
	Summary of 'Brains-on' session		
12:15-12:30	Jane Saxton & Ingrid Segers		



Program Afternoon session 19 March 2016

12:30-13:15	Lunch Break		
13:15-16:00	All about internal and external quality control, KPI's, quality assurance and more for		
	your laboratories . Practical examples!		
	Edith Coonen & Martine Nijs		
13:20-13:40	Andrology department		
	Jane Saxton, UK		
13:40-14:00	Cryobiology unit		
	Katherine Whalley		
14:00-14:20	IVF laboratory		
	Katleen Hostens		
14:20-14:40	Patients records and data management.		
	Alexia Chatziparasidou, Greece		
14:40-15:00	PGD/PGS department .		
	Edith Coonen, Netherlands		
15:00-15:20	0 Ovarian Tissue banking unit.		
	Ingrid Segers, Belgium		
15:20-15:40	Donor bank.		
	Jane Saxton, UK & Martine Nijs, Netherlands		
15:40-16:00	Coffee Break		
16:00-16:25	Total Quality Managment in the clinical department.		
	Kelly Tilleman		
16:25-16:50	Patients satisfaction: what do patients expect and what can we offer by TQM.		
	Marieke Schoonenberg, Netherlands		
16:50- 17:00	Knowledge sharing on TQM: past participants from EA TQM Workshop 1 reporting on		
	what knowledge sharing in TQM in ART brought to their daily practice in ART.		
	Emilie Jenssen, Denmark		
17:00-17:15	Summary of the TQM-2 Workshop		
	Martine Nijs, Netherlands		
17:15	Fare well		

Registration and Fees

Registration can be done through the Embryolab Academy Website: <u>www.embryolab-academy.org</u>

Fees are to be paid by Bank transfer or Pay Pal. Bank transfer costs or Pay pal transfer costs endured during payment are to be covered by the delegate.

Early bird Registration Fee before 1st of February 2016: 360 Euro

Normal registration Fee as of 1st of February 2016: 400 Euro

<u>Registration fee</u> includes Workshop registration <u>and</u> social program:

- Theoretical sessions
- 4 'Brains-on' afternoon session
- Workshop Syllabus
- Certificate of attendance
- Refreshments
- Lunches
- Friday evening Workshop reception and dinner

Accompanying person

An accompanying person can be registered for a fee of 100 Euro. The accompanying person is entitled to attend the evening Workshop reception and dinner. The accompanying person is <u>not</u> entitled to attend the workshop lecture sessions.

Cancellation fees

All cancellations must be faxed or e-mailed. Refund of registration fees will be the as follows:

- Until February 15: 100% refund (minus 60 Euro administration cost)
- After February 15: no refund on cancellations

For more information on the program and registration modalities,

please visit the Embryolab Academy website

www.embryolab-academy.org

Workshop Secretariat

Embryolab Academy

173-175 Ethnikis Antistaseos, 551 34 Kalamaria, Thessaloniki, Greece

info@embryolab-academy.org

www.embryolab-academy.org

Workshop Venue

Park Inn by Radisson Leuven

Martelarenlaan 36, 3010 Leuven, Belgium

www.parkinn.com/hotel-leuven

The Venue has very easy access from the international airport Brussels Airport by a 15 minutes train ride. The Park Inn by Radisson connects to the Leuven Central Station by a pedestrian bridge.



Accommodation

The Workshop event will take place at the Park Inn by Radisson Leuven, Martelarenlaan 36, 3010 Leuven, Belgium.

The hotel welcomes Embryolab Academy participants with a special offer:

Breakfast and wifi included Exclusive City tax €1.06/night	Single	Double
Thursday - Friday	€129.00	€139.00
Friday - Saturday	€85.00	€95.00
Saturday - Sunday	€85.00	€95.00

You can make your reservation on-line at <u>http://www.parkinn.com/hotel-leuven/hotel-</u> <u>deals/embryolab-academy</u>.

Please mention the reduction code **EATQM2** when you make your reservation by phone or e-mail.

Availability of rooms in Leuven is limited and early booking is strongly recommended.

Leuven has hotels and B&B's with different price ranges. For more information and on-line hotel room bookings, you can go to this website: http://www.booking.com/city/be/leuven.html (available in different languages).

Availability of rooms in Leuven is limited and early booking is strongly recommended!



General information

Workshop language

The official language of the Workshop is English.

Time zone

The time zone in Belgium is Eastern Europe Time Zone : UTC/GMT +1 hour.

Dress Code

Dress code for the Workshop is business casual.

Visa

International participants to the Workshop may require visas in order to enter Belgium. Participants are requested to check with their consulate or diplomatic mission in their home country or with their travel agency for visa requirements. It is the responsibility of the participant to obtain a visa if required.

Letter of Invitation

Upon request, the Secretariat of the Workshop will send a personal invitation to participants. This invitation is meant only to help visitors to raise travel funds or to obtain a visa, and is not a commitment on the part of the organisers to provide any financial support. The letter of invitation can only be send when payment of registration fee is completed.

About Leuven

Leuven is a very vibrant and pleasant city in the center of Belgium, Flemish Brabant. It is located about 25 kilometres (16 miles) east of Brussels. It is home to Anheuser-Busch InBev, the world's largest brewing group and one of the five largest consumer-goods companies in the world; and to the Katholieke Universiteit Leuven, the largest and oldest university of the Low Countries and the oldest Catholic university still in existence.

Travel to Leuven

By Plane

Direct flights are available to Brussels-Zaventem national airport from many cities around the world. Brussels National Airport is an international airport (11 km; 6.9 mi) northeast of Brussels, the capital of Belgium.

The Park Inn by Radisson Leuven is ideally located next to the Leuven railway station with a direct connection to the airport (15 minutes train ride). The airport train station is located below the terminal (basement level-1). The train to Leuven runs twice an hour. Tickets can be bought in the train station in the airport. Taxi will take more time and are more expensive.

The Park Inn by Radisson connects to Leuven Central Station by a pedestrian bridge (5 minutes walk).

You can check the timetable and buy tickets online: www.belgianrail.be/en/stations-and-train/search-a-station/4/leuven.aspx. If you come from the airport, select BRUSSEL-NATIONAAL-LUCHTHAVEN to LEUVEN, Diabolo fee.

By train

The Park Inn by Radisson Leuven is ideally located next to the Leuven railway station with a direct connection to the national airport (15 minutes train ride). The Park Inn by Radisson connects to Leuven Central Station by a pedestrian bridge.

You can check the Timetable and buy tickets online: <u>www.belgianrail.be/en/stations-and-</u> <u>train/search-a-station/4/leuven.aspx</u>. If you come from the airport, select BRUSSEL-NATIONAAL-LUCHTHAVEN to LEUVEN, Diabolo fee.

By car

Leuven is located at the junction of two important motorways: the E40 and the E314. *From E40:* Keep toward Leuven and take exit 23A (Haasrode-Research) to the N24 toward Bierbeek. Follow the N25 about 3.4 kilometres until you reach a T-junction. Turn left toward the city centre, and then follow the N3 1.5 kilometres. Take the sixth exit, to Martelarenlaan. You will find the hotel on your left-hand side.

From E314: Take exit 20 (Wilsele), and head to Kessel-Lo. Continue straight. At the third roundabout after 2.6 kilometres, turn right. After about 300 metres, turn right toward Diestsesteenweg (N2). Then, after 60 metres, turn right toward the Martelarenlaan (N292). Follow the road and you will find the hotel on your right

The Park Inn by Radisson does not provide private parking. However, parking is available for a maximum of EUR 20 per day in the public parking garage under the hotel. During weekends, the cost is EUR 10 per day.

Liability

The Workshop secretariat and organisers cannot assume liability for personal accidents, loss of or damage to private property of participants, either during, or directly arising from the Workshop. Participants should make their own arrangements with respect to health and travel insurance.

Embryolab Academy cannot be held accountable for cancellation of participation because of air strikes or serious adverse events.



Sponsors









Embryolab Academy



www.embryolab-academy.org

Embryolab Academy is a non-for-profit foundation, focused on education, training and research in assisted reproduction.

Embryolab Academy promotes close collaboration between embryologists, andrologists, fertility specialists, scientists and human geneticists to improve quality, safety and accuracy in assisted reproduction techniques, and reproductive medicine.

The objectives of the **Embryolab Academy** are to:

- Organise and host international Workshops, focused on state of the art assisted reproduction techniques, and reproductive medicine.
- Provide individual, hands-on courses and training in assisted reproduction techniques, and reproductive medicine.
- Promote and coordinate research in the field of assisted reproduction techniques, and reproductive medicine.
- Promote communication, collaboration and exchange of expertise between different specialist, working in assisted reproduction techniques, and reproductive medicine.

Director Martine Nijs PhD, M Sc, Bac Sc, Sr Clinical Embryologist

Board Alexia Chatziparasidou M Clin Embryology, M Sc, Bac Sc, Sr Clinical Embryologist

Nikos Christoforidis MRCOG, DFFP, Gyn & Obstet, Fertility Specialist



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