

Redlara Brazil

and SBRA

in collaboration with

EMBRYOLAB ACADEMY

are organising

Joint SYMPOSIUM

Quality and Risk Management in IVF laboratories

14 and 15 September 2016





Hotel Mercure Lurdes – Belo Horizonte – MG - Brazil

Realização:



Symposium Objectives

Quality Control and Risk Management in the IVF laboratory plays an important role in the success of any IVF program. Course objectives are the following:

-  To improve knowledge and understanding of all the recent advances in Quality and Risk Management for assisted reproduction technologies (ART) laboratories.
-  To focus on all processes performed within ART laboratories and how they can be improved by Total Quality Management (TQM)
-  To understand how quality assessment and TQM will provide patients with the best and most safe treatments and procedures available
-  To investigate how TQM can be a useful tool to improve efficacy and efficiency, also with respect to financial and administrative aspects

Target Audience

















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

Program

The theoretical session will give an overview of the recent advances in Quality and Risk Management for laboratories working with Assisted Reproductive Technologies. In the afternoon session different experts will focus on different methodologies/techniques to standardise, measure, validate, and control different parameters like temperature, pH, air quality etc. in ART laboratories.

In the 'Brains-on' sessions the expert team and the participants will investigate specific problems/troubles/issues that can occur 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.

Topics discussed will include the following

-  What is quality and why does it matter?
-  What is quality management?
-  What is total quality management (TQM)?
-  ISO 9001 – ISO 15189 – What is in the number?
-  How does TQM impact your day to day work in the ART laboratories: IVF, Andrology, PGD and Cryobiology laboratories
-  How to collect and manage your data
-  Internal and external quality control for IVF, Andrology, PGD and Cryobiology laboratories
-  KPI's and other stuff: How to define your success rates in TQM and the role of statistics
-  What is risk and how do you analyse it?
-  Non-conformity registration in ART: why bother?
-  How do I prepare, implement and review SOPs (Standard Operating procedures)?
-  How do I measure and validate temperatures, O₂ and pH of specific equipment in my laboratories
-  What about selection, quality and validation of media used in my laboratories?
-  I need to prevent errors and have traceability in all my laboratory activities and cryostorage system. Is there a simple way?
-  I need safe materials and equipment for my laboratory and patient related procedures. Are they safe? How to select?
-  Air quality: is it that important and if so, how to measure and control it?

Symposium Organisers

REDLARA, Brazil

PRONUCLEO, Brazil

Embryolab Academy, Thessaloniki, Greece

Symposium Directors

Dr. Adelino Amaral Silva - Dr. Martine Nijs, Greece

Symposium Coordinators

Dr. Ricardo Azambuja, Brazil-Dra Alexia Chatziparasidou, Greece

Speakers

Our speakers have been 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

Mrs. Alexia Chatziparasidou is a Sr. Clinical Embryologist with long experience of more than 30,000 IVF cycles. Her scientific interests focus mainly on the application of modern fertility preservation techniques. She has also long experience on treating male subfertility, as well as on developing methods of co-culture with homologous endometrial cells. In 2007, Mrs Chatziparasidou completed her M Sc in Clinical Embryology at the University of Leeds, UK. Since 2007 she is actively involved in preimplantation genetic diagnosis and screening in couples at risk. In 2004, Mrs Chatziparasidou founded Embryolab, and since has been the director of Embryolab, a modern state of art assisted reproduction unit in Greece. She is member of Alpha, the international society of Reproductive Scientists, the European Society of Human Reproduction and the American Society of Reproductive Medicine. Mrs Chatziparasidou is co-founder of Embryolab-Academy.



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 Clinical 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.



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. He received his Ph.D. Degree in Obstetrics and Gynaecology 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 serodiscordant 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 the statistics assessor of IVI Valencia. Dr. Garrido coordinates the fellowship courses from the Teaching Area of the IVI group and is Professor in the 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.



Brett Glazar

M.E.A. Laboratory Manager

Vitrolife, Inc, USA

Brett Glazar earned his Masters of Science in Reproductive Physiology from Colorado State University, Colorado USA. His area of research was manipulation of follicular recruitment and seasonal variation of cortisol levels in the mare. Upon graduation he took a position as Equine Reproduction Manager for an innovative veterinary practice in southern California, USA. The focus of his work was breeding management with a particular emphasis on clinical equine embryo transfer along, semen cryopreservation and embryo vitrification. Brett later began working in the human embryology field at the Fertility Center at Johns Hopkins, Maryland, USA as a Clinical Embryologist. Brett has working Vitrolife in 2007, first as a Sales and Technical Specialist then later as the manager of the M.E.A. Laboratory. He now oversees laboratory operations performing over 3000 mouse embryo assay assessing quality for raw materials and finished product. Additionally Brett is active in supporting the Regulatory Affairs group with FDA submissions and clinical data collection.



Claudia Petersen

M Sc, PhD, Sr Clin Embryologist

Clinical Embryologist at CRH- FRANCO JR, Brazil

Claudia Petersen obtained her Masters degree in Clinical Embryology at the University of Leeds, UK and her PhD in Gynecology, Obstetrics and Mastology at UNESP Botucatu /SP. Claudia has been working in the field of human reproduction for over 20 years in the Embryology Laboratory of Prof. Human Reproduction Center Franco Junior, in Ribeirão Preto / SP. She is a researcher at the Paulista Center for Diagnostics and Research, Ribeirão Preto / SP. Claudia was chief executive of the Brazilian Center for Embryologists in Reproductive Medicine for two consecutive terms (2006-2008 / 2009-2010).

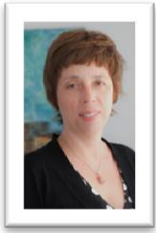


Raquel Lima Leite Soares Alvarenga

Bac Sc, M Sc, PhD

Clinical Embryologist at Reproductive Medicine Stork - Health Women's Institute, Brazil

Raquel Lima Leite Soares Alvarenga graduated in Biological Sciences from the Federal University of Minas Gerais – Brazil, she obtained her Master in Morphology and PhD in Cell Biology from UFMG. Currently she is an clinical embryologist at Reproductive Medicine Stork - Health Women's Institute. She is one of the founding Directors of Fertitech-in Assisted Reproduction Technology. She is lecturing in Cytology, embryology and biotechnology.



Martine Nijs

PhD, M Sc, Bac Sc, ESHRE accredited Sr Clin Embryologist
Scientific Director Nij Geertgen, the Greece; Research and Development Consultant Embryolab, Greece;
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 accredited senior clinical embryologist. Research as well as delivering high quality laboratory work has always been one of her passions. Martine is first author of 17 peer reviewed publications six chapters in books and co-author in 73 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-to-one Hands-on workshops. Dr. Martine Nijs is member of the Editorial Board Faculty 1000 Research and ad hoc Board member of 9 international Journals in reproductive biology and fertility treatments. She is an active member of 7 professional societies. Martine is co-founder and Director of the Embryolab-Academy, Research and Development Consultant at Embryolab in Greece and Scientific Director of a private fertility clinic Nij Geertgen in the Netherlands.



Sandro Esteves

MD, M Sc, PhD
Medical and Scientific Director of ANDROFER, Brazil

Dr. Sandro Esteves is Medical and Scientific Director of ANDROFERT - Clinical Andrology and Human Reproduction, and Associate Professor of Urology Discipline the State University of Campinas (Unicamp). His main areas of interest include male infertility, reproductive endocrinology, microsurgery, cryobiology, laboratory techniques of in vitro fertilization, and quality management applied to human reproduction. It has several publications in these areas, including the books "Quality Management in ART Clinics" and "Cleanroom Technology in ART Clinics". Sandro Esteves is Senior Researcher at the Research Center for Human Reproduction at the Cleveland Clinic Foundation, USA, and Unit of Genetics, Department of Biology, autonomous University of Madrid, Spain. It is also a Clinical Tutor of Clinical Sciences School at the Faculty of Medicine, University of Edinburgh, Scotland.

Programme 14 September 2016

Morning session

- 7:30 - 8:00 *Registration with coffee and tea*
- 8:00 - 8:10 Welcome by the Directors of the Symposium

Adelino Amaral Silva, Brazil - Martine Nijs, Netherlands
- 8:10 - 8:50 What is quality? What is quality management? What is Total Quality Management?

Edith Coonen, Netherlands
- 8:50 - 9:30 Understanding Certification and accreditation: -ISO 9001 - ISO 15189 – ABB – Brazil
standards: what's in a name, what's in a number?

Claudia Petersen - Brazil
- 9:30 - 10:00 What is risk? How do you assess it? How do you register non-conformities in ART?
What is a root cause analysis?

Alexia Chatziparasidou, Greece
- 10:00 - 10:20 *Coffee break*
- 10:20 - 11:00 Internal and external quality control for IVF, Andrology, PGD and Cryobiology
laboratories

Edith Coonen, Netherlands
- 11:00 - 11:40 How to define your success rates in TQM, KPI's and the role of statistics

Nicolás Garrido Puchalt, Spain
- 11:40 – 12:00 Discussion
- 12:00 - 13:30 *Lunch & Group pictures*

Afternoon Session: Quality Control in the laboratory

13:45 – 14:15 I need safe materials and equipment for my laboratory and patient related procedures.
Are they safe? How to select?

Martine Nijs, Netherlands

14:15 - 14:50 Air quality: is it that important and if so, how to measure and control it?

Sandro Estves - Brazil

14:50- 15:25 How do you collect and manage all your data in your Andrology and IVF Unit?

Nicolás Garrido Puchalt, Spain

15:25 – 16:00 Culture medium validation and Quality Control in your laboratory: similar or complementary to manufacturers Quality Control?

Brett Glazar, USA

16:00 - 16:20 *Coffee break*

16:20 - 16:55 Preventing errors and having traceability in all your laboratory activities and cryostorage systems – how to manage.

Alexia Chatziparasidou, Greece

16:55 - 17:30 Measuring and validating parameters like temperatures, O₂ and pH in specific equipments in my laboratories? Important or an extra burden?

Brett Glazar, USA

17:30 - 18:00 Let's get prepared for tomorrow's Brains-on session: guidelines and handing out of the Mini Posters templates

Martine Nijs, Netherlands

Programme 15 September 2016

Brains-on: 'Bring your troubles to us and we will 'shoot' them!'

Chair: All invited speakers will take part of the expert panel

8:00–12:00 Including coffee break from 10:00 – 10:20

In this interactive '**break-out**' session, expert speakers will present case reports in groups, describing a specific problem/trouble/issue encountered in an IVF laboratory. 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.

Topic examples:

- 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?
- I want to start using a new brand of ICSI dish. How do I validate them?
- We are moving to a new operating theatre for our egg collections and embryo transfers. How do I validate this? What do I need to test?
- Our gynecologist wants to start using cheaper embryo transfer catheters, but the embryologist claims they are toxic for the embryos. What to do?
- I think that one my embryologists is performing poorly? How do I test this in an objective way?

11:00 Summary of 'Brains-on' Session

11:00 – 11:30 The particular nature of IVF Total Quality Management: successes and pitfalls

Raquel Alvarenga, Brazil & Martine Nijs, Netherlands

11:30 – 12:00 Closure of the workshop

Ricardo Azambuja, Brazil

12:00 Farewell drink and Lunch

General Information

Symposium Registration

Registration will be free for members of accredited centers RED LARA. One registration per center is accepted. The number of participants is limited to 100. Confirmation of registration is based on a 'first-come-first-serve' basis.

Please register by sending and request email to **redlaraBrazil@gmail** with your **Full name, occupation, passport number, name of your Center and your e-mail address.**

Symposium Secretariat

For any information please mail to redlaraBrazil@gmail.com (Aparecida)

Symposium Venue

Mercure Lourdes, Belo Horizonte, Brazil

Symposium language

The official language of the Workshop is English. There will be simultaneous translation into Portuguese.

Liability

The Workshop secretariat and organiser 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.

Symposium Book

The lectures will be presented in a Symposium Workshop Book.

Ongoing professional education, Evaluation of Symposium and Certificate of attendance

Participants can demonstrate by means of replying to a short set of questions their understanding and learning of the specific topics presented during the Symposium.

A CPD questionnaire, together with an overall evaluation questionnaire of the Symposium will be mailed to each participant. After completion of the on-line questionnaires, delegates will be directed to a Download page to retrieve CPD Certificates and Certificates of Attendance.

Workshop pictures can be downloaded as well.

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