QUARTS WORKING GROUP

YEAR 2023

ANNUAL REPORT 2023

INFORMATION AND UPDATES
ABOUT THE QUARTS SYSTEM

PREPARED BY:
QUARTS WORKING GROUP

QUARTS
Quality for Assisted Reproductive Technologies in Switzerland

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Introduction

In this report, we aim to provide a comprehensive overview of the activities, achievements, and challenges encountered by the QUARTS Working Group throughout the past year. The QUARTS Working Group meets regularly to advance the QUARTS system, ensuring it always meets the latest developments in the field and adjustments in quality standards.

We extend our gratitude to all stakeholders, including the SGRM, the AGER, laboratories, practices, and regulatory bodies, whose support and collaboration have been instrumental in implementing and advancing the QUARTS system.

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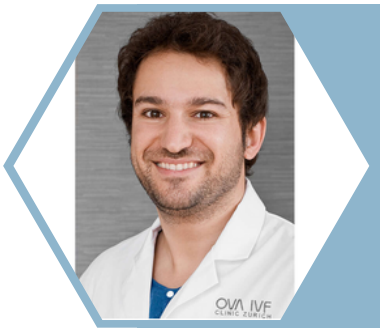

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About the QUARTS System

Background and Objectives

The specialist societies SGRM (Swiss Society of Reproductive Medicine) and AGER (Working Group for Gynaecological Endocrinology and Reproductive Medicine) of the SGGG (Swiss Society of Gynaecology and Obstetrics) took the Federal Act on Medically Assisted Reproduction (Reproductive Medicine Act, FMedG) and the Reproductive Medicine Ordinance (FMedV) as an opportunity to develop a quality label for reproductive medicine (QUARTS).

The goal was to create a label that takes the particularities of IVF laboratories into account as their processes differ considerably from other laboratories to the extent that the commonly used accreditation systems do not appear entirely suitable for demonstrating that the quality requirements demanded by law are met.

The societies have commissioned the QUARTS Working Group to develop a catalogue of requirements for QUARTS. The catalogue and its associated accreditation system has been successfully implemented in 2018.

This Requirements Specification is based on relevant document groups/standards that are significant to the accreditation of IVF laboratories.

1. Fortpflanzungsmedizinverordnung - FMedV (Reproductive Medicine Ordinance) - 1 September 2017
2. ISO 17025:2017 "Accreditation Standard for Testing and Calibration Laboratories"
3. ISO 15189:2022 "Accreditation Standard for Medical Laboratories – Quality and Competence Requirements"
4. "Revised Guidelines for Good Practice in IVF Laboratories (2015)" of the European Society of Human Reproduction and Embryology (ESHRE)
5. The Alpha consensus meeting on cryopreservation key performance indicators and benchmarks: proceedings of an expert meeting (2012)

The ISO standards set out the general framework conditions for work in laboratories whereas the ESHRE guidelines go beyond this and include issues specific to IVF. Both sets of standards cover quality management as well as the structures and processes required for the successful and safe operation of a laboratory. For the accreditation of an IVF laboratory, specific result parameters must also be met, which must be evaluated in close conjunction with the clinical treatment providers.

About the QUARTS System

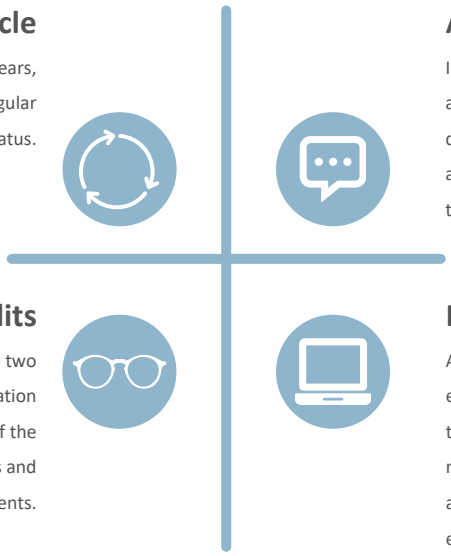
QUARTS Accreditation Process

Accreditation Cycle

The accreditation cycle spans a duration of five years, during which IVF laboratories undergo regular assessments to maintain accreditation status.

Annual Reporting

In addition to the audits, IVF laboratories are required to submit annual reports to the accreditation body. These reports provide detailed insights into the laboratory's activities, performance, and any notable developments or improvements made throughout the year.



Audits

Within this cycle, laboratories are subjected to two comprehensive audits conducted by the accreditation body. These audits serve as critical evaluations of the laboratory's adherence to quality standards and regulatory requirements.

Key Performancy Indicators (KPIs)

Alongside the annual reports, laboratories are also expected to submit Key Performance Indicators (KPIs) to the accreditation body. These KPIs offer quantitative metrics by which the laboratory's performance can be assessed, allowing for a systematic evaluation of its effectiveness and efficiency.

The accreditation process emphasizes a culture of continuous improvement, wherein laboratories are encouraged to identify areas for enhancement and implement corrective actions as necessary. Feedback from audits, annual reports, and KPIs serves as valuable input for driving ongoing improvement initiatives within the laboratory.

By adhering to this structured accreditation process, IVF laboratories demonstrate their commitment to maintaining the highest standards of quality and safety in reproductive medicine, ultimately ensuring the delivery of optimal care to patients undergoing fertility treatment.
For detailed information regarding the accreditation process, please refer to the document Accreditation Process.

About the QUARTS System

QUARTS Accredited Laboratories

The reproductive medicine laboratories of the following fertility centers have received QUARTS accreditation. The year of initial accreditation is indicated in parentheses.

- Fertisuisse AG, Olten, SO (2018)
- fiore LAB AG, St. Gallen, SG (2018)
- Gyn A.R.T. AG, Zurich, ZH (2018)
- Kinderwunsch Cham, Cham, ZG (2020)
- Kinderwunschzentrum Admira Winterthur, Winterthur, ZH, (2019)
- Kinderwunschzentrum Baden, Baden, AG (2019)
- Kinderwunschzentrum Klinik St. Anna, Lucerne, LU (2018)
- Kinderwunsch- und Hormonzentrum LUKS, Lucerne, LU (2020)
- Kopelli Klinik, Pfäffikon, SZ (2020)
- Labor für Reproduktionsmedizin Universitätsklinik für Frauenheilkunde Inselspital Bern, Bern, BE (2020)
- Milagro Kinderwunsch- und IVF-Zentrum , Kreuzlingen, TG (2020)
- OVA IVF Clinic Zurich, Zurich, ZH (2020)

The following laboratories already entered the second accreditation cycle in 2023:
Fertisuisse AG, Olten
fiore LAB AG, St. Gallen
Gyn A.R.T. AG, Zurich
Kinderwunschzentrum Klinik St. Anna, Lucerne

About the QUARTS System

Recognition by Cantonal Doctors

As stipulated by the Federal Medical Ordinance (FMedV) Article 10, Paragraph 3, cantonal authorities are tasked with evaluating the QM-system of the IVF-Laboratories. However, an exception is made if the IVF-Laboratory holds accreditation through the Swiss Accreditation Service (SAS). In such cases, the cantonal authorities are permitted to forgo this evaluation. For IVF-Laboratories lacking SAS accreditation, the cantonal doctors are obliged to conduct thorough assessments of their QM-systems. In case of QUARTS accredited laboratories, the thoroughness of these evaluations is contingent upon the level of confidence the cantonal doctor places in the QUARTS accreditation system.

QUARTS Auditors

The QUARTS auditors are trained by the accreditation body Doc-Cert AG and fulfil the requirements formulated by the QUARTS Working Group regarding education, further training, and expertise.

QUARTS Accreditation Body

The accreditation body of the QUARTS accreditation system is the Doc-Cert AG, a Swiss company holding an ISO 9001:2015 certificate from the Swiss Safety Center (SCC) AG, Wallisellen, which itself is accredited by SAS. Doc-Cert AG has been certified since 2018 for "Development, organization, and implementation of specialist accreditations on behalf of and in accordance with the requirements of medical associations (sector 35)."

Activities QUARTS Working Group

Adjustment of QUARTS Requirements Specification

In response to the updated version of the ISO 15189 standards, the QUARTS Working Group diligently reviewed and adjusted the QUARTS Requirements Specification. Furthermore, KPIs for cryopreserved oocytes have been added to the latest version of the QUARTS Requirements Specification. By aligning with the latest standards, the accreditation process remains current and reflective of best practices in the field of reproductive medicine. Further minor adjustments were made. These are highlighted in yellow in the document comparing V3.4 with V3.5.

Changes in the QUARTS Auditor Pool

One of the QUARTS auditors is no longer available due to retirement. For the year 2024, the audits will be conducted with the current auditors. However, for the year 2025, at least one new auditor will be recruited.

Adjustments of QUARTS Accreditation Costs

The costs per accreditation cycle (5 years) have been adjusted. It is the first price change since the implementation of the system.

Improving Political Acceptance of the QUARTS System

The QUARTS Working Group has focused on improving the political acceptance of the QUARTS system. This initiative aims to get support and recognition for the accreditation process from political stakeholders – especially the cantonal doctors -, thereby solidifying its standing within the IVF field.

By engaging with policymakers and advocating for the benefits of the QUARTS system, the QUARTS Working Group seeks to foster greater trust and endorsement of its role in ensuring quality and safety standards in reproductive medicine practices.

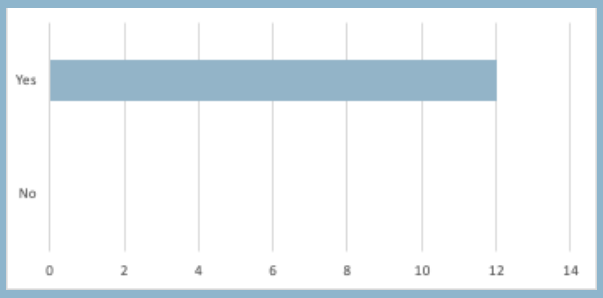
Most importantly compared to other systems, only QUARTS looks at KPIs and examines IVF-specific content. The second important aspect is that QUARTS has international independent auditors who all have a high reputation in the IVF- field.

Activities QUARTS Working Group

Analysis of a Survey conducted by the SGRM Quality in ART Commission

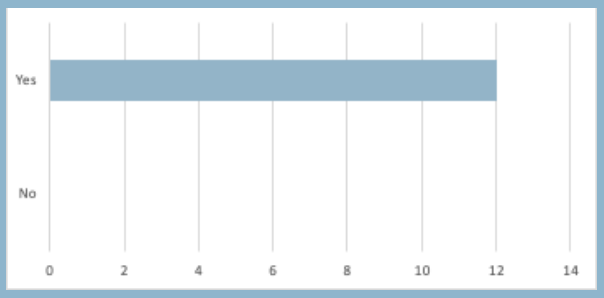
The QUARTS Working Group collaborated with the SGRM Quality in Assisted Reproductive Technology (ART) Commission to conduct a comprehensive survey that was sent to the QUARTS accredited laboratories. The survey was conducted with the aim of assessing the satisfaction of the laboratories with the QUARTS catalogue and the accreditation system regarding various parameters such as quality improvement, practicality, and others. The results were discussed at the QUARTS Working Group Meeting of the 15th of June 2023. Action steps were defined where necessary. The QUARTS Working Group was pleased with the positive feedback. It is especially notable that all laboratories reported an improvement in quality thanks to QUARTS accreditation, and they unanimously affirmed the benefits derived from accreditation (see questions 8 and 9). Access the results of the survey here.

Q8: Has the quality of your laboratory improved as a result of the QUARTS accreditation?



Number of laboratories

Q9: Do you benefit from the QUARTS accreditation?



Number of laboratories

Development of QUARTS Med

One of the significant undertakings of the QUARTS Working Group was the development of QUARTS Med, a certification system tailored specifically for IVF clinical units.

Renaming of QUARTS System and new Logo

With the development of QUARTS Med, the QUARTS Working Group has decided to rename the QUARTS system for laboratories to QUARTS Lab. Alongside this change, logos for QUARTS Lab and QUARTS Med have been created.

About the QUARTS MED System

Background and Objectives

The processes in a reproductive medicine laboratory are not carried out in isolation, but in close and varied dialogue with the clinic. For fertility treatment to be successful, the processes in both the laboratory and the clinic must be carried out to a high standard. For the clinical units, there has so far been no ART-specific procedure for sustainable quality development. ISO 9001 is suitable per se for the certification of clinical units, but does not refer to any specific speciality.

QUARTS Med was developed to provide clinical units in ART with an opportunity for systematic quality assurance and quality development in the speciality.

The QUARTS Med catalogue of requirements is based on the following document groups / standards:

1. Reproductive Medicine Ordinance - FMedV - 1 September 2017
2. Reproductive Medicine Act, FMedG - 18 December 1998 (as at 1 September 2017)
3. The Maribor consensus: report of an expert meeting on the development of performance indicators for clinical practice in ART - 2021
4. ESHRE Guidelines
5. ISO 9001:2018

QUARTS Med Working Group

The catalogue of requirements has been developed by the QUARTS Med Working Group that comprises the following members:

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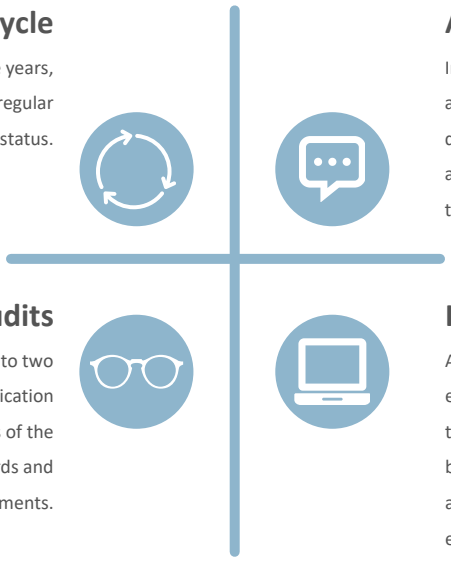
QUARTS Working Group

About the QUARTS Med System

QUARTS Med Certification Process

Certification Cycle

The certification cycle spans a duration of five years, during which IVF clinical units undergo regular assessments to maintain certification status.



Annual Reporting

In addition to the audits, IVF clinical units are required to submit annual reports to the certification body. These reports provide detailed insights into the clinical unit's activities, performance, and any notable developments or improvements made throughout the year.

Audits

Within this cycle, IVF clinical units are subjected to two comprehensive audits conducted by the certification body. These audits serve as critical evaluations of the clinical unit's adherence to quality standards and regulatory requirements.

Key Performancy Indicators (KPIs)

Alongside the annual reports, clinical units are also expected to submit Key Performance Indicators (KPIs) to the certification body. These KPIs offer quantitative metrics by which the clinical unit's performance can be assessed, allowing for a systematic evaluation of its effectiveness and efficiency.

QUARTS Med Auditors

The QUARTS Working Group has already discussed potential auditors. As soon as the QUARTS Med system is ready to be implemented, they will be contacted for the first audits.

QUARTS Med Certification Body

The certification body of the QUARTS Med certification system is the Doc-Cert AG, a Swiss company holding an ISO 9001:2015 certificate from the Swiss Safety Center (SCC) AG, Wallisellen, which itself is accredited by SAS. Doc-Cert AG has been certified since 2018 for "Development, organization, and implementation of specialist accreditations on behalf of and in accordance with the requirements of medical associations (sector 35)."

About the QUARTS Med System

Next steps

The QUARTS Med catalogue has been presented to the societies SGRM and AGER. As a next step the QUARTS Med catalogue will be implemented in one or two pilot clinical units.

OUTLOOK AND FUTURE PERSPECTIVE

Looking ahead, the QUARTS Working Group focus will be twofold: increasing the acceptance of QUARTS Lab, particularly on a political level, and implementing the QUARTS Med system.

The QUARTS Working Group remains dedicated to advancing the field of reproductive medicine through continued promotion of quality assurance initiatives such as QUARTS Lab and QUARTS Med.

By staying proactive and responsive to evolving standards, the QUARTS Working Group aims to uphold its mission of ensuring excellence in fertility treatment for the benefit of patients and society.

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