

Staff training in PGD

Sioban SenGupta
UCL Centre for PGD
UK

Outline

- ISO15189 requirements
- Details of sections

4 Management requirement

4.1.5 Laboratory management responsible for

- adequate training of all staff
- supervision by competent persons
 - purpose
 - procedures
 - assessment of results

5 Technical requirements

5.1 Personnel

5.1.2 Laboratory management maintain records of:

- certification or license
- educational and professional qualifications
- training experience
- competence of all personnel

5 Technical requirements

5.1.3 Director

- executive responsibility and the competence to assume responsibility for the services provided

5.1.4 The responsibilities of the laboratory director

- ensure sufficient qualified personnel with adequate documented training and experience
- provide educational programmes for the medical and laboratory staff and participate in educational programmes of the institution

5 Technical requirements

5.1.6 Training specifically for

- quality assurance
- quality management

5.1.7 Authorize personnel to perform particular tasks

5.1.9 Provide continuing education programme

- All staff
- All levels

5.1.10 Training to prevent / contain adverse incidents

5 Technical requirements

5.1.11 Staff competency to perform assigned tasks

- assessed following training
- periodically thereafter
- retraining and reassessment if required

5.1.12 The personnel making professional judgments

- applicable theoretical and practical background
- recent experience.
- regular professional development

5.1.13 Confidentiality of information regarding patients

Summary of sections

5.1.9 Provide continuing education programme

5.1.11 Staff competency to perform assigned tasks

5.1.6 Training for quality assurance / quality management

5.1.10 Training to prevent / contain adverse incidents

5.1.2 Maintain records of training experience /competence

5.1.9 Education Programme

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|--|---|
| <ul style="list-style-type: none">• ESHRE certification for clinical embryologists• None available for PGD• Association of Clinical Scientists<ul style="list-style-type: none">– Molecular genetics / Cytogenetics• Development of a training manual<ul style="list-style-type: none">– Based on requirements of ACS– Portfolio of competencies | <ul style="list-style-type: none">• Scientific• Clinical• Technical• Research and Development• Communication• Problem Solving• Management |
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Induction Education Programme

- Introduction to staff
- Job description
- Quality manual and accreditation information
- Fire training/health and safety/occupational health
- Data protection
- Training programme established

Education Programme Scientific Competence

- Knowledge of
 - suitability of diagnostic tests for single cell analysis
 - limitations of commonly used diagnostic tests in molecular PGD
 - genetic disorders, mutations and DNA markers
- Training
 - lecture course
 - techniques /disorders / IVF/ preimplantation embryo development
 - designing protocols for PGD
 - Workbook of optimised protocols / lab meetings - progress reports
 - Review / writing SOPs and HFEA Licence applications

Education Programme Clinical competence

- Need to
 - interpret results of a diagnostic test
 - understand clinical problems of genetic disorders
 - develop tests according to clinical picture
- Training
 - Observation / shadowing of cases
 - Review of PGD cases with embryologists and clinicians
 - Work-up for PGD cases
 - Observation days
 - Scientists, embryologists, doctors and nurses

Education Programme Technical competence

- Experience of
 - performing diagnostic procedures
 - trouble shooting
 - use of quality control and quality assurance
- Training
 - Competency tests for assigned tasks
 - Witness audits
 - Single cell isolation / PCR – Efficiency / ADO / Contamination
 - Blastomere tubing – embryologists – spares / cases
 - Protocol design and optimisation - PGD work-ups, follow-ups
 - Presentations at lab meeting, writing SOPs
 - EQA

Education Programme Research & Development competence

- Ability to
 - critically appraise literature, develop a project
 - develop and apply new technique / protocol
 - present the research finding
- Training
 - Journal Club
 - MSc, PhD, MRCPPath
 - PGD work –ups , new disorders, validation of new techniques
 - Seminars and courses
 - Presentations at conferences

Education Programme Communication competence

- Ability to
 - Respond to enquires regarding the service
 - Communicate effectively with colleagues
 - Communicate with patients, healthcare professional, public
- Training
 - Observation days / Understanding course of treatment
 - Organisational chart / Responsibilities / Contact details
 - Writing workup reports / Patient consultation reports / Diagnostic reports
 - Attendance at Lab meetings /Quality meetings / User meetings
 - Presentations in lab meetings, clinical meetings, conferences

Education Programme Problem solving competence

- Need to
 - Interpret quality control and quality assurance data
 - Recognise diagnostic problems
 - Understand underlying cause of diagnostic problems
 - Have experience in problem solving
- Training
 - Vertical and horizontal audits
 - Monitoring of quality indicators
 - Equipment maintenance
 - Follow –up of spare embryos
 - Clinical audit / diagnosis rate
 - Corrective action / Preventative action

Education Programme Management competence

- Ability to understand
 - structure / organization / finance
 - health and safety requirements
 - legal and ethical boundaries
 - limits of knowledge / skills
 - principles of clinical governance
 - need for accreditation / quality improvement
 - importance of effective communication in a multidisciplinary team
 - principles of appraisal and be able to supervise staff
 - Importance of continuing professional development

Education Programme Training Manual / Competency log

YEAR 1	YEAR 2	YEAR 3
Health & safety induction	Audit training	Vertical audits
Written PGD Review	Witness audit	Horizontal audits
Attendance at lectures	Horizontal audit	Lab presentation
Equipment training	Lab presentation	Journal club presentation
Procedure Training	Journal club presentation	Supervisor MSc project
IT training	Supervise BSc project	Submit to external meeting
Validation of protocol		EQA
Journal club presentation		Completion of Portfolio

5.1.11 Staff competency to perform assigned tasks

- Equipment training
- Procedure training
 - Read SOP
 - Observation of task
 - Undertake task under supervision
 - Assessed by test
- Date of competency
- Interval of competence
- Periodic competency test log

5.1.6 Training for quality assurance and quality management

- Attendance at workshops
- Observation of audits
- Conduct audits under supervision
- Attend quality meetings
- Responsibility to monitor a quality indicator and report to quality meetings

5.1.10 Training to prevent / contain adverse incidents

- Induction
- Responsibility to monitor a quality indicator and report to quality meetings
- Assist in corrective / preventative action
- Be responsible for corrective / preventative action

5.1.2 Maintain records of training experience /competence

- Initial Induction / after period of absence
- Training manual
- Competency log
- Periodic competency test log
- Portfolio
- Annual staff appraisal
 - Difficulties encountered
 - Training required
 - Set task for coming year

Conclusion

- Training / professional development
 - required for accreditation
 - continuous process
 - applies to all staff
