

Annexe A

Ministry	Office of the Deputy Prime Minister and Ministry for Health
Job Title	Principal Scientific Officer



OFFICE OF THE DEPUTY PRIME MINISTER AND MINISTRY FOR HEALTH
15, PALAZZO CASTELLANIA, MERCHANTS STREET, VALLETTA, MALTA

Dmirijiet u responsabbiltajiet

Id-dmirijiet ta' Principal Scientific Officer jinkludu li:

- i. Twettiq ta' proċeduri tal-laboratorju tal-embrijoloġija liċenzjati li jinvolvu l-immaniġġjar, il-valutazzjoni, l-i-proċessar, il-kultura, il-mikromanipulazzjoni, il-krijopreservazzjoni u t-trasferiment ta' gameti u embrijuni.
- ii. Monitoraġġ tal-iżvilupp tal-embrijuni u ż-żamma tal-vijabbiltà, is-sigurtà u t-traċċabilità tat-tessuti u ċ-ċelloli riproduttivi fl-istadji kollha tat-trattament.
- iii. Twettiq u dokumentazzjoni ta' proċeduri tal-laboratorju skont l-SOPs approvati, l-istandards tal-kwalità u r-rekwiżiti regolatorji.
- iv. Żgurar ta' konformità mal-approvazzjonijiet kollha tal-EPA/EEART, is-sistemi ta' traċċabilità, u r-rekwiżiti tal-Kodiċi Uniku Ewropew qabel il-bidu tal-proċeduri regolati.
- v. Żamma ta' rekords preċiżi tal-laboratorju, dokumentazzjoni tal-kontroll tal-kwalità u dejta meħtieġa mid-detentur tal-liċenzja u l-awtoritajiet rilevanti.
- vi. Partecipazzjoni f'attivitajiet ta' ġestjoni tal-kwalità, inklużi awditi, validazzjonijiet, kwalifika tat-tagħmir, monitoraġġ ambjentali, proċessi CAPA, rappurtar ta' incidenti u valutazzjonijiet tar-riskju.
- vii. Monitoraġġ u manutenzjoni ta' tagħmir tal-laboratorju, sistemi ta' krijoħażna, tankijiet tan-nitroġenu likwidu, dewars u stokkijiet konsumabbli biex jiġi żgurat provvista ta' servizz mingħajr interruzzjoni.
- viii. Kollaborazzjoni ma' kliniċisti, staff tal-infermiera, persunal tal-kwalità u partijiet interessati esterni biex tiġi żgurata kura multidixxiplinarja sikura u effettiva tal-pazjent.
- ix. Partecipazzjoni fi proċessi ta' akkwist relatati ma' mezzi, konsumabbli u tagħmir tal-laboratorju.
- x. Kontribuzzjoni għar-riċerka, l-awditjar, l-iżvilupp tas-servizz u l-implimentazzjoni ta' teknoloġiji godda fis-servizz tal-ART.
- xi. Assistenza fit-taħriġ, is-supervizjoni u l-valutazzjoni tal-kompetenza ta' embrijologi junior, trainees u persunal tal-laboratorju.
- xii. Żamma ta' żvilupp professjonali kontinwu u żamma ta' aġġornament dwar l-avvanzi fl-embrijoloġija, il-medicina riproduttiva, it-teknoloġiji tal-laboratorju u l-istandards regolatorji.
- xiii. Partecipazzjoni attiva f'laqgħat dipartimentali, multidixxiplinari u ta' governanza.
- xiv. Twettiq ta' kwalunkwe dmir ieħor relatat mar-rwol kif jista' jiġi assenjat mill-Persuna Responsabbli jew mill-Maniġment tal-Isptar skont l-eżiġenzi tas-servizz.
- xv. kwalunkwe komputu ieħor li s-superjur jista' jiddelega lilu/ha, kif jista' jkun meħtieġ;
- xvi. kwalunkwe dmir ieħor hekk kif ordnat mis-Segretarju Permanenti Ewlieni.

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Duties and responsibilities

The duties of Principal Scientific Officer include:

- i. Performing licensed embryology laboratory procedures involving the handling, assessment, processing, culture, micromanipulation, cryopreservation and transfer of gametes and embryos.
- ii. Monitoring embryo development and maintaining the viability, safety and traceability of reproductive tissues and cells throughout all stages of treatment.
- iii. Performing and documenting laboratory procedures in accordance with approved SOPs, quality standards and regulatory requirements.
- iv. Ensuring compliance with all EPA/EEART approvals, traceability systems, and Single European Code requirements prior to commencement of regulated procedures.
- v. Maintaining accurate laboratory records, quality control documentation and data required by the licence holder and relevant authorities.
- vi. Participating in quality management activities, including audits, validations, equipment qualification, environmental monitoring, CAPA processes, incident reporting and risk assessments.
- vii. Monitoring and maintaining laboratory equipment, cryostorage systems, liquid nitrogen tanks, dewars and consumable stocks to ensure uninterrupted service provision.
- viii. Liaising with clinicians, nursing staff, quality personnel and external stakeholders to ensure safe and effective multidisciplinary patient care.
- ix. Participating in procurement processes relating to laboratory media, consumables and equipment.
- x. Contributing to research, audit, service development and implementation of new technologies within the ART service.
- xi. Assisting in the training, supervision and competency assessment of junior embryologists, trainees and laboratory personnel.
- xii. Maintaining continuous professional development and keeping abreast of advances in embryology, reproductive medicine, laboratory technologies and regulatory standards.
- xiii. Participating actively in departmental, multidisciplinary and governance meetings.
- xiv. Undertaking any other duties related to the role as may be assigned by the Responsible Person or Hospital Management in accordance with service exigencies.
- xv. undertake any other tasks, which the superior may delegate to him/her, as may be required;
- xvi. any other duties as directed by the Principal Permanent Secretary.