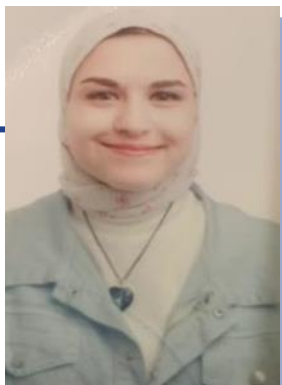




International Alliance for  
Biological Standardization



**Name, post-nominal abbreviation**

Technical manager, Biotechnology unit

12611, Giza, EGYPT

Egyptian Drug Authority(EDA)

Address: 51 wezarat el zeraa, street,  
Agouza, Giza ,government

Tel: (+2) 01123668558

E-mail: hadeerabosalem13@gmail.com

- M.Sc. holder in biochemistry and molecular biology with publication in immune cell therapies.
- **10 years** of experience in the field of biological products, Gene therapy and ATMPs at **Egyptian Drug Authority (EDA)**.
- Serving as technical manager of biotechnology unit at the Central Administration of Biological and Innovative Products and Clinical Trials, EDA.
- Member in IPRP cell and gene therapy working group.
- Performing, supervision and training others on CTD's quality module assessment for recombinant product & ATMPs throughout the product lifecycle including the reliance pathways for registration, post market variation, IMP (investigational medicinal product )and evaluation of biosimilars .
- Supervising different lab techniques performed for control the release of biological products including ELISA, tissue culture, clotting assay, gel diffusion, SDS-PAGE, Western blot and *in-vivo* techniques.

- GMP inspectors on local and overseas biological companies for recombinant products and biosimilars .
- Participating in drafting, issuing, and reviewing different EDA guidelines for biological products, biosimilars and ATMPs registration. Participating as reviewer in global regulatory framework (IPRP) for cell and gene therapy products.
- Participating as a speaker in the workshops held by EDA for biological companies training and for other assessors on the evaluation of CTD file and “Evaluation of comparability Exercise for biosimilars registration “
- Participating in Regional Centre of Excellence for Vaccines, Immunization and Health Supply Chain Management (EAC RCE-VIHSCM) training workshop held in EDA.

