Einat Souli – Quality Assurance Manager

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Experience at work

2019-Current: **Pharmaseed Ltd** as **VP QA** (pre-clinical development):
Established and managed the quality assurance system in general and in accordance to GLP requirements, internally and for the company's external test sites. Supervised a quality control team. The activities included but not limited to: documents and working contracts' review, qualification and auditing test sites and subcontractors in addition to activities' audit, performing group training, writing SOPs, maintaining and managing calibration program, QA investigations following deviations, CAPA, preparing yearly quality plan and leading Quality Forum. Providing scientific advice to support the development of high-quality, effective and safe medicines / medical devices / new chemical entities for the benefit of the customer taking into consideration regulatory requirements (e.g., ISO 10933, 11979).

2018-2019: **ProCore-bio** as **QA Director and Preclinical Manager** (Medical Device):
Issuing QA statements, preparation for ISO 13485 & ISO 9001 inspections, writing/approving SOPs, work instructions, CAPA, protocol/report validation, IQ/OQ/PQ of cleanrooms (ISO 14664), batch release, GMP.

2005-2018: **TEVA Pharmaceutical Industries** in the Global R&D as:

- **R&D Quality Analyst (GLP)**
- Reviewing and approving non-clinical study protocols, amendments and reports
- Reviewing and approving non-clinical regulatory submissions.
- Acting as QA auditor for equipment and systems by ensuring the GLP compliance:
    - Reviewing and approving installation, preventive maintenance, qualification /requalification protocols of equipment and systems and validation files
    - Reviewing and approving of equipment validation protocols and reports
    - Reviewing and approving equipment and systems change controls, critical work orders, drawings, calibration and other maintenance activities
    - Reviewing written instructions related to equipment and systems operation and maintenance (WI, OI), user manuals, laboratory layout, etc.
- Auditing and approving Analytical Data Statements
- Participating in SOPs development and review process to include issuing QA audit reports
- Performing facility audits locally and around the world (e.g., biological toxicological labs).
- **Non-Clinical Safety (NCS) Project Manager in the Non-clinical Safety Department**
- Planning and monitoring the development of the respective innovative projects to support clinical phases until submission. Working in a global environment, together with technical and managerial functions and performing due diligences for new projects
- Managing, contracting, supervising and monitoring multiple concurrent studies at subcontractors.
- Long distance management in a multiple environment in order to achieve projects' goals in regard to timelines, costs, scientific aspects and GLP environment.
- Reviewing, analyzing and presenting scientific results for further development.
- Writing regulatory submissions (FDA/EU) and environmental risk assessments.
- Involvement in CMC activities, validation requirements of analytical and bioanalytical methods, test item identification and validation, analytical reports review, etc.
- Managing GLP toxicity studies including ADME and PK studies.

Education

2003 – 2005: **M.Sc in Biotechnology and Food engineering at the Technion - Haifa**
1998 – 2002: **B.Sc in Biotechnology and Food engineering at the Technion - Haifa**
Languages: Hebrew (native tongue), English (excellent), other