SHOSHIE KATZ

PROFESSIONAL BACKGROUND

Highly knowledgeable Regulatory Affairs and Quality Assurance professional with 28 years of experience working in the bio-pharmaceutical industry. Headed the RA and QA functions in multiple companies and across several investigational drugs, biotechnology, and cell therapy products, led the regulatory strategy of the FDA 505(b)(2) and EMA hybrid application of a peptide product, from its discovery stage through pre-clinical and clinical stages to submission, approval, and marketing.

During this period, I prepared and managed all types of regulatory submissions including INDs, IMPDs, orphan drug applications, NDA and MAA, prepared briefing documents and managed full range of successful meetings with Regulatory Authorities.

I established, implemented, and maintained comprehensive QA systems in the GMP and GCP space, throughout the product lifecycle, from discovery through the pre-clinical and clinical phases, managed successful FDA inspections and supported the product commercial launch.

PROFESSIONAL EXPERIENCE

2022 – Present THERASSIST LTD., Rehovot, Israel

Regulatory Affairs and Quality Assurance Consultant, CEO

Founder and owner of TheRAssist LTD., a consulting company, providing comprehensive Regulatory and Quality Assurance support and consultation over the entire lifecycle of product development, from the earliest stages of company start-up through regulatory approval and marketing of new products.

Regulatory services include preparation of regulatory strategy, project management and assessment documents for the development program, including due diligence assessments, briefing packages for meeting with regulatory authorities as well as management of these meetings, involvement in clinical trial design and preparation of clinical documents, IND/NDA/BLA/IMPD/MAA preparation, review of pre-clinical study protocols and reports, meetings with Health Authorities, and strategic consultation.

Quality Assurance services include planning, establishment, implementation and verification of end-to-end quality system including change control, documentation control, investigation of deviations and out of specifications and effective corrective and preventive action (CAPA) system, vendor qualification, audits, and vendor quality oversight, batch review and release, risk management, complaints reporting system and training.

2008 – 2022 CHIASMA (ISRAEL) LTD., Ness Ziona, Israel
(Acquired by AMRYT PHARMA in August 2021)

VP Regulatory Affairs and Quality Assurance (2011 – 2022)

Director of Regulatory Affairs and Quality Assurance (2008 – 2011)

Established and Managed the Regulatory Affairs and Quality Assurance policies and activities:

- Prepared, reviewed and submitted regulatory documents to Regulatory Authorities, including: Orphan Drug Application, pre-IND, IND, NDA, MAA, End-of-Phase 2, Scientific Advice, pre-NDA and Type C meeting packages and attended meetings with Regulatory Authorities.
- Developed and implemented regulatory strategies and company policies in alignment with global regulatory requirements. Provided proactive regulatory and quality advice to the development, manufacturing, and analytical groups; interacted with subcontractors, consultants and with qualified person in EU.
- Initiated, implemented and maintained the company quality systems complying with US, EU and local Ministry of Health requirements for Phase I through Phase III and commercial use. Developed, reviewed, and approved

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company policies and SOPs, protocols and reports. Review and approval of manufacturing batch records and release of drug products for clinical and commercial use.
- Provided guidance to executive team on the strategic direction of the organization for new product development.
- Trained and managed the QA and RA teams.

2006 – 2008 BETA-O2 TECHNOLOGIES LTD., Petah-Tikva, Israel

Director of Regulatory Affairs and Quality Assurance

Established and managed the Regulatory Affairs and Quality Assurance activities of the company and Management of Safety:

- Provided regulatory and safety input to the development groups; initiated the company Documentation Center, including the writing and approval of controlled documents, such as SOPs and forms, development study protocols and reports, established and implemented the company safety procedures.
- Prepared and submitted regulatory documents such as a Request for Designation to the FDA, the Office of Combination Products and Requests for Studies in Animals to the Ethical Committee; managed subcontractors and regulatory consultants and coordinated a study in primates in Singapore.

2002 – 2006 PRONEURON BIOTECHNOLOGIES LTD., Rehovot, Israel

Director of Regulatory Affairs and Quality Assurance

Managed the Regulatory Affairs and Quality Assurance activities of the company:

- Quality oversight, review and approval of all CMC, pre-clinical and clinical activities and documents, internal and external audits.
- Coordination of preparation and review of regulatory submissions: pre-IND, supplements and amendments to IND and safety reports, Orphan Drug Designation Application, IND and Orphan Drug Annual Reports.
- Participation in meetings with the FDA review group, including an End of Phase 1 meeting, and conference calls with FDA, preparation and submission of responses to FDA comments.

1999 – 2002 BIO-TECHNOLOGY GENERAL (ISRAEL) LTD., Rehovot, Israel

Regulatory Affairs Unit Head (2000 – 2002)

Regulatory Affairs Associate (1999 – 2000)

- Regulatory Affairs Department

1994 – 1999 BIORELIANCE, Rockville, MD, USA

Quality Assurance Manager, (1998 – 1999)

Quality Assurance Auditor (1995 – 1998)

- Quality Assurance Department

Senior Biologist, (1994-1995)

Biologist III (1994)

- Molecular Biology Lab, Biotechnology Department

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1990 – 1994 TEL AVIV UNIVERSITY, Tel Aviv, Israel

Research Assistant (1991 – 1994)

Teaching Assistant (1990 – 1991)

- Department of Cell Research and Immunology, Faculty of Life Sciences

EDUCATION

M.Sc., Microbiology (Cell Biology and Immunology), *magna cum laude*, Faculty of Life Sciences, TEL AVIV UNIVERSITY, Tel Aviv, Israel (1989 – 1992)

B.Sc., Biology, Faculty of Life Sciences, TEL AVIV UNIVERSITY, Tel Aviv, Israel. (1983 – 1986)

PROFESSIONAL MEMBERSHIPS

Active member of the Parenteral Drug Association (PDA) and PDA Israeli Chapter.

Active member of the Regulatory Affairs Professionals Society (RAPS)

ABSTRACTS AND PUBLICATIONS

1. S. Tuvia, J. Atsmon, S. L. Teichman, **S. Katz**, P. Salama, D. Pelled, I. Landau,I. Karmeli, M. Bidlingmaier, C. J. Strasburger, D. L. Kleinberg, S. Melmed, and R. Mamluk (2012). Oral Octreotide Absorption in Human Subjects: Comparable Pharmacokinetics to Parenteral Octreotide and Effective Growth Hormone Suppression. J Clin Endocrinol Metab, 97(7):2362–2369
2. S. Tuvia, P. Salama, I. Weinstein, K. Marom, E. Neumark, M.L. Arama, N. Mishli, S. Levy, T. Lapidot, R. Kadoshi, **S. Katz**, A. Judelman, R. Mamluk (2010). Octreolin a safe oral alternative for parenteral octreotide treatment. Growth Horm IGF Res 20(Suppl 1):S35–S36
3. **S. Katz** Livni & R. Ehrlich (1994). De Novo Methylation of a MHC Class I Transgene Following Transformation With Human Adenoviruses is not Correlated With its Altered Expression. DNA and Cell Biology 13:321-331.

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