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SUMMARY OF EXPERIENCE

With over 15 years of experience in Regulatory Affairs and 10 years in Clinical Affairs, I have successfully led global CMC regulatory strategies from the clinical phase through to marketing approval. I also have a strong track record in the design and conduct of clinical trials. My expertise spans regulatory activities across the full product lifecycle—supporting clinical development, marketing authorization, and post-approval maintenance—in the U.S., EU, Canada, U.K., and Israel.

PROFESIONAL EXPERIENCE

2025-Present: Principal Consultant at RCSS

2014-2024: SciVac Ltd. (subsidiary of VBI Vaccines)

Regulatory Affairs – Progressively Senior Roles

Titles Held:

- Vice President, Global Regulatory Affairs (2021-2024)
- Vice President, Regulatory Affairs, Europe & RoW (2019–2021)
- Senior Director, Clinical & Regulatory Affairs (2017–2019)
- Director, Clinical & Regulatory Affairs (2015–2017)
- Director, Regulatory Affairs (2014)

Therapeutic areas: Vaccine, Oncology.

Territories & Agencies: U.S. (FDA-CBER), EU (EMA), Canada (Health Canada), Israel (Israeli Ministry of Health), Rest of the world (Hong Kong, Latin America, Russia).

2022-2024: Vice President, Global Regulatory Affairs

- Managed 30 post-approval submissions in the U.S. (PAS, CBE-30, annual reports), EU (Type II, IB, IA) and Canada (levels II and III), in compliance with applicable regulations, ensuring uninterrupted supply.
- Achieved FDA clearance for a complex CMC IND amendment with multiple major changes, unlocking the start of a Phase IIb clinical trial.
- Secured marketing authorization in Russia.
- Configured and implemented a Regulatory Affairs management tool.
- Managed the CMC Regulatory Affairs team based in Israel and the Clinical Affairs team based in Canada.

2019–2022: Vice President, Regulatory Affairs, Europe & RoW

CMC Regulatory Achievements Toward Licensure

- Developed and executed the CMC regulatory strategy and activities supporting product licensure in the U.S., EU, and Canada.
- Led CMC-related pre-submission interactions with FDA (pre-BLA), EMA (pre-submission), and Health Canada (pre-NDS), including development of questions and briefing packages.
- Led and contributed to the authoring of all CMC sections —Quality Overall Summary and Module 3— of marketing applications (BLA, NDA, NDS), in compliance with CTD format and regional requirements.
- Led the strategy and authored responses to CMC-related questions from Health Authorities throughout the marketing authorization review process.
- Managed over 70 CMC post-approval changes (Type II, IB, and IA variations) in Israel.

Cross-Functional and Broader Regulatory Contributions

- Oversaw regulatory activities in the EU and Rest of World (RoW) markets.
- Investigated and resolved a complex manufacturing deviation by directing experimental activities conducted by the R&D team.
- Contributed to the preparation of non-clinical and clinical components of the marketing authorization applications.
- Ensured labelling compliance for the U.S. market, including prescribing information and secondary packaging.

2017–2019: Senior Director, Clinical & Regulatory Affairs

CMC Regulatory Achievements

- Led multidisciplinary teams to address CMC gaps toward licensure in the U.S., EU, and Canada, including involvement in study design and protocol review.
- Led two Type C meetings with FDA on CMC-related topics (process validation, facility renovation, potency assay, and new clinical program), including development of questions and preparation of briefing packages.
- Led Scientific Advice meeting with the EMA on CMC-related topics for a new clinical program, including development of questions and preparation of briefing packages.
- Led IND maintenance including amendments and annual reports.
- Managed post-approval submissions in Israel in compliance with EU regulations.
- Directed registration activities for new markets, including Hong Kong and Russia.
- Managed the CMC Regulatory Affairs department, including team leadership and strategic oversight.

Clinical Achievements

- Led and managed defined areas of clinical trial operations for two global Phase III studies conducted across multiple sites in the U.S., EU, and Canada, including:
 - Oversight of investigational product supply, labelling configuration, and packaging.
 - Led central laboratory selection, oversaw validation of the assay supporting the primary efficacy endpoint, and implemented end-to-end logistics for sample handling across all clinical sites
- Led the Clinical Operations team based in Israel.

2015–2017: Director, Clinical & Regulatory Affairs

CMC Regulatory Achievements

- Directed CMC regulatory strategy for Phase III trial initiation (FDA, EMA, HC), including gap identification and risk mitigation.
- Led regulatory interactions with health authorities on CMC-related topics (pre-IND, scientific advice, pre-CTA), including development of questions and preparation of briefing packages.
- Led authoring of CMC sections of INDs and CTAs for several EU countries and Canada.
- Managed post-approval submissions in Israel in compliance with EU regulations.
- Built and led the CMC Regulatory Affairs department, including recruitment, management, and strategic oversight.

Clinical Achievements

- Designed and conducted a Phase IV efficacy clinical trial in compliance with GCP; results were accepted by FDA, EMA, and Health Canada during marketing authorization review in 2020.
 - Authored the study protocol, clinical documentation, and clinical study report.
 - Managed site selection, activation, and closure.
 - Selection and management of CRO and laboratory partners.
 - Designed and conducted an ancillary study on memory B cells.
- Built and led the Clinical Operations department, including recruitment, management, and strategic direction.

2014: Director, Regulatory Affairs

- Directed data strategy and oversight of CMC submissions for post-approval maintenance in Israel, ensuring compliance with EU requirements.
- Led product registration activities in Latin America, coordinating regional regulatory strategy and submissions.

2010–2014: Teva Pharmaceuticals Ltd. (Innovative Division)

Regulatory Affairs – Progressively Senior Roles

Titles Held:

- Senior Manager, Global Regulatory Affairs (2012–2014)
- Global Regulatory Affairs Project Leader (2011–2012)
- Assistant Global Regulatory Project Leader (2010–2011)

Therapeutic Areas: Neurology, Gastroenterology, Autoimmune Diseases.

Territories & Agencies: U.S. (FDA–CDER), EU (EMA)

- Contributed to regulatory activities supporting Phase III trial completion and preparation for licensure, including preparations for a Type B / Pre-NDA meeting with the FDA.
- Led planning and submission for a Type A / protocol assistance meeting with the FDA.
- Supported global deployment of a Phase III clinical trial across 40 countries.
- Participated in a Clinical Advisory Board meeting as the regulatory representative.
- Reviewed non-clinical and clinical documents to ensure regulatory compliance, clarity, and alignment with submission strategy.
- Authored the pharmacology and mechanism of action sections of the Investigator Brochure.
- Advanced through roles of increasing responsibility, contributing to global development strategy, cross-functional leadership, and Agency interactions.

2008–2010: Omrix Biopharmaceuticals Ltd. (acquired by Johnson & Johnson)

Regulatory Affairs Project Manager

Therapeutic Areas: Immunodeficiency, Infectious Diseases, Surgical Adhesion Management.

Territories & Agencies: U.S. (FDA–CDER), Israel (Ministry of Health)

- Led a major manufacturing change and submitted a corresponding major IND amendment.
- Managed post-approval submissions in Israel, ensuring alignment with EU regulatory requirements.
- Authored an Orphan Drug Designation application.
- Designed and conducted a non-clinical local toxicity study.
- Retained as a key employee retained post-acquisition by Johnson & Johnson in recognition of regulatory expertise and project leadership.

EDUCATION

2007-2008:

Postdoctoral Research in Biological Regulation — Weizmann Institute of Science, Rehovot, ISRAEL

Research: Hormonal regulation of metastasis.

2002-2007:

PhD in Immunology — Weizmann Institute of Science, Rehovot, ISRAEL

Thesis: Recombinant flagella-MUC1 based vaccines for breast cancer therapy.

1999-2001:

MSc in Oncology and Immunology — Faculty of Medicine, la Timone and University of Sciences, Marseille, FRANCE.

Thesis: Genetic analysis of inflammatory breast cancer.

LIST OF PUBLICATIONS

- Atsmon J, Machluf N, Yayon-Gur V, Sabbah C, Spaans JN, Yassin-Rajkumar B, Anderson DE, Popovic V, Diaz-Mitoma F.
Rapid and high seroprotection rates achieved with a tri-antigenic Hepatitis B vaccine in healthy young adults: Results from a Phase IV study.
Vaccine. 2021 Feb;39(8):1328-1332.
DOI: 10.1016/j.vaccine.2020.12.050.
- Vesikari T, Langley JM, Segall N, Ward BJ, Cooper C, Poliquin G, Smith B, Gantt S, McElhaney JE, Dionne M, van Damme P, Leroux-Roels I, Leroux-Roels G, Machluf N, Spaans JN, Yassin-Rajkumar B, Anderson DE, Popovic V, Diaz-Mitoma F; PROTECT Study Group.
Immunogenicity and safety of a tri-antigenic versus a mono-antigenic hepatitis B vaccine in adults (PROTECT): a randomised, double-blind, phase 3 trial.
Lancet Infect Dis. 2021 Sep;21(9):1271-1281.
DOI: 10.1016/S1473-3099(20)30780-5.
- Vesikari T, Finn A, van Damme P, Leroux-Roels I, Leroux-Roels G, Segall N, Toma A, Vallieres G, Aronson R, Reich D, Arora S, Ruane PJ, Cone CL, Manns M, Cosgrove C, Faust SN, Ramasamy MN, Machluf N, Spaans JN, Yassin-Rajkumar B, Anderson D, Popovic V, Diaz-Mitoma F; CONSTANT Study Group.
Immunogenicity and Safety of a 3-Antigen Hepatitis B Vaccine vs a Single-Antigen Hepatitis B Vaccine: A Phase 3 Randomized Clinical Trial.
JAMA Netw Open. 2021 Oct;4(10):e2128652.
DOI:10.1001/jamanetworkopen.2021.28652.
- Nathalie Machluf, Ruth Arnon.
Therapeutic MUC1-Based Cancer Vaccine Expressed in Flagella-Efficacy in an Aggressive Model of Breast Cancer.
World Journal of Vaccines, Aug 2012, 2, 109-120.
DOI: 10.4236/wjv.2012.23015

- Demange L, Noguchi T, Sauvan R, Moyal-Amsellem N, Birnbaum D, Eisinger F, Sobol H. **A novel germline in frame deletion (4128del3) of the BRCA2 gene detected in a breast/ovarian cancer family with fallopian tube and brain tumors identified in the north of France.**
Hum Mutat. 2001 Feb;17(2):155.
DOI: 10.1002/1098-1004(200102)17:2<155::AID-HUMU15>3.0.CO;2-C
- Noguchi T, Sauvan R, Moyal-Amsellem N, Boubli L, Eisinger F, Birnbaum D, H Sobol H. **Three novel BRCA2 germline mutations (1864 delT, 6132 del4, 8208 del5) detected in breast cancer families identified in the south of France.**
Hum Mutat. 2001 Feb;17(2):155.
DOI:10.1002/1098-1004(200102)17:2<155::AID-HUMU14>3.0.CO;2-F
- Sauvan R, Noguchi T, Moyal-Amsellem N, Serin D, Eisinger F, Birnbaum D, Sobol H. **Three novel BRCA1 germline mutations (1104delAA, 1276delTT, 3747delGA) detected in breast/ovarian cancer families identified in the south of France.**
Hum Mutat. 2001 Feb;17(2):154.
DOI: 10.1002/1098-1004(200102)17:2<154::AID-HUMU13>3.0.CO;2-L