

CURRICULUM VITAE

Martin Kohan, Ph.D, ERT, DABT

PERSONAL DATA

Languages: Spanish, English, Hebrew

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WORK EXPERIENCE

9/2022 – Present Managing Toxicologist

Trinity Consultants - SafeBridge Europe, Limited

Provision of toxicology support and potent compound safety program development related to occupational exposure and product safety issues, as well as support of other regulatory matters and requirements, as appropriate. Support and assist in marketing and client relations, as required.

8/2018 – 9/2022 Senior Occupational Toxicologist

AstraZeneca UK

Safety, Health and Environment, Global Sustainability

Provision of expert support for occupational and product quality-related toxicology within Global Safety, Health and Environment (GSHE) and Sustainability for AstraZeneca to contribute to the overall strategy that enables a harmonized and consistent approach for occupational toxicology and product quality disciplines across the entire product pipeline, including both biologically-derived and chemically synthesized biopharmaceuticals at all stages from development through commercialization.

6/2018 – 9/2022 Consultant, Occupational & Quality Toxicology

Avraham Ami - ICG

Provision of occupational and product quality-related toxicology expert support and training on project-basis to a number of Chemical and Pharmaceutical Companies globally including assessment and interpretation of toxicological & pharmacological data, development of Exposure Limits/Bands (OELs, PDEs/ADEs, and OEBs/OHCs) for drug substances and intermediates, and toxicological risk assessments for impurities as well as extractables & leachables.

4/2018 - 6/2018 Director, Global Occupational Toxicology

Teva Pharmaceutical Industries; Global Environment, Health and Safety, Global Operations

5/2015 - 4/2018 Associate Director, Global Occupational Toxicology

Teva Pharmaceutical Industries; Global Environment, Health and Safety, Global Operations

6/2013 - 5/2015 Manager, Global Occupational Toxicology

Teva Pharmaceutical Industries; Global Environment, Health and Safety, Global Operations

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Responsible for Occupational Toxicology related programs and activities at Teva Pharmaceuticals. Duties and responsibilities performed on a full-time job basis include:

1. Evaluation and interpretation of toxicological & pharmacological information available for active pharmaceutical ingredients (APIs) to establish Occupational Exposure Limits (OELs), Occupational Health Categories (OHCs or exposure bands) and Acceptable/Permitted Daily Exposure (PDE/ADE) as well as development and preparation of respective supporting scientific documents/reports for more than 500 active compounds using currently accepted Industry approaches (e.g. EMA Guideline EMA/CHMP/CVMP/SWP/169430/2012 and ISPE Risk MaPP).
2. Coordination, supervision, and comprehensive review of toxicological assessments and exposure limits/bands determinations for more than 300 active compounds performed for Teva by External Consultants including SafeBridge Consultants, EV Sargent LLC, Sauerhoff & Associates, and Toxicology Regulatory Services (TRS).
3. Development and preparation of internal training strategies (technical lectures & e-learning interactive courses) to increase awareness and understanding on basic concepts of toxicology and occupational toxicology among colleagues representing various functional groups across the Teva enterprise.
4. Evaluation and characterization of potential toxicity and activity of isolated intermediates on an occupational perspective, including the preparation of assessment reports, based on:
 - a. Identification of toxicological alerts associated with chemical structural elements of the intermediate based on in-silico structure-activity relationship determinations.
 - b. Assessment of potential pharmacological potency considering the presence or absence of known pharmacophores in the intermediate, especially those associated with the known mode of action of the API.

11/2010 - 6/2013 Non-Clinical Safety Project Leader Teva Pharmaceutical Industries; Non-clinical Safety Department, Global R&D

Responsible for planning and monitoring the non-clinical safety (NCS) studies of a given project to facilitate the initiation of human clinical trials and provide adequate support towards approval for marketing. Duties and responsibilities performed on a full-time job basis included:

1. Planning of the NCS development of a given new chemical entity (NCE) including the design of relevant studies such as genotoxicity studies, safety pharmacology studies, and toxicology studies [e.g. 7-day maximum tolerable dose (MTD) toxicity studies, 14-day dose finding range (DFR) toxicity studies].
2. Supervision and monitoring of the execution of outsourced NCS studies in order to evaluate safety pharmacology, genotoxicity, toxicology, ADME, and pharmacokinetics/toxicokinetics of new chemical entities with potential to be introduced to the Company's pipeline.
3. Review of study protocols and reports (both partial and final) as well as performing the analysis and interpretation of toxicity study data.
4. Contribution to the design of NCS programs and to the preparation and writing of documents related to NCS programs for regulatory submissions and internal decision making processes.

EDUCATION

- 2005 - 2012** Hadassah-Hebrew University Medical Center, Jerusalem
Institute of Medical Sciences, Institute of Pulmonology
PhD Thesis: “Fibroblast activation and differentiation in airway remodeling in asthma”
Supervisors: Prof. Neville Berkman and Prof. Raphael Breuer
- 2002 - 2005** School of Pharmacy, Hebrew University of Jerusalem
Department of Pharmacology
MSc Thesis: “Effect of the cellular redox state on the nuclear translocation of the Aryl hydrocarbon Receptor (AhR)”
Supervisor: Prof. Jaime Kapitulnik (Magna Cum Laude)
- 2000 - 2001** University of Delaware, Newark, DE, USA
English Language Institute (ELI), **Intensive English Program**
Graduated with Honors - Advanced English Level
- 1992 - 2000** National University of La Plata, Argentina
Faculty of Exact Sciences
BSc Degree in **Chemistry**
MSc Degree in **Biochemistry**

MEMBERSHIPS IN PROFESSIONAL SOCIETIES

- 2013 - Present** Occupational Toxicology Roundtable (OTR)
2018 - Present British Toxicology Society (BTS)

PROFESSIONAL CERTIFICATIONS

- 2017 - Present** Diplomate - American Board of Toxicology
2017 - Present European Registered Toxicologist
2017 - Present UK Registered Toxicologist

RELEVANT TOXICOLOGY-RELATED COURSES & MEETINGS

- 2011** “**Toxicology for Industrial and Regulatory Scientists**”
American College of Toxicology, Falls Church, VA
- 2012** “**Reproductive Toxicology**”
Modular Training Programme in Applied Toxicology, Faculty of Health and Medical Sciences, University of Surrey, England
- 2013** “**Carcinogenicity and Mutagenicity**”
Modular Training Programme in Applied Toxicology, Faculty of Health and Medical Sciences, University of Surrey, England

- 2013** **“Occupational Toxicology”**
Modular Training Programme in Applied Toxicology, Faculty of Health and Medical Sciences, University of Surrey, England
- 2017** **“Mid-America Toxicology”**
Kansas City, MI
- 2019** **British Toxicology Society (BTS) Annual meeting**
Cambridge, UK
- 2020** **4th Annual Conference Highly Potent Active Pharmaceutical Ingredients**
Online (virtual) conference, organized by the SMi Group
- 2020** **4th Annual MarketsandMarkets High Potent Medicines Virtual Conference**
Online (virtual) conference, organized by MarketsandMarkets
- 2020** **9th Annual High Potent APIs Summit**
Online (virtual) conference, organized by Hanson Wade
- 2020** **High Potent APIs Online Forum**
Online (virtual) conference, organized by Amistat Group
- 2021** **6th High Potent APIs Annual Summit**
Online (virtual) conference, organized by the Vonlanthen Group
- 2021** **5th Annual Conference Highly Potent Active Pharmaceutical Ingredients**
Online (virtual) conference, organized by the SMi Group
- 2021** **HPAPI Handling and Manufacturing Summit**
Online (virtual) conference, organized by Uventia
- 2021** **6th Annual MarketsandMarkets High Potent Medicines Virtual Conference**
Online (virtual) conference, organized by MarketsandMarkets
- 2022** **Highly Potent API Summit (Virtual Format)**
Online (virtual) conference, organized by Innovatrix
- 2022** **5th Annual Conference Highly Potent Active Pharmaceutical Ingredients**
London UK, organized by the SMi Group
- 2022** **Cleaning Validation & HPAPI Manufacturing Summit**
Munich, Germany, organized by the Vonlanthen Group

LIST OF PUBLICATIONS

A. Papers in peer-reviewed journals

1. Parris P, Whelan G, Burild A, Whritenour J, Bruen U, Bercu J, Callis C, Graham J, Johann E, Griffin T, Kohan M, Martin EA, Masuda-

- Herrera M, Stanard B, Tien E, Cruz M, Nagao L. **Framework for sensitization assessment of extractables and leachables in pharmaceuticals**. Crit Rev Toxicol (2022);52:125-138
2. Gromek K, Hawkins W, Bernier T, Sehner C, Zeller E, Schwind M, Pfister T, Kohan M, Osadolor O, Glogovac M, Tuschl G, Dolan DG, Lovsin Barle E. **Deriving harmonised permitted daily exposures (PDEs) for paracetamol (acetaminophen) CAS #: 103-90-2**. Regul Toxicol Pharmacol; 115:104692. doi: 10.1016/j.yrtph.2020.104692. Epub 2020 Jun 6.
 3. Assayag M, Moshel S, Kohan M, Berkman N. **The effect of omalizumab treatment on the low affinity immunoglobulin E receptor (CD23/fc epsilon RII) in patients with severe allergic asthma**. Allergy Asthma Proc (2018);39:36-42
 4. Hirshoren N, Kohan M, Assayag M, Neuman T, Vernea F, Muro A, Eliashar R, Berkman N. **Extra domain-A fibronectin is necessary for the development of nasal remodeling in chronic allergen-induced rhinitis**. Ann Allergy Asthma Immunol (2013);110:322-7
 5. Kohan M, Muro AF, Bader R, Berkman N. **The EDA domain of fibronectin is essential for allergen-induced airway fibrosis and hyperresponsiveness in mice**. J Allergy Clin Immunol (2011);127:439-446
 6. Kohan M, Muro AF, White ES, Berkman N. **EDA-containing fibronectin induces fibroblast differentiation through binding to $\alpha_4\beta_7$ integrin receptor and MAPK/Erk1/2-dependent signaling**. FASEB J (2010);24:4503-12
 7. Fridlender ZG, Schwartz A, Kohan M, Amir G, Glazer M, Berkman N. **Association between CD14 gene polymorphisms and disease phenotype in sarcoidosis**. Resp Med (2010);104:1336-43
 8. Lecht S, Arien-Zakay H, Kohan M, Lelkes PI, Lazarovici P. **Angiostatic effects of K252a, a Trk inhibitor, in murine brain capillary endothelial cells**. Mol Cell Biochem (2010);339:201-13
 9. Kohan M, Puxeddu I, Reich R, Levi-Schaffer F, Berkman N. **Eotaxin-2/CCL24 and eotaxin-3/CCL26 exert differential pro-fibrogenic effects on human lung fibroblasts**. Ann Allergy Asthma Immunol (2010);104:66-72
 10. Kohan M, Breuer R, Berkman N. **Osteopontin Induces Airway Remodeling and Lung Fibroblast Activation in a Murine Model of Asthma**. Am J Respir Cell Mol Biol (2009);41:290-96
 11. Kohan M, Bader R, Puxeddu I, Levi-Schaffer F, Breuer R, Berkman N. **Enhanced osteopontin expression in a murine model of allergen-induced airway remodelling**. Clin Exp Allergy (2007);37:1444-54

B. Conference abstracts/presentations/Speaking Invitations (from 2016)

1. **Kohan M. Occupational Toxicology - OEBs, OELs and the Importance of a Qualified Expert.** Invited speaker; 2nd Highly Potent Active Pharmaceutical Ingredients Hybrid Forum organized by the Amistat Group. November 2022
2. **Kohan M. Permissible daily exposures (PDE) for cleaning validation.** Invited speaker; 5th Cleaning Validation & 8th Annual Highly Potent Active Pharmaceutical Ingredients Summit organized by the Vonlanthen Group. October 2022
3. **Kohan M. Toxicology aspects in Worker & Patient Safety – Basic concepts & regulatory implications.** Invited speaker; 11th Annual High Potent APIs Summit; Boston, MA; organized by Hanson Wade. June 2022
4. **Kohan M. Guidance for establishing Health-Based Exposure Limits (HBELs).** Invited speaker; 6th Annual Conference Highly Potent Active Pharmaceutical Ingredients; London UK; organized by the SMi Group. May 2022
5. **Kohan M. Identifying HPAPIs - How Much is Too Much?** Invited speaker; Highly Potent API Summit (Virtual Format) organized by Innovatrix. February 2022
6. **Kohan M. Occupational Exposure Bands (OEBs).** Invited speaker; 6th Annual MarketsandMarkets High Potent Medicines Virtual Conference. November 2021
7. **Kohan M. Occupational Exposure Bands (OEBs).** Invited speaker; HPAPI Handling and Manufacturing Summit (Virtual conference) organized by the Uventia. September 2021
8. **Kohan M. Calculation of Health-Based Exposure Limits (HBELs) - The Importance of a Qualified Expert.** Invited speaker; 5th Annual Conference Highly Potent Active Pharmaceutical Ingredients (Virtual conference) organized by the SMi Group. May 2021
9. **Kohan M. Highly Potent APIs (HPAPIs) & Health-Based Exposure Limits (HBELs) - How Much is Too Much?** Invited speaker; 6th High Potent APIs Annual Summit (Virtual) organized by the Vonlanthen Group. March 2021
10. **Kohan M. Identifying High Potent APIs and Setting High Quality Health-Based Exposure Limits (HBELs) for Them.** Invited speaker; High Potent APIs Online Forum organized by the Amistat Group. December 2020
11. **Kohan M. Identifying Approaches for Gaining Data for OELs – Innovation vs. Generics.** Invited speaker; 9th Annual High Potent

APIs Summit (virtual conference) organized by Hanson Wade. November 2020

12. **Kohan M. Getting good health-based exposure limits (HBELs).** Invited speaker; 4th Annual MarketsandMarkets High Potent Medicines Virtual Conference. September 2020
13. **Kohan M. Characterising Highly Potent APIs - Introduction to Occupational Toxicology.** Invited speaker; 4th Annual Conference Highly Potent Active Pharmaceutical Ingredients (Remote conference) organized by the SMi Group. May 2020
14. **Lovsin-Barle E and Kohan M. Default Health-Based Exposure Limits (HBELs) for High Molecular Weight Compounds.** Presented at the 2019 Occupational Toxicology Roundtable. Sonoma, CA
15. **Kohan M. Introduction to Occupational Toxicology.** Invited lecture presented at Amos Gazit Ltd., a leading Israeli company specialized in import, marketing, export and service for safety and medicine products. Petach Tikva. May 2018
16. **Sachedva K and Kohan M. Inhalation Bioavailability for Topically Applied Corticosteroids.** Presented at the 2017 Occupational Toxicology Roundtable. Austin, TX
17. **Kohan M. Classification Strategy for Isolated Intermediates from an API Manufacturer Perspective.** Presented at the 2016 Occupational Toxicology Roundtable. Philadelphia, PA
18. **Kohan M. Introduction to Occupational Toxicology.** Invited lecture presented at the Israeli Ministry of Health. Jerusalem, 2016