

Elina Kolosovsky-Simberg

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Ten years of experience in pharmaceutical CMC (R&D, analytical chemistry, formulations and regulatory affairs). Excellent project management and interpersonal skills in a corporate environment.

EXPERTISE

- Project management of GLP and GMP activities (active pharmaceutical ingredient and drug development);
- Writing CMC sections for IND (investigational new drug) submission;
- Proficiency in regulatory FDA requirements for early drug development stage and FDA regulations for quality control in GMP and GLP environment for pharmaceutical industry;
- Work with CROs (contract research organizations): method development, transfer and validation, reference standard characterization and release of API, intermediates and starting materials and phase I drug product (solution / suspension, bulk in capsule);
- Setting specifications for API and drug products;
- Genotoxic impurities: control, specification, analytical method development;
- Physicochemical characterization of APIs and routine testing;
- Forensic analysis of drug products: method development and testing;
- Analytical method development and validation for drug products, drug substances, intermediates and starting materials;
- Writing development reports, test methods, validation protocols and reports SOPs and CoAs (certificate of analysis);
- Excellent expertise in separation and analytical chemistry techniques;
- Successful interfacing between multidisciplinary teams;
- Excellent interpersonal communication, problem solving, project management and leadership qualities;
- Strong verbal and written skills.

PROFESSIONAL EXPERIENCE

INDEPENDENT CONSULTANT, for Takeda California

2013

- Writing CMC section for IND submission;
- Managing analytical development activities for API manufacturing and first in man formulation;
- Review of documentation for GMP campaign, release of API and stability studies;

TAKEDA CALIFORNIA, Analytical sciences and DMPK group

Associate Scientist

2013

Senior Research Associate II

2011-2013

- Writing CMC section for IND submission to FDA;
- CMC activities and project management;
- Review of documentation for GMP campaign, release of API and stability studies;
- Design and project management of analytical development activities for API GLP/GMP campaigns and phase I drug product (solution / suspension, bulk in capsule);
- Perform analytical method development (chiral and achiral) and verification for characterization of APIs, synthetic route intermediates, starting materials, residual solvents and impurities, potentially genotoxic impurities;
- Perform analytical method development (chiral and achiral) and verification for characterization of Tox study dose solutions and drug product for Ph I clinical study;
- Stability study of APIs, formulations for Tox study, drug product for Ph I clinical study;
- Perform FDS (forced degradation studies);
- In- process impurities and API degradants identification;
- Work with CROs on method development, validations and stability studies to provide analytical support for GLP and GMP API release, Tox study dose solutions, drug product for Ph I clinical study;
- Setting specifications for GMP campaign of API synthesis and drug products;
- Support analytical and physicochemical testing, creating SoAs;
- Research initiatives: EDCI method development, automated forced degradation studies;
- Writing reports, protocols and SOPs;
- Interfacing and coordinating between QA, project development and analytical development teams

Senior Research Associate I

2007-2011

- Perform analytical method development (chiral and achiral) and verification for characterization of APIs;
- Perform forced degradation studies and API stability studies;
- In- process impurities and API degradants identification;
- Method development and sample analysis for forensic testing of drug products;
- Support analytical and physicochemical testing, creating SoAs;
- Preparation of formulation vehicles;

- Research initiatives: HPLC to UPLC method transfers and parallel screening & Drylab analytical method development;
- Process chemistry analytical instruments maintenance and troubleshooting;
- Writing reports, protocols and SOPs;

NEUROCRINE Biosciences, Pharmacology Development

Research Associate

2005-2007

- Perform analytical method development and validation for identification and characterization of new APIs, synthetic route intermediates, residual solvents and impurities, using HPLC, GC, MS;
- Support of analytical testing of process chemistry, prototype formulations and finished drug products, using HPLC, GC, MS, KF, FTIR, X-Ray, TGA, DSC, DTA;
- Conduct research to identify unknown impurities, using HPLC, GC, MS, DSC, microscopy;
- Writing reports, protocols and SOPs;
- Strong hands-on experience in method development for chiral compounds HPLC (reverse and normal phase) and GC.

PFIZER, La Jolla, Analytical R&D

Research Associate

2005

- HPLC Method Development and Validation;
- Stability testing of APIs and drug products;
- Participated in releases of starting materials, key intermediates and APIs;
- CRO Support Analytical Testing.

TEVA Pharmaceutical Industries, QC laboratory, Jerusalem

Analytical Chemist (Stability Group)

2003-2004

- Stability and QC testing of API and drug products (assay, uniformity, identification of product degradations, dissolution tests);
- Perform degradation studies.

EDUCATION

The Hebrew University of Jerusalem, Organic Chemistry department, Jerusalem

Master's degree

2001-2003

- MS and GC/MS testing for identification of the biomarkers (alcohols, hydrocarbons, alkenones etc) from different organic matter origins;
Title of the Master's Thesis: "Reconstruction of paleotemperatures and determination of origin of organic matter in sediments from the Eastern Mediterranean Sea"

Voronezh University, Russia

B.Sc. in Chemistry

1995-2000

TRAINING

Professional course: "High Efficiency Enantiomeric Separation" by Dan Armstrong;
Professional course: "Modern analytical method development techniques" EAS 2009

POSTERS

"Streamlined Automated Forced Degradation Studies for Early Stage API Development."
Presented at Takeda CMC conference 2012

PUBLICATIONS

Almogi-Labin A, Bar-Matthews M, Shriki D, Kolosovsky E, Paterne M, Schilman B, Ayalon A, Aizenshtat Z, Matthews A. "Climatic variability during the last w90 ka of the southern and northern Levantine Basin as evident from marine records and speleothems" *Quaternary Science Reviews*, v. 28, iss. 25-26, p. 2882-2896.