



FRANCISCO KURI BREÑA ROMERO DE TERREROS

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Born in Mexico City, México (Oct-1961)

BioEstadística, S.C.: Director, Quality & Regulatory Affairs Division. Jul-2024 to date
Associate Consultant. Sep 2023 to date

PROFESSIONAL ACTIVITIES

- **BioEstadística, S.C.**
Associate Consultant, Sep 2023 to date.
- **Independent Consultor for Pharma Industry.**
Experience in Due Diligences, Road Shows, Technical Audits, Trouble Shooting, Biotechnology, Genomics, Drug Development, Regulatory Affairs, Medical Cannabis and Lobbying.
 - Advisor in Biotechnology for AMELAF (Since 2022)
 - Biotechnology Products Expert Committee Coordinator in FEUM (Since 2010).
 - STEP Expert in USP (Since 2018).
 - Member of the UNAM Chemistry Faculty Patronage (Since 2021).
- **Research and Development and Validation Director for Mexico and LatAm at Sanfer Labs, in the Grimann Plant.**
Lerma de Villada, Estado de México. Direct Reports 82.
 - Pharmaceutical Development
 - Analytical Development
 - Validations
 - Technical Support
- **New Developments Director, Landsteiner Scientific, Mexico City (Apr 2013–May 2020).**
 - New developments director for small molecules and biotechnology products as well as in genomic medicine projects and Medical Cannabis.
 - Includes strategic planning and market positioning. Direct Reports 60.
 - Experience with Due diligences and Road Shows.
 - Official Public Speaker.
- **New Products Manager, Probiomed, S.A. de C.V. Mexico City (Sep 2009–May 2013).**
 - New products coordination, Biotechnology, and pharma-chemical products.
 - Dossier coordination for registration in Mexico and elsewhere.
 - Government-industry-academy vinculation.
 - Active participant in the Biotechnology Regulation Task Force for Biosimilars in Mexico.
 - Direct reports: 7, Indirect reports; Pharmaceutical development and analytical development groups.

- **Technical and Regulatory Affairs Director, Probiomed, S.A. de C.V. Tenancingo, Mexico (Aug 2005–Sep 2009).**
 - Biopharmaceutical regulation in Mexico and elsewhere.
 - ISO 9001:2000 certified Biotechnological Plant for recombinant protein production and vaccines.
 - Technology Transfer and product development.
 - Expert in Quality and Technical troubleshooting in the industrial-scale production of recombinant human proteins in Bacteria, Yeast, and mammalian cell lines.
 - Change and deviation control in API and in Pharmaceutical production.
 - Knowledge suppliers and academia relationship link. Vinculation with governmental Agencies (SSA, STPS, SEMARNAT).
 - Internal relationship with Production, Quality, Validation, Engineering, Projects, R & D, Finance, Strategic Partners.
 - Direct reports: 3. Indirect reports: The whole Plant Engineering, Projects, R & D, Finance, Strategic Partners. Direct reports: 3. Indirect reports: The whole Plant

- **Technical Director, Probiomed, S.A. de C.V. Mexico City (1999 – 2005).**
 - Quality and Technical Trouble shooting. Scale-up.
 - Experience with therapeutic protein formulation.
 - Internal relationship with Production, Quality, Technical Services, Regulation, Strategic Partners, Academia.
 - Direct reports: 7.

- **Manufacturing Director, Probiomed, S.A. de C.V. Mexico City (1998 – 1999).**
 - Industrial-scale production of recombinant human proteins in bacteria, mammalian cells, and yeast.
 - Technology Transfer. Relationship with Quality and Technical Services.
 - Direct Reports: 20

- **Process Optimization, Roche-Syntex Group, Cuernavaca, Mexico City (1995 – 1998).**
 - Laboratory Coordinator. Quality Centre in Cuernavaca, Morelos.
 - Process Optimization. Trouble shooting.
 - Technology Transfer.
 - Personnel training.
 - Relationship with Production and Quality Control. Expert in Biotransformation of synthetic substrates into biologically active compounds.

- **Research and Development Department, Syntex, S.A. Cuernavaca, Mexico City (1992 – 1995).**
 - Researcher. Chemical Plant in Cuernavaca, Morelos.
 - Pharmaceutical product syntheses.
 - Organic synthesis in general.
 - Process validation and Technology transfer.
 - Large experience in Pharmaceutical product syntheses.
 - Organic synthesis in general. Process validation and Technology Transfer.
 - API Production

EDUCATION

- **Philosophy Doctor (Organic Chemistry)**
The University of British Columbia – Vancouver, Canada, 1992
- **Maestro en Ciencias (Química Orgánica).**
Universidad Nacional Autónoma de México – Mexico City, 1987
- **Licenciatura en Química (Mención Honorífica).**
Universidad Nacional Autónoma de México – Mexico City, 1985

ACADEMIC EXPERIENCE

- **Universidad Autónoma del Estado de Morelos.**
Part-time professor. División de estudios de posgrado. Maestría en Ciencias Químicas.
Cuernavaca, Morelos. 1993-1998
- **United States Pharmacopoeia Spanish Translation Expert Panel Member**
Rockville, MD, USA 2018 to date

AWARDS

- **Medalla Gabino Barreda al Mérito Universitario.**
Universidad Nacional Autónoma de México. Mexico City 1989.
- **Syntex scholarship for graduate studies.**
PhD in Organic Chemistry. Cuernavaca, Morelos. 1998-1992.
- **Syntex scholarship for graduate studies.**
MSc in Synthetic Organic Chemistry, Cuernavaca, Morelos. 1985-1987.