

SETON HALL | LAW

Healthcare Compliance
Certificate Program



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Professional profile

Luis J Serrano, is part of IRIS GLOBAL LLC, in the Mexico office, a firm that provides consulting services for all of America (Caribbean, Central, North and South America). Iris guides clients to transform regional ideas and concepts into local tactics (market entry, compliance, new product registrations and lifecycle management). Using core principles of integrity, creativity, and agility, IRIS has expanded its US-based consulting firm to other Latin American countries and supported pharmaceutical, medical device, and cosmetic companies enter the US markets, Mexico and Latin America and begin marketing and distribution operations (in Ecuador in 2016). He has led startups (market entry), due diligence, mergers, acquisitions, spin-offs, and transition projects for several companies in the United States and Europe. Currently Luis J Serrano supports by providing experience and leadership for the growth of IRIS GLOBAL.

Luis J Serrano has more than 22 years of experience in global regulation (USA, Health Canada, Colombia, Brazil, Argentina, Chile, CAM, EMA) mainly in the areas of health supplies and cosmetics, participating in technical areas, compliance, and new businesses, for medicines (Biotechnological, small molecules and OTC's), medical devices, homeopathic, herbal, food supplements among others.

He has led multidisciplinary teams for the purchase and sale of manufacturing plants, multinational due diligence for the purchase of new portfolios, reengineering of manufacturing processes, construction of new manufacturing plants, pre-audits for certification of Good Manufacturing Practices from high-level regulatory agencies. health regulation, audits of foreign suppliers, audits of national and international maquiladoras.

He has participated in various regulatory groups with the health authority on behalf of the pharmaceutical industry in the review of various official Mexican standards and guides, mainly in medical devices and pharmacovigilance.

Education

Candidate for Doctor of Research in Medicine (ESM-IPN)

2006 - 2009

Master in Neurosciences (CINVESTAV-IPN)

2003 - 2006

Chemist Pharmaceutical Biologist (UNAM)

1993 – 1998

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