

**LIFE SCIENCES
INDUSTRY GROUP**





Life Sciences Industry Group

The Life Sciences Industry Group is a multidisciplinary group of lawyers who, for more than 18 years, have provided practical and effective advice in the key legal areas for healthcare and life sciences clients.

As a multidisciplinary group, we are in a unique position to offer the different players in the healthcare and life sciences industries comprehensive and specialized legal analysis sensitive to the peculiarities of their businesses.



What we do

We offer specialized counsel to advise industry players require in the following key legal areas: Regulatory Compliance, Anti-corruption, Data Privacy, Intellectual Property, International Trade, Administrative Litigation, Corporate Transactional and M&A, Tax, and, Legal advisory on Public Market Access.

Regulatory Compliance

- » Advice on regulation, contracting, internal auditing, and implications on M&A processes regarding pharmaceutical products and related substances; restricted substances; medical devices (including nuclear safeguards); products posing health risks for humans, animals, or plants; food and beverages; dietary supplements; cosmetic products; tobacco products; alcoholic beverages and regulated agricultural products.
- » Assistance with the drafting and negotiation of agreements for industries subject to regulatory compliance including: raw material processing, manufacturing, hosting, supply, licensing, marketing, and distribution.
- » We also assist our clients in connection with possible advantages arising from the existence of diverse free trade agreements or other international instruments executed by Mexico that may permit these regulated activities to optimize efficiencies and facilitate their operations within Mexico and internationally.
- » Advise in connection with activities regarding regulated products and activities including advertisement, information disclosure, events and activities organization, internal and industry codes of ethics and applicable legal provisions. Assistance in connection with recall and similar procedure for products having potential effects or harm on human, animal or plant health.

Intellectual Property

- » Advice on the design and implementation of IP strategies in the life sciences industry, including research and development in scientific and technological matters. General advice on interactions between Intellectual Property and Regulatory authorities on issues such as patent linkage, regulatory data exclusivity, brand name approvals and the like.
- » We also advise on specialized prosecution and litigation of IP rights in the life sciences arena, both based on local laws and International Treaties.
- » Our expertise has also been helpful in several public policy projects, by providing legal support to initiatives by Government affairs teams.

Corporate Transactional and M&A

- » Integrated advice on mergers, acquisitions, investment and divestment transactions, corporate and group restructurings, liquidations, sale and purchase of entities and assets, spin-offs, due diligence and regulatory compliance reviews (including for the sale of companies), privatizations and joint ventures.

Anti-Corruption

- » Advice on internal investigations due to potential violations of FCPA and other international anti-corruption statutes (arising from activities in Mexico), Mexican anti-corruption regulations or breach of internal policies.
- » Advice on the performance of local risk assessments and training of key personnel on Mexican anti-corruption and anti-money laundering laws as well as assistance in the rollout of policies.
- » Assistance in the revision of internal anti-corruption programs to make them fit the new Mexican anti-corruption legal framework as well as advice on internal vetting procedures for distributors, agents and service providers.

International Trade & Customs

- » Advice on strategic planning on international trade operations for companies subject to specific health and related regulations. This includes advice on tariff and non-tariff requirements, free trade agreements, rules of origin, exceptions to benefits, and related issues.
- » Advice in connection with permits, authorizations and registries required for the importation and exportation of regulated products into and from Mexico as well as export controls related to medical, health and similar products to specific jurisdictions and individuals.
- » Procedures before diverse administrative authorities to obtain the necessary permits, authorizations and registries required for the importation and/ or exportation of products subject to health and sanitary requirements.
- » Advice regarding general import requirements for regulated products and those specifically subject to particular provisions among which are sectorial registries, customs valuation, transportation requirements, etc.
- » Assistance with customs and administrative audits regarding regulated products and tailoring of compliance policies, and representation before Mexican authorities in settlement or compliance correction processes.

Tax

- » Federal and local tax optimization for new or existing operations and expansion projects, national and international corporate reorganizations, acquisitions or divestitures. Application of international treaties to tax matters. Advice on transfer pricing and value creation support, including planning, consulting, and defense. Advice and defense in federal and local tax audits.

Data Privacy

- » Advice on the Mexican Federal Law for the Protection of Personal Data in Possession of Private Entities and its regulations in the handling of personal data, confidential information, and trade secrets, including implementation, privacy notices, internal compliance policies and directives, security policies, codes of conduct and best practices, related training, and representation in administrative proceedings relating to personal data and information security.

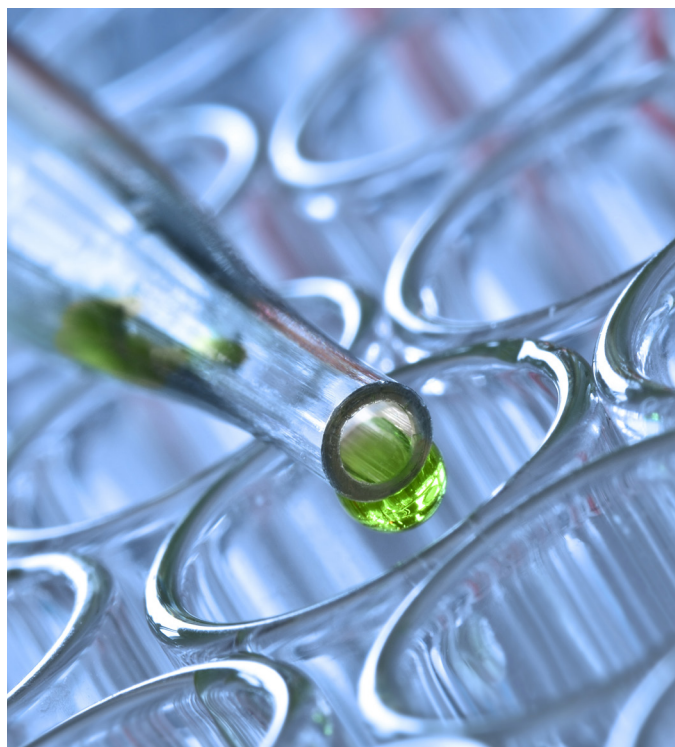
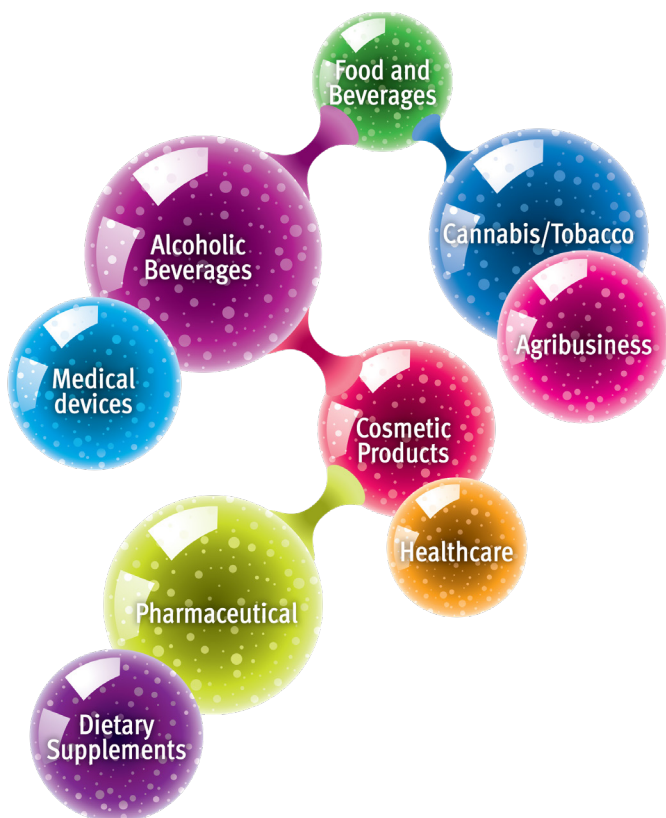
Administrative Litigation

- » Advice in administrative litigation including regulatory compliance, international trade and customs, tax, data privacy and intellectual property against several Mexican authorities for companies in the life sciences industry.

Legal Advisory on Public Market Access

- » We have full capacities to aid our clients in government procurement efforts, including advisory on public purchase proceedings, relevant regulations and negotiations with specific authorities.

Life Sciences Industry Practice at Sánchez Devanny provides legal advice to companies in these sectors:



REPRESENTATIVE EXPERIENCE

- » Acted as lead legal, regulatory and tax counsel for a German food company on its acquisition of a major Mexican food products manufacturer. We conducted the legal audit for the acquisition, which required extensive and detailed legal analysis regarding complex industrial processes, formulations, intellectual property and assets holding structure of the seller as well as the existing information technology platform. Our advice allowed us to optimize the efficiencies of the investment structure design, preparation and negotiation of the stock purchase agreement and all ancillary documents. In close collaboration with the company's internal tax team, we developed the leveraged financing structure to maximize returns and minimize the cross border tax burden of the transaction
- » Represented a German beverage company and acted as lead legal, regulatory and tax counsel on its acquisition of a Mexican wine and alcoholic beverages manufacturer. We conducted the legal audit for the acquisition, which required extensive and detailed analysis regarding heavily regulated industrial processes and formulations. Our advice allowed us to optimize the efficiencies of the investment structure design, preparation and negotiation of the stock purchase agreement and all ancillary documents.
- » Supported two clients in the pharmaceutical industry with anti-corruption and improper payment clauses included in their distribution, services, and supply agreements.
- » Represented the joint venture between an important European clinical research company and a Mexican counterpart on the structuring and development of a clinical research operation for LATAM based in Mexico, with operations extending to Brazil, Argentina and locally in Mexico.
- » Advised a US consumer products company in the Mexican portion of an international acquisition of a major animal food producer and distributor. This transaction included a due diligence process and review and drafting of documents. Our advice included structuring, contractual, corporate, tax planning, foreign trade, labor, compliance and regulatory matters.
- » Assisted in the design and execution of a compliance investigation for a client in the medical industry that led to the performance of a full assessment of its Mexico operations' labor practices.
- » Assisted a client in identifying distributors that have misused its registered trademarks to sell counterfeited medicines to the health sector in Mexico, and helped to design an effective legal strategy to stop infringement and the sale of counterfeited goods.
- » Advised a US based food products company regarding a commercial relationship with a Mexican entity. Our advice included determining the US Principal Party in Interest (USPPI), analyzing possible obligations

arising from the relationship, establishing possible corrective measures to avoid contingencies, and implementing legal solutions in Mexico and the US.

- » Advised a client in the importation of raw materials, parts and components into Mexico for the manufacturing processes of cosmetic products. Counsel focused on the advantages of having manufacturing facilities and activities in Mexico for purposes of origin compliance for exports to NAFTA and other countries with free trade agreements in Latin America.
- » Secured a landmark ruling from Mexico's tax courts confirming the application of a 0% VAT rate on corporate services provided to a client's foreign affiliates. This reversed the previous understanding of the authorities, which was that a 16% rate was applicable. Through this ruling, the client will be able to recover corporate costs for services rendered by the head office to its multinational subsidiaries throughout Latin America, allowing it to reduce or eliminate withholding taxes in a number of Latin American jurisdictions and to reduce the allocable portion of its corporate costs.
- » Advised one of the major pharmaceutical products manufacturers in Mexico in connection with potential liabilities arising from the execution of Phase IV clinical trials in Mexico without the necessary authorizations by the competent authorities as well as the determination of the actual activities that may be considered as clinical trials subject to control by the competent authorities.
- » We acted as lead tax advisor for the 13.5 billion dollar corporate reorganization of this publicly traded Mexican multinational. The undertaking implied the tax-free reorganization of the company's beverage and snacks business into two separate sub-holdings and encompassed its subsidiaries in Argentina, Ecuador, Peru, Spain and the United States. In parallel, we acted as lead tax counsel for the 2.7 billion dollar acquisition of a U.S. bottling company by the bottling sub-holding company.
- » We are currently advising a multinational innovation-based company on litigation proceedings to enforce its intellectual property rights against generic drug competition.
- » Advised a drug manufacturers association with available alternatives to challenge determinations by regulatory authorities regarding criteria to approve advertising materials.

Team

José A. Campos-Vargas – Partner
jacampos@sanchezdevanny.com
Mariana Eguarte-Morett – Partner
meguarte@sanchezdevanny.com
Daniel Maldonado-Alcántara – Partner
dmaldonado@sanchezdevanny.com
Humberto Morales-Barrón – Partner
hmorales@sanchezdevanny.com
Ricardo León-Santacruz – Partner
rls@sanchezdevanny.com
Turena Ramírez-Ortiz – Partner
tramirez@sanchezdevanny.com
Ernesto Silvas-Medina – Partner
esm@sanchezdevanny.com
Juan Luis Serrano-Leets – Partner
jserrano@sanchezdevanny.com

Who we are

Sánchez Devanny is a leading Mexican law firm that provides full-service legal advice both to Mexican and international clients.

More than attorney-client services

We build enduring client relationships that go beyond individual service contracts because we make every effort to understand our clients' businesses and expectations, to serve as an ally, and to provide complete, accessible and personalized advice. As a testament to these efforts, we continue to advise clients today who have trusted us with their legal matters since the firm was founded in 1996.

Experience and creativity

Throughout the firm, we take pride in serving our clients with a combined approach of experience and creativity because we recognize that when you know how things are done it is easier to think outside the box. Our partners offer a wealth of experience, including in prior roles as in-house counsels at global companies and government agencies, and key roles within international law firms.

With offices in Mexico City, Monterrey, and Querétaro, as well as several strategic alliances worldwide, the firm is well-positioned to quickly and efficiently represent and respond to clients' needs, shortening the distance between us and our clients. Our services are delivered in an efficient, professional, cost effective and timely manner, keeping always in mind that, as lawyers, we are business facilitators for our clients and must maintain a proactive and preventive approach.

Location

Mexico City:

Av. Paseo de las Palmas #525 Piso 6
Col. Lomas de Chapultepec, 11000
Ciudad de México
T. +52 (55) 5029 8500

Monterrey:

José Clemente Orozco #335 Piso 4
Despacho 401 Col. Valle Oriente, 66269
San Pedro Garza García N.L.
T. +52 (81) 8153 3900

Querétaro:

Av. Antea #1090 Piso 2 Int 206
Col. Jurica
Querétaro, Qro
T. +52 (442) 296 6400



Sánchez Devanny Eseverri S.C.



@SanchezDevanny



/sanchezdevannymx

www.sanchezdevanny.com

Sánchez Devanny refers to Sánchez-Devanny Eseverri, S.C., a leading Mexican law firm that provides full-service legal advice both to Mexican and international clients.

This publication contains general information only and is just for informative purposes. Sánchez Devanny is not rendering legal advice or services by means of this publication. To obtain legal advice or services and before making any decision or taking any action that may affect your business you should consult a qualified professional advisor.

Sánchez Devanny provides legal services in the areas of Corporate and M&A; Corporate and Project Finance; International Trade and Customs; Real Estate, Infrastructure and Hospitality; Tax; Labor, Social Security and Immigration; Corporate Governance and Regulatory Compliance; Energy, Natural Resources and Environmental; Life Sciences; Intellectual Property, Entertainment and Sports Law; Litigation and Alternative Dispute Resolution; Antitrust; Financial Institutions and Services; Private Wealth Management and Estate Planning and Data Privacy and Information Technology to both public and private clients, especially in the automotive, retail, pharmaceutical, manufacturing, real estate and energy industries.