Igor Linhares de Castro

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AREAS OF EXPERTISE

PHARMACEUTICAL INDUSTRY

REGULATORY AFFAIRS / QUALITY / BUSINESS DEVELOPMENT

Over 20 years of experience in pharmaceutical industry-related areas in Latin America. Regional representation within health authorities: ANVISA (Brazil), COFEPRIS (Mexico), INVIMA (Colombia), ANMAT (Argentina), ISP (Chile), DIGEMID (Peru), ARCSA (Ecuador), CECMED (Cuba) and Central America (CEAM) agencies. Deputy General Manager of LATAM regional operations. Responsible Pharmacist (QP) and Legal Responsible of local office in Brazil. Regulatory affairs, quality, business development and strategy roles, each of them with increasing amounts of executive and managerial duties.

Portfolio of achievements include successful strategies and reduction of regulatory timelines for marketing authorizations for biologics and small molecules across LATAM, successful GMP certification of manufacturing sites in Russia by LATAM health authorities (inc. PIC/S agencies), approval of clinical trials protocols in ANVISA and CONEP, public-private partnerships in Brazil, increasing sales through building business partnerships and supporting marketing initiatives in the region. Successful leadership of diverse projects.

Good analytical skills and the ability to draw strategic conclusions based on risk-assessment. Ability to work both individually and lead team projects. Relationship builder with the ability to influence and guide others aiming the achievement of the company's annual and long-term goals.

Depth understanding of local operations, regional management and global strategy. Capacity to build and develop high-performance teams, integrating regulatory actions to business goals, creating processes, policies, and procedures, leading and determining the annual KPIs.

Guide organizations towards an ethical attitude to achieve sustainable results in the best interest of the patients and stakeholders.

Strong participation in professional associations at international and local levels:

- International Pharmaceutical Federation (FIP): +12 years at the Executive Committee on Industrial Pharmacy, current Secretary (4 years) and former Treasurer (8 years). Support to organizing committee of 12 editions of FIP Congresses (2010-2022) and 8 events with ANVISA and SINDUSFARMA in Brazil, the Symposia "New Frontiers of Pharmaceutical Sciences" (2012-2019);

- SINDUSFARMA (Syndicate of Pharmaceutical Industries of Sao Paulo): +18 years of company representation, participation in working groups, guidelines review, and organizing training events;

- +10 years collaborating with the Brazilian Academy of Pharmaceutical Sciences (ABCF);

- +20 years cooperating in training events by the Federal Council of Pharmacy (CFF) and the Regional Council of Pharmacy of Sao Paulo State (CRF-SP);

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- Regular lecturer of post-graduation courses for BYOXENTIS and LATFAR, teaching about regulatory affairs and biotechnology-related subjects.

Specialties:

- Leadership of cross-functional teams
- Developing regulatory strategy as member of the global team by providing consolidated regulatory input, requirements, and competitive analysis from Latin America countries
- Driving and steering implementation of marketing authorization plans
- Providing strategic guidance to R&D activities, market research and health outcomes Building strong Latin America Launch Team.

EDUCATION

- **MSc in Regulatory Affairs for Drugs, Biologics and Medical Devices /**

  Northeastern University (US, 2015)
- **MBA in Business Management /** *Getúlio Vargas Foundation – FGV (Brazil, 2008)*
- **Pharmacy Diploma (with Major in Industrial Pharmacy)** / *Oswaldo Cruz Faculties (Brazil, 2004)*

LANGUAGE SKILLS

English (Fluent level) / **Spanish** (Fluent level) / **Portuguese** (Mother language)

COMPUTER SKILLS

- MS-Office suite and Communication tools (Teams, Zoom, Google Meet)
- Kanban and Project management tools
- ERP / SAP (user level)

PROFESSIONAL HYSTORY

Sep/12 – Present	BIOCADBRAZIL FARMACÊUTICA LTDA. **Deputy General Manager (Brazil), Senior Director of Regulatory Affairs & QP, Head of Regulatory Affairs for LATAM**
Mar/12 – Sep/12	CIE PHARMA SERVIÇOS REGULATÓRIOS E DE NEGÓCIOS LTDA. **Executive Consultant – Pharmaceutical Business & Regulatory Affairs**
Mar/11 – Feb/12	ASTRAZENECA DO BRASIL LTDA **Senior Regulatory Affairs Associate**
Apr/08 – Mar/11	ACHÉ LABORATÓRIOS FARMACÊUTICOS S.A. **International Regulatory Affairs Specialist** Extra: volunteer teacher in company's social responsibility project: professional education for needed students of Guarulhos region (Project "Formare").
Apr/04 – Apr/08	BIOSINTÉTICA FARMACÊUTICA LTDA (an Aché company since 2005) **Regulatory Affairs Specialist**
Jan/03 – Apr/04	SOBRAVIME – *Brazilian Society for Medicines' Surveillance* **Drug Information Center / Trainee**

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PROFISSIONAL BACKGROUND

- **BiocadBrazil (current)**, besides being the company's Technical Responsible Pharmacist (QP equivalent) and deputy General Manager in Brazil, I respond for the company's regulatory strategies in Latin America. **Main activities: A)** Regulatory strategies within business partners in Latin America; **B)** Creation of the importer/distributor structure and quality system, including a complete Quality Control laboratory for the analysis of small molecules; **C)** Public-private partnerships involving biotechnology transfer from Russia to public laboratories in Brazil; **D)** Support to CROs on clinical trials' arms in Brazil and Colombia; **E)** Representation technical meetings in ANVISA, the Ministry of Health and other local health authorities; **F)** Review of technical data (CTD format) and dossier adaptation to ANVISA guidelines; **G)** Participation in technical committees from professional bodies.
- **CIE Pharma** (2012): consultancy to foreign companies to expand their business operations in Brazil and Latin America, advising on feasible business models and potential partners, developing strategies for regulatory applications.
- **AstraZeneca** (2011-2012): responsible for the regulatory intelligence activities; analysis and translation of international technical data (CTD format); and regulatory performance reports to direct managers (KPI's).
- **Aché / Biosintética** (2005-2011): leadership role in exportation-focused projects, analyzing and preparing compliant dossiers to other countries. Expressive reduction of the market authorizations' timelines in LATAM countries (Mexico -60%, Peru -30% and Chile -30%). Support to national and international partners.
- **Sobravime:** cooperation with Brazilian agency ANVISA e the Ministry of Health in pharmacosurveillance projects, research, and production of scientific data. Support to Ad-Hoc consultants of ANVISA's Medicines Technical Chamber (CATEME). Cooperation projects with other Latin health organizations (OPAS, AIS and Mexican Pharmacopeia).

PUBLICATIONS

- 2019 Castro, I. L. ***BIOSIMILARES: aspectos regulatorios y económicos.*** **Revista Farma & Cosmética**, No. 5 (Noviembre, 2019), pp.32-35. F&C Group (F&C, 2019).

- 2011 Moretto, L. D. & Botet, J. ***Knowledge management: the new challenge of the pharmaceutical industry.*** Translated by Castro, I.L. **IPS Newsletter**, Vol. 8, Issue 3 (Sep. 2011), pp.2-3. International Pharmaceutical Federation (FIP, 2011).

- 2008 Bonfim, J.R.A. & Castro, I.L. (2008). ***The market evolution of generic pharmaceutical products in Brazil***. Organized by: P.M., Cavalheiro, J.R. & Casas, C.P.R. (Eds.). Medicines in Brazil: Innovation and Access (pp. 61-78). Rio de Janeiro, BRA: **FIOCRUZ – Oswaldo Cruz Foundation, Brazilian Ministry of Health**. (Available in Portuguese, only).

- 2001 Castro, I.L. et al. ***Microbiological analysis of the health quality status of water from the drinking fountains of Oswaldo Cruz Faculties and Dr. Alarico Silveira Elementary and High School.*** Brazilian Journal of Pharmaceutical Sciences (vol. 37, supl. 2). São Paulo, BRA: Pharmaceutical Sciences' School. Federal University of São Paulo (USP)**.** (Available in Portuguese, only).

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