

Gerardo Lin

Pharmaceutical Chemist (M.Sc.) | EN<>ES Regulatory Documentation Specialist
CMC (CTD Module 3) & Labeling | Biologics & Small Molecules | Latin American Submissions

EXPERIENCE PORTFOLIO

Scientia | Uruguay (UTC-3)
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3.5M+

words of regulatory content since 2021

1.1M

words of biologics CMC

7+

Latin American health authorities, from Mexico to Argentina

15+

years in pharma regulatory documentation

WORK BY DOCUMENT TYPE

CMC / Quality (Module 3, 2.3)	52%
Labeling (CCDS, PI, SmPC, IFU)	17%
Clinical summaries (2.4 to 2.7)	11%
Device technical files	9%
Safety / PV (RMP, PBRER)	8%
GMP, guidelines, other	3%

Share of words since 2021.

WORK BY THERAPEUTIC AREA

Oncology	28%
Endocrinology & metabolism	23%
Reproductive health	19%
Drug delivery devices	9%
Neurology (MS)	7%
Cardiovascular and other	14%

PRODUCT EXPERIENCE INCLUDES

- **Biologics:** monoclonal antibodies, recombinant gonadotropins, somatropin, interferons, VHH antibodies, veterinary vaccines
- **Oncology:** kinase, proteasome and aromatase inhibitors, alkylating agents, antimetabolites
- **Hormones and peptides:** contraceptives, HRT, thyroid hormones, GnRH antagonists, somatostatin analogues
- **Other:** antidiabetics, cardiovascular, antithrombotics, antiepileptics, HCV antivirals, antibiotics
- **Devices and diagnostics:** autoinjectors, pen injectors, ELISA kits, among other product classes

SELECTED TECHNIQUES AND TOPICS

- Peptide and glycan mapping, sialylation, charge variants (iCE, CZE), CE-SDS, MEKC, SE-HPLC
- Potency bioassays, viral clearance, cell culture, Protein A purification
- Method validation, impurities, stability statistics, structure elucidation (NMR, MS)
- Aseptic filling, filter validation, isolators, process validation
- among others

REGULATORY FRAMEWORKS (SELECTION)

Destination authorities: COFEPRIS (Mexico), INVIMA (Colombia), DIGEMID (Peru), ARCSA (Ecuador), ANMAT (Argentina), AGEMED (Bolivia), MSP (Uruguay) and Central American authorities. Reference dossiers prepared for EMA and MHRA.

ICH: M4Q; Q1A to Q1E; Q2 and Q14; Q3A to Q3D; Q5A, Q5C, Q5E; Q6A, Q6B; Q7 to Q12; E2C, E2E.

Regional: EU Variations Regulation and classification guideline; EU GMP Annexes 1, 2 and 15; GVP Modules V and VII; QRD templates; Ph. Eur.; Mexican NOM-059, NOM-072, NOM-073 and NOM-257; Colombian Decree 1782/2014; Central American Technical Regulations (RTCA); WHO and PIC/S GMP.

Devices: EU MDR 2017/745; ISO 13485; ISO 14971; IEC 62366-1; IEC 62304; ISO 11608; ISO 11135 and ISO 10993-7; IMDRF/GHTF STED.

REPRESENTATIVE WORK (ANONYMIZED)

- **Monoclonal antibody (oncology):** Module 3 drug substance and drug product across the initial application and post-approval variations, including cell culture, viral clearance, reference standards and stability statistics. Over 600,000 words, 2021 to 2024.
- **Recombinant gonadotropin:** quality overall summary, analytical procedures (glycan and peptide mapping, MEKC), new aseptic filling line, device change variations and labeling. 2022 to 2025.
- **Oral antidiabetic portfolio:** full EU risk management plan, clinical and nonclinical overviews, Module 3 and DMF variations.
- **Autoinjector combination product:** STED, GSPR checklists, risk management and usability files for the EU, Canada, Australia and the UK.
- **Veterinary biotech CRO:** website content, technical and business proposals written from scratch and translated; terminology standardization across the company's materials.
- **LatAm regulatory guidelines:** INVIMA biologics registration guidelines (90,000 words) and COFEPRIS software as a medical device regulation.

BACKGROUND

M.Sc. in Chemistry (glycan structural elucidation by NMR, MALDI-TOF and HPLC; 5 peer-reviewed papers, including *Glycobiology*). Former Technical Director at a chemical manufacturer: production, quality control, safety data sheets, document management, laboratory design and product registrations. Postgraduate Degree in Translation. Tools: memoQ, translation memory and terminology management, OCR and complex PDF recovery.

Figures from a project log of assignments since December 2020; labeling volume estimated. Products described by class only; no client or confidential data. Lists are representative, not exhaustive.