Roberto CASTILLO

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Quality
&
Regulatory Affairs

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French - Peruvian nationalities

- Keywords -

- Monoclonal Antibodies products: Dupixent®, Kevzara®, Praluent® and Interleukin 33.
- Pre-filled syringes / Aseptic Process
- Manufacturing Single-Use Systems by Millipore-Merck and PALL
- Regulations : ICH Q1A, ICH Q3D,
  <USP> 381, 382, 1381, 1382, 1663, 1664
  [Ph.Eur.] 3.1.3, 3.1.5, 3.1.6, 3.1.15, 3.2.2.1
  <JP> 7.01, 7.02, 7.03
- Regulatory Dossier: BLA, MAA, GSS (e-CTD); Notified Body

Scientific Publications
goo.gl/BPJ6j0
goo.gl/rf7WDW
goo.gl/G4vhqW

Analytical skills
HPLC-DAD-MS,GC-FID-MS, HPLC-GC-FID, GCxGC-MS. Granulometry, Colorimetry, Infrared (IRFT), Turbidimetry, Calorimetry (DSC), Accelerated extraction (ASE).

Other activities
Fitness, French Boxing

PROFILE

- **Ph.D. in Analytical Chemistry and Food Engineering with over 15-years' experience conducting scientific and quality projects.**
- **Risk Assessments on Container-Content compatibility : contact materials analyses during manufacturing and shelf-life of biological products. Clinical & Commercial stage of sterile oral and parenteral solutions.**
- **Strong interpersonal skills : Problem-solving, Motivation, Positive reinforcement Active listening, Curiosity, Teamwork.**
- **Experience in multicultural and cross-functional environments.**
- **Full Professional Proficiency in English, French and Spanish.**

WORK EXPERIENCE

Quality - Regulatory Affairs Coordinator *2017 - 2021*
SANOFI / Altran (Pharmaceuticals) *Normandie, FRANCE*

- Ensuring the scientific robustness and compliance with current regulatory policies: Polymer materials and Medical Devices in Primary Packaging.
- Extractable and Leachable responsible for Monoclonal-antibodies Pre-filled syringes in manufacturing process and primary packaging: evaluation of CAPA and Change Control, review of suppliers' documentation and draft of Risk Assessments.
- Developing new Leachable strategies (30% of cost reduction): Calling for analytical laboratories proposals, verification of quotation, reviewing protocols and approving results.
- Ensuring scientific knowledge and providing scientific support and scientific surveillance to Regulatory affairs team. Preparation of additional information and responses as requested by regulatory agencies.
- Assisting in the preparation, quality control, and submission of Biological License Application (BLA) Marketing Authorization Application (MAA) and Global Simultaneous Submission (GSS) by common technical documents (e-CTD).

Analytical Chemistry Manager *2015 - 2017*
STALLERGENES - GREER (Pharmaceuticals) *Ile-de-France, FRANCE*

- Monitoring and launching stability studies. Following up suppliers' results.
- Analyzing trends of chemical, microbiological and immunological results.
- Executing experimental studies to identify indicator-stability test.
- Implementing KPIs. Managing a 4-person team and $250,000 budget.

Project Coordinator *2009-2014*
INRAE / Claranor SA – McCain / Lesieur (Food Industry) *Paris, FRANCE*

- Managing 4 research projects with a multidisciplinary international team
- Designing and implementing experimental methodologies for Surface disinfection, Stability of emulsion and Twin-screw extrusion.
- Primary Packaging characterization after disinfection (Pulsed light, E-Beam). Identifying and quantifying *Non-Intentionally Added Substances*.
- Providing technical (20% analysis-time reduction) and scientific monitoring.

Quality Engineer *2004-2008*
SODEXO - ARAMARK - FRIO AEREO (Food Industry) *Lima, PERU*

- Monitoring quality compliance system (GMP).
  Implementing quality system (HACCP) validated by SGS. Planning audits.
- Improving processes to reduce canteen access time by 50%.

EDUCATION

- ***Ph.D. in Sciences on Food and Bioproducts: Analytical Chemistry*** *2011 - 2014*
  AgroParisTech *Paris, FRANCE*
- ***M.Sc. Risk analysis of biocontaminants in Food*** *2008 - 2011*
  AgroParisTech *Paris, FRANCE*
- ***Biological and Food Processing Engineering*** *1999 - 2004*
  UNALM *Lima, PERU*