MONICA ESCOBAR, Ph.D., RAC
Monica.escobar@uga.edu

I have over 25 years of experience in the pharmaceutical industry, responsible for the development of CMC regulatory strategy for investigational and marketed products. I have experience with human and veterinary small molecule drugs and with oral formulations, parenteral liquids and drug device combination products, specifically transdermal and topical patches. I was most recently supporting topical and transdermal patches for 15 years and my experience in animal health with Merial also extends into the EU. I have authored the CMC sections of NDAs, NADAs, INDs, DMFs, and ANDAs. I also have experience submitting CMC postapproval changes. I am an assistant professor at the University of Georgia, International Biomedical Regulatory Sciences Program, teaching the online Regulatory CMC and GMP courses. I develop online regulatory course curricula and prepare slides and lectures, contributing to several courses.

WORK EXPERIENCE

University of Georgia, International Biomedical Regulatory Sciences Program
Assistant Professor, 2021 – present

- Instructor for Regulatory CMC & GMP courses.
- Develop online Regulatory course curriculum and slides/lectures.

NDA Group, Jan 2023 – present
Principal Consultant & Consulting Manager
Support pharmaceutical clients with CMC regulatory affairs expertise at all stages of development and commercialization.

Noven Pharmaceuticals, Regulatory CMC & Regulatory Operations, Miami, FL, Jun 2008 – Jan 2023
Senior Director, Regulatory CMC & Regulatory Operations, 2016 - present
Director, Regulatory CMC & Regulatory Operations, 2014 - 2016
Associate Director, Regulatory CMC & Regulatory Operations, 2012 - 2014
Senior Manager, CMC, Regulatory Affairs 2008 - 2012
Responsible for CMC Regulatory Affairs for combination products/transdermal patches in development and commercial. Manage Regulatory Operations group.

- Prepare or review US IND, ANDA, DMF, and NDA CMC eCTD sections for new products.
- Develop filing strategy and prepare postapproval change supplements for marketed oral and transdermal products.
- Represent department on product development project teams.
- Review and approve development and commercial product change controls.
- Lead regulatory operations team responsible for compiling electronic regulatory submissions and managing state licenses and registrations. Manage contractor publishing and electronic FDA submissions. Business administrator for Veeva RIM software.
- Develop strategy, author, review, and compile documents in support of Agency meetings, representing CMC issues.
- Lead cross-functional teams to respond to Agency information requests.
- Work with Business Development to evaluate partner opportunities and answer partner questions.

Merial (formerly a Merck/sanofi-aventis joint venture) 2001 - 2008

Senior Manager, Regulatory, CMC, Duluth, GA, 2005-2008

- Prepare CMC section of worldwide filings for new products (small molecule).
- Represent department on multiple new product development project teams.
- Primary plant and customer contact for CMC changes to marketed products.
- Prepare annual reports and post-approval supplements and EMA variations.
- Serve as CMC expert during negotiations and interactions with regulatory authorities.

Associate Director, Analytical Research & Development, NJ 2004

- Direct development of studies, protocols, and reports for the basis of chemical and pharmaceutical documentation for worldwide registration in accordance with GLP/cGMP and VICH/ICH requirements.
- Led up to 17 scientists to develop and validate analytical methods in support of API development, formulation optimization, safety assessment, clinical trials, and stability studies.
- Manage and maintain project budgets and timelines.

Scientist, Analytical Research & Development, North Brunswick, NJ, 2001-2004

- Support development and marketed product re-formulation, method development, validation, and stability using HPLC, dissolution.
- Represent department on multiple new product development project teams.
- Manage group of analytical chemists, B.S., M.S., Ph.D. levels.

Solvay Pharmaceuticals, Analytical Development, R&D

Research Scientist 1999-2000

Sr. Research Scientist 2000-2001

Procter & Gamble Pharmaceuticals, Product Development

Scientist, Analytical Chemistry 1995 - 1999

EDUCATION

Ph.D., University of Florida, Gainesville, FL Major:Analytical Chemistry
Advisor:James D. Winefordner Thesis topic:Inductively Coupled Plasma - Mass Spectrometry

B.S., Florida Atlantic University, Boca Raton, FL Major:Chemistry, ACS Certification

RELEVANT TRAINING

Six Sigma – Yellow Belt Certification, Noven Pharmaceuticals, 2012
Six Sigma – Green Belt Certification, Noven Pharmaceuticals, 2013

HONORS AND AWARDS

Noven Platinum Award, 2011, 2012, 2015, 2018, 2019, 2022
Noven Presidents Award for Innovation, 2012
Solvay Celebration Award, 2000

CURRENT LICENSURE/CERTIFICATION

Regulatory Affairs Professional Society - Regulatory Affairs Certification