Marco Rossetti

Formulation Scientist
Pharmaceutical & Preclinical Development

Marco joined the pharmaceutical industry as a chemist in 1989 in API manufacturing plants before moving to Quality Control. He moved to Product Development within R&D in 1997 as an analyst and then in Developability & Physical Properties groups, as a solid state specialist. He supported physical-chemical characterization activities on several molecules and drug products at different development phases (from early phase to submission), including process technology transfer for both API and drug product. He was mainly involved in solid state characterization of drug substances and related impact on manufacturing processes and drug product performance throughout all the development phases.

He has experience in applying Quality by Design concepts to API and drug product development and manufacturing, which includes extensive use of risk assessment tools and DoE approaches for process understanding and risk mitigation strategies. He has been actively involved in writing regulatory documentation to support submission of new drug products, and supported FDA pre-approval inspections at commercial manufacturing sites.

Marco is a formulation scientist in the Formulation Development and Material Sciences group within Pharmaceutical & Preclinical Sciences; he is currently involved in preparing formulation strategy, design and execution of experiments and processes for the development and optimization of oral, injectable and inhaled drug products, in addition to process transfer, scale up and supervision of GMP clinical manufacturing.