



International Alliance for
Biological Standardization

Europe



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Experienced CMC executive with 25 years of building and leading cross-functional teams in the biotechnology industry. Skilled in biologics product development, including cell line, cell culture, purification, analytical and formulations development, quality control, scale up, tech transfer, process characterization and validation, selecting/partnering with contract manufacturers, CMC project management, supply chain and logistics. Contributed to 3 commercial (Adcetris, Andexanet alfa, Natrecor) and 24+ clinical programs. Ruby Casareno, PhD, served as SVP, Head of CMC and Technical Operations at Allakos Inc for 5 years taking the lead program from Ph2 to completion of BLA-enabling activities, and phase-appropriate buildup of the CMC team. Prior to that, Ruby supported the approval of Andexa at Portola as Director of Outsourced Manufacturing and MSAT and Adcetris at Seattle Genetics. In addition, Ruby supported 9 clinical programs as Director of Process Devt and Manufacturing at OncoMed. Ruby has been an independent Biologics CMC consultant since 2022, helping clients with their drug development efforts, evaluating/selecting CDMOs, providing Module 3 writing/editing services and performing due diligence. Ruby received her PhD from The Ohio State University and held Postdoctoral Fellowships at Washington University School of Medicine and at UCSF.

