Alpaslan Yaman, Ph.D.

Senior Drug Product Consultant

Core Competencies

- Sterile Formulation
- Due Diligence Audits
- Combo Device Products
- FDA and EMA Experience
- Biotech and Medical Device
- Six Sigma Black Belt
- Blow/Fill/Seal Technology
- Lyophilization

Products

- Redipen®
- Levaquin IV®
- Temodar IV®
- Chirocaine®
- Cypher Drug Eluting Stents

Professional Summary

Dr. Yaman has expertise in sterile and non-sterile formulation development, process development (including automation) and scale-up, validation, technology transfer and technical services. Over the course of his 20+ year career he has scaled up and validated more than 40 products ranging from sterile powders to lyophilized reconstituted products. His expertise includes both traditional and biotech (peptides, proteins, and nucleotide) drugs.

- Gamma irradiation of macromolecules and microwave sterilization,
- Third party manufacturers and service providers in the arena of technical support and quality compliance,
- Novel delivery systems such as liposomes, microspheres, and drug/device combination products.

Dr. Yaman earned his Ph.D. in Pharmaceutical Sciences with a major in Industrial Pharmaceutics and a minor in Physical Chemistry. Prior to consulting, he served as Vice President, Technical Operations and Manufacturing at Edge Therapeutics and as Executive Director, Process Engineering, Worldwide Technical Operations at Johnson & Johnson.

Education

Ph.D.	Pharmaceutical Science	University of Missouri
B.S.	Pharmacy	Drake University
B.A.	Chemistry and Biology	Drake University

Professional Experience

Design Space Inpharmatics, LLC **2019-Present**

Senior Drug Product Consultant

Technical consulting with regards to development and commercialization of complex product and processes, development of quality systems and strategic planning. Skilled negotiator of contracts with suppliers and third-party contract manufacturing service providers.

Edge Therapeutics **2014-2018**

Vice President, Technical Operations and Manufacturing

- Commercial manufacture and supply of both active pharmaceutical ingredients and finished pharmaceutical products worldwide,
- CMC development for all products in the pipeline from early concept through commercialization supporting product development with oversight through IND and NDA filings,
- Negotiations of commercial supply agreements with vendors and contract manufacturing organizations.

Johnson & Johnson, Cordis **2005-2008**

Sr. Research Fellow, Product Support/Technical Services
Executive Director, Process Engineering, Worldwide Technical Operations

- Responsible for three process engineering groups: Drug/Device Combination Products, Cardiology and Endovascular/Neurovascular Device,
- Subject Matter Expert (SME) for drug/device combination products, by leading or supporting directly the product improvement of commercial products,
- Technology transfer through PQ and PPQ of device and drug/device products, and process optimizations for the operational sites in the manufacturing of a wide variety of medical device products.

Schering-Plough **2001-2005**

Director, Pharmaceutical Technology Transfer, Global Technical Services

- Directed technology transfer through the scale-up and validation of sterile and non-sterile liquid and semisolid pharmaceutical products,
- Prepared technology transfer, strategy plans, and GAP analysis for project transfers between development and operations or from one operating Site to another.

Purdue Pharma, L.P. **1999-2001**

Assistant Director, Parenteral Technology Transfer, Parenteral Formulations

- Responsible for parenteral products scale-up and validation group,
- Optimization of complex processes for the manufacture of injectable controlled release formulations,
- Prepared and executed protocols for process and equipment validations (e.g. IQOQPQ).