

Alpaslan Yaman, Ph.D., R.Ph.

ayaman@biopharmadvice.com

(973) 896 8047

CAREER SUMMARY

Ph.D. in Pharmaceutical Sciences and a J&J Certified Process Excellence (6-Sigma) Black Belt. Overall 22 years experience in the biotech, pharmaceutical and medical device industry in sterile and non-sterile formulation development, process development and scale-up, validation, technology transfer and technical services, also experienced with Parenteral facility design and validation. Have scaled up and validated more than 28 products ranging from sterile powders to lyophilized reconstituted products. Have working experience with gamma irradiation of macromolecules, microwave sterilization, and with blow/fill/seal technology. Have working experience with both traditional and biotech (peptides, proteins and nucleotide) drugs and novel delivery systems such as liposomes, microspheres and drug/device combination products. Have served as a task force member in the validation of 2 facilities and am experienced with facilities in Sweden, Switzerland, France, Germany, Austria, Puerto Rico, Ireland and Singapore. In addition, am experienced with preapproval inspections both here in the US and in Europe involving the FDA and the EMA. Have extensive experience with third party manufacturers and service providers both in the arena of technical support and quality/compliance. Have experience with the performance of quality compliance audits (GXP: GCP, GDP, GMP and GLP).

EDUCATION

Ph.D. in Pharmaceutical Science (Major in Industrial Pharmaceutics with minor in Physical Chemistry) from the University of Missouri, Kansas City, Missouri in 1992. BS in Pharmacy in 1987 and BA in Chemistry and Biology in 1984 from Drake University, Des Moines, IA.

EXPERIENCE

QbD Auditing, Inc.

Website: www.qbdauditing.com

(7/09 – Present)

Cofounder – Principal Consultant

This is a newly formed company which is actively working with regulated industries to provide technical assessments and c'GXP audits of all aspects of their operation with recommendations for migration of risk.

Biotech, Pharma & Device Consulting, LLC

Website: www.biopharmadvice.com

(an affiliate of QbD Auditing, Inc.)

(1/09 – Present)

Principal Consultant.

Am providing technical review and input as an independent contract technical resource for the Biotech, Pharmaceutical and Medical Device (with specific emphasis on drug/device combination products) industries. A recognized Subject Matter Expert and Certified Process Excellence (Six Sigma) Black Belt professional with over 22 years of experience in the Pharmaceutical, Biotech and Medical Device Industries whose areas of expertise encompasses formulations, process development, technology transfer, commercialization, regulatory filings and inspections, post market life cycle management and product technical support for most pharmaceutical products with specific expertise in Parenteral product dosage forms of solution, solid and semisolid. Parenteral process experience include lyophilization, aseptic dry powder processes, microspheres, liposomes, suspension and other complex drug delivery systems.

Available experience also encompasses regulatory filings and site inspections in North America, Europe and South East Asia.

ALPASLAN YAMAN, Ph.D.

Page 2 of 6.

Johnson & Johnson

Cordis Corp.

(4/05 – 12/08)

Sr. Research Fellow, Product Support/Technical Services (4/2007 – 12/2008).

Responsibilities included providing base business support as a Subject Matter Expert (SME) for drug/device combination products, by leading or supporting directly the product improvement of commercial products, as well as process optimizations for the operational sites in the manufacturing of a wide variety of medical device products. Prepared project plans and involved with design review, PMA submissions and PAI readiness.

Executive Director, Process Engineering, Worldwide Technical Operations (4/2005 – 4/2007).

Responsible for three process engineering groups: Drug / Device Combination Products, Cardiology and Endovascular/Neurovascular Device. Responsibilities included leading and directing technology transfer through PQ and PPQ of device and drug/device products, as well as process optimizations and base business support for the operational sites in the manufacturing of a wide variety of medical device products. Prepared project strategy plans and involved with design review, PMA submissions and PAI readiness. Served as the Technical Operations representative member on the project team to ensure that the final process was commercially feasible and efficient.

Worked towards the development of a training module to provide a basic pharmaceutical science understanding within the organization to facilitate and drive for future success within the development of drug/device combination products.

Schering-Plough

Kenilworth, NJ

(7/30/01 – 3/31/2005)

Director, Pharmaceutical Technology Transfer, Global Technical Services (7/01 – 3/31/2005).

Responsibilities included leading and directing technology transfer through the scale-up and validation of sterile and non-sterile liquid and semisolid pharmaceutical products. Preparing technology transfer, strategy plans, and GAP analysis for project transfers between development and operations or from one operating Site to another. Served as the Technical Operations representative member on the project team, the CMC sub-team, and the technology transfer team to insure that the final process was commercially feasible and efficient.

Purdue Pharma, L.P.

Ardsley, NY

(8/99 – 7/01)

Assistant Director, Parenteral Technology Transfer, Parenteral Formulations (8/99 – 7/01).

Responsibilities included leading and directing the technology transfer group through the scale-up and validation of parenteral products. Also involved with equipment acquisitions, the writing and reviewing of equipment specifications and related SOPs. Prepared and executed protocols for process and equipment validations (e.g. IQOQPQ). Involved in the optimization of complex processes for the manufacture of injectable controlled release formulations. Involved in the development of the CMC section for NDA and BLA submission and with preapproval inspections.

ALPASLAN YAMAN, Ph.D.

Page 3 of 6.

Novartis Pharmaceuticals, Inc.

E. Hanover, NJ

(5/97- 8/99)

Research Fellow II, Pharmaceutical Development (1/99 – 8/99). Responsibilities included leading and directing a group through the early development, scale-up and validation of liquid pharmaceutical commercial processes (oral liquids and sterile products). Worked with multidisciplinary groups to assess the feasibility of new chemical entities. Involved with the identification of new technologies, equipment acquisitions, and the writing and reviewing of equipment specifications and related SOPs. Prepared and executed protocols for process and equipment validations (e.g. IQOQPQ). Involved in the development of the CMC section for NDA and BLA submission and with preapproval inspections.

Assistant Director, Process Research and Development, Head, Liquids/Technical Life Cycle Management (5/97 - 1/99). Responsibilities included leading and directing the liquids group through the scale-up and validation of liquid pharmaceutical commercial processes (oral liquids and sterile products). Also involved with equipment acquisitions, the writing and reviewing of equipment specifications and related SOPs. Prepared and executed protocols for process and equipment validations (e.g. IQOQPQ). Involved in the development of the CMC section for NDA and BLA submission and with preapproval inspections.

Hoffmann-LaRoche

Nutley, NJ

(4/96-4/97)

Pharmaceutical Process Investigator (Roche manager level), Pharmaceutical Process and Technical Development in the Process and Package Development Department (4/96-4/97). Responsibilities included the scale-up and validation of sterile pharmaceutical commercial processes. Also involved with equipment acquisitions, the writing and reviewing of equipment specifications and related SOPs. Prepared and executed protocols for process and equipment validations (e.g. IQOQPQ). Involved in the development of the CMC section for NDA and BLA submission and with preapproval inspections.

Also involved as the chairman of the Co-Development Team and liaison to the International Project Team from the Pharmaceutical Operations area. This involved the leading of multidisciplinary teams consisting of personnel from all departments associated with bringing products from Phase II through validation and on to launch.

Johnson & Johnson

The R.W. Johnson Pharmaceutical Research Institute

Raritan, NJ

(12/92-4/96)

Senior Scientist, Parenterals, Pharmaceutical Process Development and Technical Service in the Department of Pharmaceutical Development and Technical Service (1/95-4/96) Responsibilities included the scale-up and validation of sterile pharmaceutical commercial processes. Also involved with the set-up, design, and validation of parenteral manufacturing facilities in the US and Europe. Involved in the development of the CMC section for NDA, BLA, and dossier submissions and with preapproval inspections.

Scientist, Parenterals, Pharmaceutical Process Development and Technical Service in the Department of Pharmaceutical Development and Technical Service (12/92-1/95) Responsibilities included the scale-up and validation of sterile pharmaceutical commercial processes. Also involved with the set-up, design, and validation of parenteral manufacturing facilities in the US and Europe. Involved in the development of the CMC section for NDA, BLA, and dossier submissions and with preapproval inspections.

ALPASLAN YAMAN, Ph.D.

Page 4 of 6.

Fujisawa, USA

Melrose Park, IL
(3/92-11/92)

Senior Scientist, Product Transfer of the Corporate Quality Assurance Department (3/92-11/92). Responsibilities included the scale-up and validation of sterile pharmaceutical commercial processes. Also, wrote and executed IQOQPQ equipment protocols for validation of a facility under a Consent Decree. The inspection of facilities for cGMP compliance with participation in the task force for the reconciliation of technical service issues.

OTHER EXPERIENCE

Staff Pharmacist

Kansas City, MO
(9/87-2/92)

Worked as a staff Pharmacist for various hospital and retail settings. Experience proved valuable in understanding how products are used in the clinical and retail settings and provided insight for later commercial product development.

Marion Laboratories

Kansas City, MO
(5/89-8/89)

Graduate Research Intern, responsible for the determination of the collapse temperature for a collagen slurry (artificial skin product) and lyophilization optimization in the pilot and production facility.

Sandoz Research Institute

E. Hanover, NJ
(5/86-10/86 & 5/87-8/87)

Research Intern, responsible for experiments in the development of transdermal and iontophoretic patches for a peptide product. Developed of a computer integrated automated HPLC/diffusion set-up and refined as necessary the required analytical methods.

PUBLICATIONS & PRESENTATIONS

Alpaslan Yaman, "Leveraging Documents in Medical Device Development," Medical Device & Diagnostic Industry (MDDI): Sept. 2009, p.32.

Alpaslan Yaman, "Alternative Methods of Terminal Sterilization for Biologically Active Macromolecules," Current Opinion in Drug Discover & Development (2001) 4:760-763.

Lally Samuel, Monica A. Kwarcinski and Alpaslan Yaman, "Compatibility and Stability of Levobupivacaine Infusion Bags With Fentanyl or Clonidine," American Journal of Health-System Pharmacy. 58(20); 1962-1982, October 15, 2001.

Alpaslan Yaman (1995) "Engineering Considerations in Sterile Powder Processes", Kenneth E. Avis, Sterile Pharmaceutical Products: Process Engineering Applications, INTERPHARM Press.

Alpaslan Yaman (1992) "Process Development for Air-Free Injectables" Dissertation.

Alpaslan Yaman, "Science-Based Product Development", Invited Speaker, New Jersey Pharmaceutical Association for Science and Technology (NJPhAST), Washington Township, NJ (December 2007).

ALPASLAN YAMAN, Ph.D.

Page 5 of 6.

Alpaslan Yaman, "Alternative Methods of Terminal Sterilization", Invited Speaker, International Society of Pharmaceutical Engineers (ISPE) Winter Conference, Tampa, FL (February 2006).

Alpaslan Yaman, "Science-Based Product Development", Invited Speaker, Food and Drug Administration (FDA), Rockville, MD (September 2004).

Alpaslan Yaman, "Alternative Methods of Terminal Sterilization", Invited Speaker, PDA SciTech Summit, Orlando, FL (March 9, 2004).

Alpaslan Yaman, "Science-Based Process Validation", Invited Speaker, 39th Annual Pharmaceutical Technologies Conference at Arden House (AAPS: Jan. 2004).

Alpaslan Yaman, "Alternative Methods of Terminal Sterilization", symposium AAPS Annual Meeting, Toronto, ONT (2002).

Alpaslan Yaman, "Full Scale-up – Liquids", 35th Annual Pharmaceutical Technologies Conference at Arden House Conference (AAPS: Jan. 2000).

Alpaslan Yaman, Robert Butler, and Hirayuki Takashima, "Sparging Optimization for Oxidation Labile Drugs in Parenteral Solutions" AAPS Ninth Annual Meeting (1994).

Alpaslan Yaman and Lester Chafetz, "Process Development for Air-Free Injectables" AAPS Sixth Annual Meeting (1991)

B.A. Clark and A. Yaman, "Calorimetric and Conductimetric Determination of Collapse Temperature of Collagen Co-Precipitates and Application in Lyophilization Development" AAPS Fourth Annual Meeting (1989)

HONORS

Selected as Subject Matter Expert (SME) by International Soc. Pharm Eng. (ISPE: 2007)

Recognized areas of expertise:

1. Pharmaceutical Product Development: pre- formulations, formulations, process development and scale-up (for sterile and non-sterile liquids and semisolid products including controlled release)
2. Tech transfer, Commercialization, Process Validation and PAI Readiness and Support
3. Equipment Qualification, Process Automation and Sterile Manufacturing
4. cGMP, Regulatory Applications (specifically pertaining to CMC sections of IND, NDA, BLAs and PMA)

Sr. Research Fellow – Johnson & Johnson Corporate Office of Science and Technology (2007)

Team Excellence Award – Cordis Corp (2005)

President's Award Schering-Plough Research Institute (2003)

Leadership Awards – AAPS (2000 & 2003)

Member of RHO CHI

Marion Laboratories Fellowship in Pharmaceutical Technology (1989-1990)

Chancellor's Award, University of Missouri-Kansas City (1988-1991)

Marion Laboratories Summer Graduate Research Internship (1989)

NPC Research Intensive Internship - Sandoz Research Institute (1986)

ALPASLAN YAMAN, Ph.D.

Page 6 of 6.

ORGANIZATIONS

American Chemical Society (ACS)

American Association of Pharmaceutical Scientist (AAPS)

Parenteral Drug Association (PDA)

International Society of Pharmaceutical Engineers (ISPE)

New Jersey Pharmaceutical Association of Science and Technology (NJPhAST)

TRAINING

Process Excellence (DMAI²C Certified Blackbelt: J&J)

Lean Champion Training (J&J)

Project Management

OTHER ACTIVITIES

Invited to participate in the ISPE Examination Development Committee for the development of certification examination questions for the CPIP (Certified Pharmaceutical Industry Professional) program.

Referee for manuscripts submitted for publication in Pharmaceutical Research (AAPS) (2003 – 2005)

Vice Chair, Chair-Elect, Chair and Past Chair, Pharmaceutical Technology (PT) Section of American Association of Pharmaceutical Scientist (AAPS) (2001-2005).

Arden House Conference 2000, "Technical Transfer of Pharmaceutical Products from the Laboratory to Commercial Production", Planning Committee Chair (1999-2000)

Chairman of the Paperscreening Committee, Pharmaceutical Technology (PT) Section (AAPS) (1998)

President, Pharmaceutical Sciences Graduate Student Association (PSGSA) (1989-1991).

Voting Member, Graduate Programs & Admission Committee, School of Pharmacy (1989-1991).

Vice President, Pharmaceutical Sciences Graduate Student Association (PSGSA) (1987-1989).