

RALPH TARANTINO, RPh, PhD

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OVERVIEW

Extensive experience in formulation development, clinical manufacturing and drug delivery systems. Sterile Product Subject Matter Expert and Former Head, Sterile Product Formulation Development and Technology Transfer at Roche, Nutley. Peptide/Protein formulation expert. Leadership role in development of 9 marketed products and Sterile Product Head of Sterile Clinical Manufacturing with 7 successful Pre-Approval Inspections Substantial GMP, FDA R&D and manufacturing experience. Advise pharma, legal and investment firms. Technical Team Leader for several projects over 3 year period.

AREAS OF EXPERTISE

- Formulation Development
- Drug Development
- Sterile Products
- Drug Delivery
- Aseptic Processing
- Sustained Release Parenteral
- Clinical Manufacturing
- Development Pharmaceuticals
- Excipients
- IND/NDA
- Inter Partes Patent Review
- Technology Transfer
- Excipient/Package Selection
- Injection Devices
- Solubilization
- Criticality Analysis
- Common Technical Document
- ICH Q 8, 9 and 10
- Patent Infringement/Validity
- Claim Construction
- Expert Reports
- Testimony in Patent Litigation

EXPERIENCE

STERITECH SOLUTIONS LLC, MIDDLETOWN, NJ

Pharmaceutical Consultant and Principal, April 2011 -

Provide technical guidance and report writing to manufacturers, investment firms and legal firms in all aspects of drug product development.

Key Pharma Projects

- Formulation Consultant – Validus (2020)
- CMC Consultant/Writer – Synchrogenix Inc. (2018)
- Primary Packaging for Proteins (2017)
- Microneedles for delivery of peptides/proteins (2017)
- Excipients for sterile dosage forms – lyophilized powders (2016)
- Biopharma Contract Manufacturing Research (2014)
- Therapeutic Area Pipeline Review (2014)
- Webcast Presentation - Drug Delivery Systems for Proteins and Peptides (2014)
- Peptide Excipients and Packaging (2014)
- Technical Writing (QBD) Criticality Analysis – Large and Small Molecules (2012 - 2013)
- Professional Blogging – The Female Patient/Quadrant Communications (2012 – 2013)
- Selection of CMOs (2012)
- Manufacturing Processes for Sterile Products (2012)
- Primary Packaging for Sterile Pharmaceuticals (2012)
- Injection Delivery Devices (2012)
- Business Plan - Web-Based KPO (2011)
- Selecting Target Product Profiles (2011)

Key Patent Litigation Projects

- Patent Consultation: GLP1 Injection Formulation (2020-)
- Patent Consultation: Antihypertensive Injection Formulation (2020-)
- Patent Consultation: Peptide Hormone Injection Formulation (2018-)
 - Opening Report
 - Reply Report
 - Deposition
- Patent Consultation: Prostaglandin Vasodilator Injection Formulation (2019)
 - Opening Report
 - Reply Report
- Patent Consultation: Osmotic Delivery Technology
 - Expert Declaration
- Patent Consultation: mAb Injection Formulation (2017)
- Patent Consultation: Hypoglycemic Agent Injection Formulation (2017)
- Patent Litigation: GLP 1 Analog formulation (2017)
- Deposition: Patent Litigation for Intramuscular Injection Formulation (2016)
- Patent Consultation: Formulation for Diagnostic Product (2016)
- Patent Consultation – Patent Litigation for Diagnostic Product
- Rebuttal Expert Declaration of Ralph Tarantino, Ph.D., Patent for Intravenous Diagnostic Product. (2016)
- Patent Consultation - Sustained Release Hormone Formulation (2016)

- Patent Consultation: Antimicrobial Effectiveness of Injectable Antiarrhythmic Formulations (2016)
- Patent Consultation Hypocalcemic Agent Formulation and Packaging (2015)
- Inter Partes Review: Exendin Analogs and Formulation pH (2015)
- Deposition Patent Litigation: - Fast Disintegrating Tablet Formulations (2015)
- Patent Consultation: Fast Disintegrating Tablet Formulations (2015)
- Testimony at Markman Hearing – Excipients for Peptide Formulations (2015)
- Patent Consultation: Retinoid Formulations in Soft Gelatin Capsules (2014)
- Patent Consultation: Intravenous Antihypertensive Injectable Buffers and Packaging (2014)
- Deposition: Antibiotic Formulation and Packaging (2013)
- Patent Consultation – Antibiotic Formulation and Packaging (2013)

HOFFMANN - LA ROCHE INC., NUTLEY, NJ

Research Director, Global Head Sterile Product Formulation (2009-2011)

Led sterile formulations group (15 scientists and technicians), including GLP and GMP manufacturing and peptide delivery efforts. Evaluated drug delivery systems and devices for investigational and marketed products. Managed international technology transfer, harmonization processes and clinical manufacturing outsourcing for sterile clinical products.

Research Director – Sterile Product Formulation & Clinical Mfg. (2000-2009)

Led sterile formulations and package research group, including GLP and GMP manufacturing. Evaluated drug delivery systems and devices for investigational and marketed products. Managed international technology transfer, harmonization processes and clinical manufacturing outsourcing for sterile clinical products.

Director - Clinical Manufacturing (1995-2000)

Led clinical manufacturing and packaging group for all Roche US clinical supplies, sterile and oral dosage forms. Evaluated drug delivery systems and devices for investigational and marketed products. Founded and led Drug Discovery Support Group. Served as CMC Leader for 3 development programs. Responsible for departmental compliance and directed the Preformulation Group.

Research Leader – Formulation and Toxicology Supply (1994)

Research Investigator – Formulation Development (1992-1993)

Associate Research Investigator – Formulation (1989-1992)

SCHERING-PLOUGH INC. KENILWORTH, NJ***Senior Scientist – Animal Health Formulation (1987-1989)******Scientist – Animal Health Formulation (1985-1987)***

Developed animal health dosage forms and manufactured clinical supplies. Projects included sustained release injectable formulations and a semi-solid otic product. Successfully developed semi-solid product from inception through NADA submission and approval.

HOFFMANN - LA ROCHE INC., NUTLEY, NJ***Associate Scientist – Parenteral Formulation (1981 -1985)***

Developed injectable dosage forms. Successfully reformulated major product in LVP dosage form. Additional experience was gained in oral dosage form development. Successfully reformulated major product to improve oral bioavailability. Special projects included SEG capsule formulation and solubilization of oil soluble vitamins.

KEY INDUSTRY ACHIEVEMENTS

Leadership role in development of 9 marketed products and Sterile Product Subject Matter Expert for Sterile products at Roche Nutley. Global Peptide Delivery Champion. Head of Sterile Clinical Manufacturing with 7 successful Pre-Approval Inspections. Very High success rate for providing clinical batches on time. Extensive FDA interactions and FDA trainer for Biopharmaceutical Formulation and Stability. Leader in international harmonization and Chair International Formulation technology Working Group for Sterile Products. Successful CMC leader.

EDUCATION

St. John's University, Queens, NY

Doctor of Philosophy, Pharmaceutical Sciences

Long Island University, Brooklyn, NY

Bachelor of Science, Magna cum Laude, Pharmacy

New York University, New York, NY

Pre-Professional Coursework

LICENSE

Registered Pharmacist, New York State

HONORS/APPOINTMENTS

- FDA Trainer “Formulation and Stability Evaluation of Therapeutic Proteins”
- Invited Lecturer, American Association of Pharmaceutical Scientists Eastern Regional Meeting, “Technology Transfer for Sterile Dosage Forms”
- Clinical Assistant Professor of Pharmaceutics, Long Island University
- Elected Chair, Basic Pharmaceutical Sciences, Academy of Research and Science, Basic Pharmaceutical Sciences Representative, Education Standing Committee

EXPERT REPORTS

- Reply Report Peptide Hormone Injection Formulation (2019)
- Opening Expert Report for Peptide Hormone Injection Formulation (2018)
- Reply Report for Prostaglandin Vasodilator Injection Formulation (2019)
- Opening Expert Report for Prostaglandin Vasodilator Injection Formulation (2018)
- Expert Declaration for Osmotic Delivery Technology (2018)
- Supplementary Expert Report of Ralph Tarantino, Ph.D. Regarding Infringement of Patent for Sustained Release Hormone Intramuscular Formulation (2016)
- Expert Report of Ralph Tarantino, Ph.D. Regarding Infringement of Patent for Sustained Release Hormone Intramuscular Formulation (2016)
- Expert Declaration U.S. Patent for Antimicrobial Effectiveness of Injectable Formulation (2016)
- Inter Partes Review - U.S. Patent for Antimicrobial Effectiveness of Injectable Formulation Declaration of Ralph Tarantino, Ph.D. (2015)
- Reply Expert Report Of Ralph Tarantino, Ph.D. Hypocalcemic Agent Formulation and Packaging (2015)
- Rebuttal Expert Report of Ralph Tarantino, Ph.D. Hypocalcemic Agent Formulation and Packaging (2015)
- Inter Partes Review of U.S. Patent No. 7,297,761 - Declaration of Ralph Tarantino, Ph.D. Hypocalcemic Agent Formulation and Packaging (2015)
- Responsive Expert Report of Ralph Tarantino, Ph.D. Regarding Non-infringement Of Fast Dissolving Tablet Formulation (2015)
- Inter Partes Review of Lipopeptide Antibiotic Formulation (2015)
- Inter Partes Review - Declaration of Ralph Tarantino, Ph.D. Lipopeptide Antibiotic Formulation (June, 2015)
- Opening Expert Report of Ralph Tarantino, Ph.D. Regarding Infringement Injectable Peptide Formulation (June, 2015)
- Review of Indications for CNS Drug (June, 2015)
- Expert Declaration - Claim Construction for Injectable Peptide Formulation (2014)
- Consultant for Plaintiffs’ Responses To Defendants’ Preliminary Invalidity Contentions - Oral Retinoid Soft Gelatin Capsule Formulation (2014)
- Declaration of Ralph Tarantino on Obviousness– Injectable Peptide Formulation (2014)

- Opposition Expert Report – Injectable Antibiotic Formulation 2014)
- Expert Report Regarding Infringement – Injectable Formulation (2013)
- Declaration on Infringement – Oral Retinoid Soft Gelatin Capsule Formulation (2013)
- Declaration for Claim Construction – Antibiotic formulation and packaging (2013)
- Criticality Analysis Consultant, Johnson And Johnson, Inc., Raritan, NJ - Led international project teams in the criticality analyses of late development and marketed products. Wrote and issued 3 major criticality analyses for small molecule and biotechnology products. (2012 -2013)

PHARMA REPORTS

- Lyophilization – Development Through Tech Transfer, Workshop Leader (20176)
- Review of Indications for CNS Drug (2015)
- Biopharma Contract Manufacturing Report (2014)
- Webcast Presentation - Drug Delivery Systems for Proteins and Peptides (2014)
- Therapeutic Area Pipeline Review (2014)
- Criticality Analysis (QBD) for Small Molecule (2013)
- Criticality Analysis (QBD) for Large Molecule (2013)
- Criticality Analysis (QBD) for Small Molecule (2012)
- Business Plan - Web-Based KPO (2011)

PROFESSIONAL BLOGS

- R.Tarantino. "The Versatile Pharmacist" Pharmacist U Pharmacy Blog, 31Jan2013.Web. <http://www.pharmacistu.com/pharmacy-blog/the-versatile-pharmacist/>
- R.Tarantino. Pharmacy...The Emerging Healthcare Profession" Pharmacist U Pharmacy Blog, 15Jan2013.Web. <http://www.pharmacistu.com/pharmacy-blog/emergence-in-pharmacy/>
- R.Tarantino. "Substitution of Doxil in Ovarian Cancer? There Must Be a Better Way." The Female Patient Quadrant Health Communications, 28 Feb 2012. Web. <http://www.femalepatient.com/blog/post/2012/02/28/Substitution-of-Doxil-in-Ovarian-Cancer?--There-Must-Be-a-Better-Way.aspx>
- R.Tarantino. "Take Two Prozac and Call Me in the Morning"." The Female Patient Blog. Quadrant Health Communications, 10 Feb 2012. Web. <http://www.femalepatient.com/blog/post/2012/02/10/Take-Two-Prozac-and-Call-Me-in-the-Morning.aspx>
- R.Tarantino. "Personalized Medicine is not Everything, It's the Only Thing." The Female Patient Blog. Quadrant Health Communications, 25 Jan 2012. Web. <http://www.femalepatient.com/blog/post/2012/01/25/Personalized-Medicine-Innovation-Isn't-Everything-It's-the-Only-Thing.aspx>
- R.Tarantino. "When a Drug is Not a Medicine." The Female Patient Blog. Quadrant Health Communications, 11 Jan 2012. Web.

<http://www.femalepatient.com/blog/post/2012/01/11/When-a-Drug-is-Not-a-Medicine.asp&xgt>

PUBLISHED ABSTRACTS/PRESENTATIONS/PATENT

- Tarantino, R (2016, April 29). Workshop Leader, “Lyophilization – Development Through Tech Transfer” SMI Workshop, Iselin, NJ
- Tarantino, R. (2014, August 21). Drug Delivery Systems for Peptides and Proteins. Webcast conducted for Gearson Lehrman Group.
- F. Qureshi, Char H, A. Galasso, F. Aberg, Z. Quraishi Z, S. Husain, J. Moschera, S. Del Terzo and R.Tarantino High concentration pegylated peptide solution impacts syringeability; Poster presentation at 2013 AAPS Annual Meeting and Exposition; San Antonio Texas, November 2013.
- F. Qureshi, R. Smith, Z. Quraishi and R.Tarantino. Hydroxypropyl Beta Cyclodextrin enabled IV formulation increases the solubility of HIV Protease Inhibitor and prevents injection site reaction; Poster presentation at 2013 AAPS Annual Meeting and Exposition; San Antonio Texas, November 2013.
- F. Qureshi, R. Smith, R.Tarantino, Z. Quraishi, Development of a lyophilized formulation of a poorly water soluble drug using cyclodextrin inclusion complexation. Poster Presentation at AAPS National Meeting. Washington, DC, October 2011. Published Abstract
- F. Qureshi, S. Zhang, Y. Zhao, B. Wang, R. Smith and R.Tarantino. Cationic liposomes and biomaterials for gene delivery. 37th Annual Meeting and Exposition of the Controlled Release Society, Oregon, July 2010
- F. Qureshi, R. Chari, L. Jiscinszky, R.Smith, R.Tarantino, J. Moschera, and D. Kalonia. Empirical models for predicting solubility enhancement of poorly soluble drugs using cyclodextrin. International Cyclodextrin Symposium, Vienna, May 2010
- F. Qureshi, L. Jiscinszky, R.Smith, R.Tarantino, J. Moschera, S. Zhan and H. Chokshi. Development of an investigational medicinal product using cyclodextrin-case study of compound 1, International Cyclodextrin Symposium, Vienna, May 2010
- F. Qureshi, R.Smith, R.Tarantino, and L. Szent. Comparison of molecular modeling approach and solubility isotherm for preliminary ranking of cyclodextrin enabled formulations, International Cyclodextrin Symposium, Vienna, May 2010
- R.Chari, F. Qureshi, J. Moschera, R.Tarantino, D. Kalonia Development of Improved Empirical Models for Estimating the Binding Constant of a β -Cyclodextrin Inclusion Complex. Pharmaceutical Research. 26, 151 (2009)
- R Payne, R. Nayar, R.Tarantino, S. Del Terzo J. Moschera, J. Die, D. Heilman, B.Bray, M. Manning, C. Henry. Second virial coefficient determination of a therapeutic peptide by self-interaction chromatography. Peptide Science, 84, 527 (2006).

- S.S. Qadry, T.H. Roshdy, H. Char, S. Del Terzo, R. Tarantino, J. Moschera, Evaluation of CZ-resin vials for packaging protein-based parenteral formulations, *International Journal of Pharmaceutics*, 252, 207–212(2003)
- C. Bailey, R. Margolis, A. Railkar, H.K. Sandhu, E. Spence, R.Tarantino, the Discovery -Development Interface: Early Formulation Strategies for Poorly Soluble Small Molecule Therapeutics. Podium Presentation at AAPS National Meeting. Seattle Washington, October 1996. Published Abstract
- R.Tarantino, (1996), US Patent No 5,863,549 US Patent and Trademark Office, Alexandria, Virginia
- C. Bailey, A. Railkar, R.Tarantino. Along the Development Superhighway: At the Interface Between Discovery and Development of Orally Active Small Molecules. Podium Presentation. American Chemical Society Meeting. New Orleans, Louisiana, March, 1996. Published Abstract
- J. Lepore, H.K. Sandhu and R.Tarantino. The Thermal Isomerization of the Vitamin D Analogue Ro 24-2090 and Comparison to Calcitriol and Cholecalciferol. Podium Presentation at AAPS Meeting, Orlando Florida, November 1995 .Published Abstract
- S. Del Terzo, A. Divincenzo, s. Kumar, J. Lepore, R. Margolis, H.K. Sandhu, and R.Tarantino. Effect of Storage and Handling on the Stability of Benzyl Alcohol. Poster Presentation at AAPS Meeting, Orlando Florida, November 1995 .Published Abstract
- C. Bailey, P. Bryla, A. W. Malick, E. Spence and R.Tarantino. The Use of In-Vitro Release Profiles from Disposable Transport Units for Rapid Screening of Semi-Solid Sustained Release Dosage Forms. Podium Presentation at AAPS Meeting, San Diego, California, November, 1994. Published Abstract.
- R.Tarantino, E. Bishop, F. C. Chen, K. Iqbal and A. W. Malick. 8-Methyl-2-Pyrrolidone as a Cosolvent: Relationship of Cosolvent Effect with Solute Polarity and the Presence of Proton Donating Groups on Model Drug Compounds. *J. Pharm. Sci.*, 83, 1213 (1995).
- M. T. Carvajal, P. Gasior, E. M. Phillips, A. Weinrib, R.Tarantino and A. W. Malick. Spray Drying Optimization to Produce Powder for Inhalation. Podium Presentation at AAPS Meeting, San Diego, California, November, 1994. Published Abstract.
- N. H. Shah, A. S. Railkar, F. C. Chen, R.Tarantino, S. Kumar, M. Murjani, D. Palmer, M. H. Infeld and A. W. Malick. A Biodegradable Injectable Implant for Delivering Micro and Macromolecules Using (lactic-co-glycolic) Acid (PLGA) Copolymers. *Journ. Cont. Rel. Soc.*, 27, 139 (1993).
- R.Tarantino, R. Vladyka, A. Cutie, E. Bishop, M. Infeld and A. W. Malick. Evaluation of a Solvent Precipitation Method for Fabricating Poly(lactide-co-glycolide) Biodegradable Implants. Poster Presentation at AAPS Meeting, San Antonio, Texas, November, 1992. Published Abstract.
- N. H. Shah, A. S. Railkar, F. C. Chen, R.Tarantino, S. Kumar, M. H. Infeld and A. W. Malick. A Novel Formulation for a Biodegradable Injectable Implant Using PLGA.

Poster Presentation at AAPS Meeting, San Antonio, Texas, November, 1992.
Published Abstract.

- R.Tarantino, A. Pagan, K. Iqbal and A. W. Malick. Critical Factors for Maintaining Low Oxygen Levels in Sterile Solutions. Poster Presentation at AAPS Eastern Regional Meeting, New Brunswick, New Jersey, June, 1992.
- E. Bishop, R.Tarantino, T. Vangieri and K. Iqbal. Stability of Roferon-A in Dextrose 5% Injection, USP During Preparation and Simulated Administration Using an Ambulatory Infusion Apparatus. Poster at AAPS Eastern Regional Meeting, New Brunswick, New Jersey, June, 1992.
- R.Tarantino, E. Bishop, F. C. Chen, K. Iqbal and A. W. Malick. N-Methyl-2-Pyrrolidone as a Cosolvent: Correlation of Cosolvency Properties with Estimated Partition Coefficients and Deviation from Log-Linear Solubilization. Podium Presentation, AAPS Meeting, Washington, DC, November, 1991. Published Abstract.
- R.Tarantino, S. Negit, K. Iqbal and A. W. Malick. A Rapid Screen for Selecting Chelating Agents for Solution Dosage Forms. Poster Presentation, AAPS Meeting, Las Vegas, Nevada, November, 1990. Published Abstract.
- R.Tarantino, D. W. Adair, S. Bolton. In-Vitro and In-Vivo Release of Salicylic Acid from Povidone/Polydimethylsiloxane Matrices. Drug Dev. Ind. Pharm., 16, 1217 (1990).
- R.Tarantino, D. W. Adair, S. Bolton. In-Vitro and In-Vivo Release of Salicylic Acid from Povidone/Polydimethylsiloxane Matrices. Drug Dev. Ind. Pharm., 16, 1217 (1990).

PROFESSIONAL AFFILIATIONS

American Association of Pharmaceutical Scientists

American Pharmacy Association

Parenteral Drug Association