ANTONIO MORONI, PH.D., M.B.A.
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Experienced, creative, insightful, **Research and Development Scientist** with international credentials, solid business sense, and successful track record solving problems, characterizing materials, coordinating projects, , supporting sales, and evaluating/developing technologies and intellectual property. Effective people skills to bridge cultural differences. Fluent in English and Italian, knowledgeable of Spanish, Portuguese and French. Published over 30 articles on pharmaceuticals chemistry, and polymers. 6 Sigma Advocate. Ten patents.

Areas of expertise

Chemistry and Biomaterials: Sourced, developed and evaluated materials and technologies for use in pharmaceutical and medical device industries. Knowledge of Pharmaceutical processing. Proficiency in FTIR, GC, GPC/SEC^3, HPLC, DSC, TGA, and rheology.

Polymers/ Material Science: Polymer, processing, extrusion, blending, characterization, stability determination, degradation, and optimization for high performance pharmaceutical, coating, and medical applications.

Competences

- **Pharmaceuticals**: Pre-formulation, formulation, excipient uses and performances, solid & semisolid dosage forms, controlled, extended, delayed release systems, absorption enhancement, hydrogels, coatings and process development scale up. API selection and evaluation. CRO supervision.
- **Medical Devices**: Development of vascular prostheses and other implantable devices. Selection and sourcing of materials for disposables. Developed technologies, and supported FDA submissions.
- **Technology**: Surveyed technology landscape for pharmaceutical oral and controlled delivery technologies, assessed technologies of interest, contacted and set up meeting with technology holders, evaluated technology and made recommendation about its use.
- **Intellectual Property**: Evaluation, landscaping, monitoring through Micropatent/Aurigin, of IP issues related to technologies of interest. Support patent applications filing.
- **Management**: Supervised teams of 3-7 scientists. Driven progress on assigned projects. Developed and monitored budgets. Negotiated and executed contracts with various external service providers.
- **Business**: International business development, international coordination, R&D direction and support of marketing/sales, in/out licensing, technology evaluation/ outsourcing.

PROFESSIONAL EXPERIENCE

Proteus Digital Health, Hayward CA *2018- 2018*
Pharmaceuticals and Medical Devices Integration Consultant
Developed IR and CR pharmaceutical tablets containing electronic device to monitor patient compliance with dosing regimen and adjust regimen to individual needs. Supervised CMC operations

- Developed solid dosage forms (tablets) of a number of drugs that could benefit from improved patient compliance. Compliance it is verified by monitoring a radio signal emitted by the device upon assumption.
- Supervised CMC development operations at outside contract research organization
- Equipped small scale pharmaceutical development lab with suitable machinery and instrumentation

Cordis Health, Miami Lakes FL *2016-2017*
Polymer Material Scientist Consultant
Performing feasibility study to develop medical tubings of various materials (PTFE, polyamide copolymer) for the manufacturing of angioplasty catheters.

- Studied materials properties and developed a structure/properties relationship
- Supervised materials characterization laboratory
- Used “Change Order” procedures to implement changes in a regulated environment with the PLM system.

Johnson & Johnson 3D printing Laboratory, Jacksonville FL *2016-2016*
Polymer Material Scientist Consultant
Performed short feasibility study to develop UV curable acrylic resins for 3D printing and coating of medical devices applications capable to withstand repeated autoclave sterilization cycles.

- Tested and evaluated prototypes. Written comprehensive summary report

Becton Dickinson, Franklin Lakes, NJ *2015 – 2016*
Polymer Material Scientist Consultant
Developed low absorption SBR rubber syringe stoppers that maintain drug potency over time. Evaluated UV curable reactive silicone based lubricants for syringe barrels and rubber stoppers to solve drug stability problems that may entail several millions $/year savings.

- Supervised team of technical personnel to develop and implement visual testing evaluation of syringe stoppers performance upon exposure to different challenging conditions.
- Supervised identification and testing of materials currently used in the production of syringes, rubber stoppers, medical tubing and packaging using FT-IR, Raman, DSC, TGA.
- Coordinated drug potency testing activities with other company sites.

The Lubrizol Company, Brecksville, OH *2014- 2015*
Senior Scientist, Life Science Polymers
Used my extensive material science experience to developed new applications for Carbopol (carbomer) and poly(urethane)polymers for topicals, cosmetic creams, films, drug delivery systems, and oral care applications.
- Developed novel carbomer based cream formulation with time extended performances
- Developed Carbopol based sustained release tablet technology for high loading tablets

Becton Dickinson, Franklin Lakes, NJ 2012 – 2014
Polymer Material Scientist Consultant
Evaluated and characterized alternative "green" polymeric materials for medical devices, TPE tubings, adhesives, coatings and packaging used to minimize environmental impact. Supervised polymer characterization laboratory and trained technicians.
- Evaluated performance of current and new materials for sterilized and non-sterilized products in the manufacturing of medical devices used in extrusion and thermoforming processes.
- Supported design validation of new products by analyzing data, writing protocols and test reports.
- Coordinated sterilization and testing activities with other company sites and contractors.

Glaxo SmithKline Consumer Health R&D, Parsippany NJ *2008 –2011*
Manager/Principal Scientist, Dental Care, New Products Development
Lead group of 5 scientists to support existing and develop new products for dental care applications, including cleansers and denture adhesive creams. Supervised development of new products for mouth applications using novel hydrogel bases ingredients, processes and technologies. Applied for one patent.
- Developed a commercial scale extrusion process to produce adhesive creams optimized for dental applications; this allowed the company to recapture an "impaired asset" worth several million dollars.
- Supervised external development (India) of novel synthetic process for polymer with adhesive properties; this new material had significantly better adhesion performance.
- Managed interactions with Basic Research and Manufacturing groups and other sites of GSK Pharma to bring new products ideas (i.e. extrusion) from conception to pilot plant to plant manufacturing trials.
- Implemented Quality by Design and ISO certification approaches to product development resulting in increased scientific excellence in all product development activities during my stay at the company

Kedrion Biopharmaceuticals, Lucca, Italy *2007-2008*
Validation Consultant
Performed validation of blood storage cold chambers. Written validation reports, SOPs and trained workforce.

Mendel Penwest Pharmaceuticals, Patterson, NY *2002-2007*
Principal Scientist, Pharmaceutical Research and New Technologies Development
Directed a team of 4 scientists with the strategic function of extending hydrogel controlled release technology.
- Contributed to gain FDA approval and to launch Opana SR (oral oxymorphone analgesic)
- Identified opportunities for creating or acquiring new technological capabilities from outside providers
- Strengthened company's intellectual property portfolio by furnishing ideas to develop a patent strategy.
- Selected, evaluated and audited API suppliers both in the US and abroad to insure quality of supply

International Specialty Products, Wayne, NJ *1999 –2002*
Manager, Pharmaceutical Research and Development
Supervised pharmaceutical development laboratory in US, Europe and Asia directed toward novel use of pharmaceutical excipients in formulation, cosmetics, drug delivery systems, and coatings. Furnished technical support to marketing. Supervised staff of five researchers. Promoted once. Four patents ISSUED.
- Interacted with worldwide customers to determine needs, suggest new uses for products or technologies, troubleshoot, and support marketing and sales activities that resulted in increased sales.
- Used novel excipients such as Plasdone S-630 to improve performances of pharmaceutical products
- Developed novel coating system for ibuprofen tablets that resulted in shortened manufacturing time.

All these activities resulted in a significant sales increase and the reestablishment of the alginates franchise.

Meadox Medicals, Oakland, NJ *1993 –1999*
Senior Scientist/Polymer Characterization Lab Supervisor
Performed world wide search for new technologies and sources of biocompatible polymers for medical devices. Coordinated efforts on critical project tasks with outside consultants, contractors, and universities, in the US and abroad. Set up and supervised polymer characterization laboratory. Four issued patents.

- Solved critical raw material supply problem by securing agreement with overseas producer that included the development of an extrusion process to produce medical grade materials (PET & ePTFE) for implantable prostheses and sutures.
- Created, developed, patented novel coating and radio-opaque sealing of stents and prostheses.

All these activities contributed to the company being sold for a substantially above market price.

Warner Lambert, Morris Plains, NJ *1988 –1993*

Research Associate

Developed novel solid dosage forms and sustained release formulations. Coordinated research efforts between Pharmaceutical R&D and NOVON biodegradable polymers divisions to apply Extruded Starches in drug delivery. Inventor of record of six discoveries with one patent application published.

- Developed new solid dosage forms for new chemical entities, blockbuster drugs, including sustained release formulations for Lopid, Benadryl, theophylline.
- Developed targeted polymer blends, hydrogels and extrudates to enhance the performance of pharmaceutical solid dosage forms, sustained release systems, and increase drug solubility.

EDUCATION

Postdoctoral Fellow, Polymer Characterization, Polytechnic University, Brooklyn, NY
Ph.D., Organic and Polymer Chemistry, University of Pisa, Italy.
M.B.A., Management and International Business, Seton Hall University, NJ.

PATENTS

- Moroni, A., Adusumilli, P. "Fixatives with High Molecular Weight Polymer". In preparation, 2011 to GlaxoSmithKline Co.
- Zeng, M., Moroni, A., Ketsela, S., Baichwal, A., Goliber, P., McNamara, D. "Controlled release dosage forms incorporating drug solubilization system." US 20070104778A1 May 07, 2007 to Penwest Pharmaceutical Co.
- Moroni, A., Nerella, N.G., Drefko, W., "Pharmaceutical Tablet Coating Composition". US20040001884A1, Jan. 01, 2004, to ISP Investments.
- Moroni, A., Nerella, N.G., Drefko, W.: "Tablet Coating Composition". US Patent 6,620,426 B2, September 16, 2003 and WO 2002098393 A1, December 12, 2002 to ISP Investments, Inc.
- Moroni, A.: "Implantable Prostheses with Improved Mechanical and Chemical Properties." US Patent 7,083,644 B1, August 1, 2006, EP 1299136 A2, April 9, 2003 and WO 0189594 A2, November 29, 2001 to Boston Scientific Ltd.
- Moroni, A., DuBrowny, G., Nerella, N.G.: "Synergistic Filler Composition". US Patent 6,524,617 B1, February 25, 2003 and WO 2003011253 A1, February 13, 2003 to ISP Investments, Inc.
- Moroni, A., Drefko, W.: "pH-dependent Sustained Release, Drug Delivery Compositions." US Patent 6,4650,14 B1, October 15, 2002 and WO 2002076429 A1, October 3, 2001 to ISP Investments, Inc.
- Moroni, A.: "Radiopaque Composition for Visualization of Medical Devices". US Patent 6,426,145 B1, July 30, 2002 and WO 0071182 A1, Nov. 30, 2000 to Scimed Life Systems, Inc.
- D.J. Lentz, G.L. Loomis, A. Moroni, J. DePreker: "Improved Bioresorbable Sealants for Porous Vascular Grafts". EP 0941131 A1, September 15, 1999 and WO 9810804 A1 March 19, 1998 to Meadox Medicals, Inc.
- D.J. Lentz, G.L. Loomis, A. Moroni, J. DePreker: "Bioresorbable Sealants for Porous Vascular Grafts". US Patent 5,851,229, December 22, 1998 to Meadox Medicals, Inc.
- D. Lentz, A. Moroni, K.S. Murthy, G. Radebaugh, M. Fawzi, M. Williams, S.R. Chercury: "Starch Based Controlled Release Compositions". US Patent Application 664173 and WO 92, 15285 A1, September 17, 1992 to Warner-Lambert Company.

PUBLICATIONS & PRESENTATIONS

Peer Reviewed Papers

- Moroni, W. Drefko, G. Thorne; "Formulation of Zero-order, pH-dependent Sustained Release Matrix System by Ionotropic Gelation of alginate containing Mixtures". *Drug Del. Ind. Pharm., Vol. 37(2), 216-224 (2011).*
- M. Rinaudo and A. Moroni; "Rheological behavior of binary and ternary mixtures of polysaccharides in aqueous medium."; *J. Food Hydrocolloids, Vol.23, No.7(Oct. 2009), 1720-28.*
- Moroni and T.J. Havard: "Characterization of Polyesters and Polyamides through SEC and Light Scattering using 1,1,1,3,3,3 Hexafluoro-2-propanol as Eluent". *ACS Symposium Series 731, "Chromathography of Polymers: Hyphenated and Multidimensional Techniques", 249-262, 1999.*
- Moroni: "Computer Optimization of Molecular Mass Distribution in Low Molecular Mass Acrylic Polymers". *International Journal of Polymeric Materials, 43, 89-103 (1999).*
- Moroni and I. Ghebre-Sellassie : "Application of Poly(ethylene oxide) Homopolymers in Sustained Release Formulations". *Drug Dev. Ind.l Pharm., 21(12), 1411-28 (1995).*

- Moroni, J. Mijovic , E.M. Pearce, C.C. Foun : "Cure Kinetic of Epoxy Resins with Aromatic Diamines". *Journal of Applied Polymer Science, 32 (2), 3761, (1986).*
- G. Bellucci, G.C. Berti, R. Bianchini, G. Ingrosso and A. Moroni : "The Steric Course of The Reaction of Ethylene Oxide with Hydrogen Halides in the Gas Phase." *Journal of the Chemical Society, Perkin II, 1336, (1981).*

Industry Presentations

- J. Ahn, A. Moroni; "Semisolid Formulation Strength Improvement through the addition of Silicon Dioxide". *Proc. 2011 AAPS Meeting, October 23-28, 2003 Washington, DC, paper T2236.*
- C. Dullea, D. O'Mullane, D. Grant, J. Biddescomb, A. Moroni and B. Marken; "Evaluation of in-vitro combined food stain plaque model." IADR 2009 Conference, Miami, FL, Paper # 2600.
- H. Zeng, A. Moroni, S. Ali, A. Baichwal; A New Solubilization Formulation for Carvedilol: Alcohol-Free Microemulsion Formed by Vitamin E-TPGS and Lutrol F-127; presented at the *33th Symp. Contr. Rel. Bioact. Mater., July 22-26, 2006, Vienna, Austria.*
- S. Labudzinski, A. Moroni, T. Jaworski, K. Venema, E. Zeijdner; Evaluation of a Novel Polysaccharide-based Drug Delivery System in a Dynamic Dissolution Apparatus; *Proc. 31st Symp. Contr. Rel. Bioact. Mater.*, June 12-16, 2004, Honolulu, HI, USA.
- S. Labudzinski, A. Moroni, T. Jaworski, K. Venema, E. Zeijdner; Evaluating a Novel Gum-based Drug Delivery System in a Dynamic Dissolution Apparatus; *Proc. 2003 AAPS Meeting, October 26-30, 2003 Salt Lake City, UT, paper T3177.*
- I. Wilding, A. Moroni, P. Woodcock, S. Gilday, R. Higgins, A. Baichwal, D. Ball, A. Connor; "Dual-isotope Neutron Activation and Pharmacoscintigraphy to Asses the In-Vivo Performance of an Oral Chronotherapeutic Delivery System"; *Proc. 2003 AAPS Meeting, October 26-30, 2003 Salt Lake City, UT, paper T3189.*
- A. Moroni, P. Woodcock, S. Gilday, R. Higgins, A. Baichwal, D. Ball, I. Wilding. "In-Vivo performance of Chronotherapeutic Drug Delivery System Using Compression Coating of a Polysaccharide Hydrogel Matrix System. " *Proc. 30th Symp. Contr. Rel, Bioact. Mater.*, July 19-23, 2003, Glasgow, Scotland, U.K. Paper presented at the convention.
- A. Moroni, A. Barkley: "Plasdone S-630 as an Additive for Tablets Coatings with Improved Appearance and Performances." *Proc. 2002 AAPS Meeting, November 10-14, 2002 Toronto, Ontario, CA,, Abstract 0577.*
- A. Moroni and W. Drefko: "Applications of alginate mixtures as pH dependent sustained release systems II". *29th International Symposium on Controlled Release of Bioactive Materials,* July 20-25, 2002, Seoul, Korea. Paper presented at the convention.
- W. Drefko and A. Moroni: "Applications of alginate mixtures as pH dependent sustained release systems". *28th International Symposium on Controlled Release of Bioactive Materials*, June 23-27, 2001, San Diego, CA. Paper presented at the convention.
- A. Moroni, N. Nerella, and G. DuBrowny: "Application of Plasdone S-630 mixtures as binders for dry granulation and direct compression". *Pharm. Congress of the Americas*, March 23-27, 2001, Orlando, FL. Paper presented at the convention.
- A. Moroni, N. Nerella, and G. DuBrowny:" Application of Plasdone S-630 as high performance dry granulation binder". *2000 AAPS Meeting*, October 23, 28, Indianapolis, IN, Abstract 2818. Paper presented at the convention.
- Moroni and T.J. Havard: "Characterization of Polyesters and Polyamides through SEC and Light Scattering using 1,1,1,3,3,3 Hexafluoro-2-propanol as Eluent". *Proceedings of the American Chemical Society, Division of Polymeric Materials: Science and Engineering,* 1997 Fall Meeting, Las Vegas, NE, 77, 14-16. Paper presented at the convention.
- A. Moroni and T.J. Havard: "Characterization of Polyesters and Polyamides through SEC and Light Scattering using HFIP as Eluent." *Proceedings of International GPC Symposium 1996, Hotel del Coronado, San Diego, CA, pp. 229-45*. Paper presented at the Symposium.
- Moroni, M. Fawzi, J. Weiss and I. Ghebre-Sellassie: "Application of Poly(ethylene oxide) Homopolymers in Sustained Release Formulations". *Pharm. Res., 6 (9), s-65 Sept 1989*. Presented at the 4th meeting of the American Association of Pharmaceutical Scientists, Atlanta GA (1989).
- A. Moroni, J. Mijovic, E.M. Pearce, C.C. Foun : "Chemoreology of Epoxy Resins with Aromatic Diamines." *Society of Plastic Engineers, 43rd Analytical Tech. Conf.*, Washington DC (1985). Paper presented at the Convention.
- C.C. Foun, A. Moroni, E.M. Pearce, J. Mijovic : "Kinetic Study of Curing Reaction of Epoxy Resins with Aromatic Diamines (II)." *Proc. 13th Ann. NATAS Conf., Philadelphia, PA, 418-23 (1984)*. Paper presented at the Convention.
- C.C. Foun, A. Moroni, E.M. Pearce, J. Mijovic : " Kinetic Study of Curing Reaction of Epoxy Resins with Aromatic Diamines. " *ACS PMSE Preprints, 51,411-20 (1984)*. Paper presented during the 188th meeting of A.C.S. in Philadelphia, PA.

Industry Magazines Articles

- Moroni. A." A Novel Copovidone Binder for Dry Granulation and Direct-Compression Tableting." *Pharmaceutical Technology, Controlled Drug Delivery Supplement*, September 2001.
- A. Moroni: "Copolyvidonium for direct compression tableting." *Life Sciences Today*, February 2000, 21-22.
- Moroni, F. Ciardelli, G. L. Beccaria, E. Taburoni :" Molecular Masses and Their Distribution in Polymers Of Functional Acrylic Monomers Useful for High Solids Coatings." *Pitture e Vernici, 59 (10), 77-84 (1983)*. Paper presented during the Symposium on Paints and Coatings organized by C.N.R. in Milan (Italy) on November 1983.
- C. Carlini, A. Moroni, S. Dal Canto, D. Donati : " Synthesis of Polymeric UV Photoinitiators and Study of Their Efficiency. " *Pitture e Vernici , 59 (10) , 73-76 (1983)* .

Internal Company Presentations

- A. Moroni, L.A. McPherson, M. Mavani, M. P. Lodaya, K. F. Seefeldt, B. E. Frederick, and J. Sienkiewicz; "Semisolids Extrusion Process Optimization and Scale-Up Using Multivariate Analysis". *GSK Process Modelling Conference, June, 8-9th, 2010, Ware, UK.*
- "Plasdone S-630: A Formulation Additive for Improved Tablet Coatings." *ISP Pharmaceutical Technical Bulletin Pharm 0017 10/2003.*