

Erning Xia, Ph.D.

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585-489-2647 (C)

EDUCATION

Ph.D. in Pharmaceutics, University of Iowa

M.S. in Biopharmaceutics, China Pharmaceutical University

B.S. in Pharmacy, Nanjing College of Pharmacy

KEY MARKETED PRODUCTS

Peroxi Clear™	2014
Lotemax Gel (NDA)	2012
Biotrue™ (MPS)	2010
Soothe XH (Xtra Hydration™)	2010
Besivance® (NDA)	2009
Soothe PF	2007
ReNu MPS (MoistureLoc™)	2004
Brimonidine Tartrate (ANDA)	2003
Ciprofloxacin Eye Drop (ANDA)	2001
Collyrium Eye Wash	1999
Preservision Tablet	1998
ReNu MPS (MultiPlus™)	1997



**DISTINGUISHED
RESEARCH FELLOW
CHIEF TECHNOLOGY OFFICER**

PROFESSIONAL EXPERIENCE

Fulcrum International Technologies, Inc., Sep. 2013 – Present, CTO

- Technology Consulting
- Developed water-soluble based nutritional product for eye fatigue (7-Hours™)
- Disinfection technology development for medical devices
- Contact lens related solution developments such as extraction, hydration, packaging, cleaning and comforting
- Eye drop platforms for daily disposable contact lens
- Zero uptake of preservative systems for contact lens applications
- Eye cream/eye drop double action system for treating pulp eyes
- Ophthalmic composition for eye whitening
- Generic Ophthalmic Product developments
- Periocular skin care compositions comprising gentle preservative
- Developed healthy eye lash serum - Sedusoie™

Valeant Pharmaceuticals, Rochester, NY, 2009-Aug. 2013, Program Director/Research Fellow

- Expert in ANDA/505B(2) with QbD Implementation
- Business Development Committee
- Led Vision Care ideation initiatives

- Developed an enhanced and stabilized Hydrogen Peroxide platform with a controlled neutralization profile (Peroxi Clear™)
- Developed Hyaluronan-based multi-purpose solution platform (Biotrue™)
- B+L FDA Design Control Expert.
- Strong interpersonal, negotiation, communication, and problem solving skills.
- Experienced in working with cross-functional teams with demonstrated ability to mentor and develop the necessary leadership skills in the subordinates.
- Proven ability to form credible relationships with clients, and internal peers and subordinates
- Provides technical direction for the development, design, and products integration for customer engagement from definition phase through implementation.
- Applies significant knowledge of industry trends and developments to improve service to our customers.
- Makes sure that company marketing strategy matches capability of R & D.
- Easily recognizes system deficiencies and implements effective solutions.
- Developed an aseptic processing concept for biopolymer(s)

B + L, Rochester, NY. 2006-2008, Site Leader/Research Fellow

- Integrated Jinan (50 FTE's China) R&D and RA into Bausch + Lomb Global R&D and provided technical support and service in following areas – liquid formulation, Vitamin formulation, Q/Q matches, new preservative synthesis, global product registrations in China, global clinical trials etc)
- Established a bilingual SOP system for quality risk management (in China facility)
- Established the very first preservative efficacy testing facility (both USP and EP) in China
- Established an capability of synthesizing drug related compounds for LE family of products
- Established one of the best Vitamin testing facility in China
- Developed and validated product specific analytical methods for each of B + L Preservision products with a precision less than 1.0%
- Established state-of-the-art analytical testing facility and provided services for B & L Global R&D and marketed products in China

B + L, Rochester, NY. 2004-2005, Research Fellow

- Managed GPS (Gentle preservative systems) initiatives in US R&D
- Developed Alginate-based dry eye platform (Soothe™)
- Led dry eye initiatives and dry eye portfolio management (both OTC and Rx)
- Represent R&D at critical senior level meetings with corporate executives as well as external collaboration
- Identify lead formulation candidates and compound selection for clinical development via preformulation studies
- Leader of Globe Supply Strategy Team (API's and Chemicals)
- Developed strategic business partners to discover new technologies related to product developments
- Committee Member of Bausch + Lomb Technical Ladder Committee
- Patent review committees for both pharmaceutical and vision care

B + L, Rochester, NY. 2001-2004, Sr. Principal Formulation Process Scientist

- Managed and prepared Product Development Manuals and CMC sections for NDA and ANDA.

- Managed a development group in the areas of sterile products for eye care markets such as antibiotic, anti-inflammatory, Glaucoma, anti-allergy, artificial tears, ocular lubricants, AMD, contact lens solutions and other nutraceuticals.
- Managed to develop new controlled delivery systems (emulsions, nano-suspensions, In-situ gelling system, implants, tablets, capsules etc.).
- Managed formulation transfer and established specifications based on the capability of the manufacturing process and the analytical methods.
- Heavily involved in multi-functional trouble shooting and problem solving (product recalls, reformulation, de-formulation etc.).
- Developing an opportunistic approach for new category of pharmaceuticals and/or eye care products with increased patentabilities.
- External technology evaluations

B + L, Rochester, NY. 1999-2001, Principal Formulation Process Scientist

- Actively involved in the formulation and development of new products (such as: sustained release solid/liquid dosage forms) for general eye care products and contact lens care products.
- Engaged in the formulation and development of surgical products for general eye care.
- Transferred technology (internationally and domestically).
- Served as a technical liaison between formulation dept., process development dept., manufacturing facilities and QA dept.

B + L, Rochester, NY. 1995-1999, Sr. Formulation Process Scientist

- Actively involved in the formulation and development of parenteral products for general eye care products and contact lens care products.
- Actively involved in the formulation and development of solid and semi-solid form for general eye care products and contact lens care products.
- Actively involved in the searching and research of new disinfectants for ophthalmic dosage forms.
- Good hands-on experiences of developing sterile filtration and bulk sterilization processes for various parenteral products.
- Introduced hands-off cleaning and disinfecting concepts and developed No-rub cleaning and disinfecting solutions for lens care/general eye care products and product strategies.
- Evaluated and developed laboratory/pilot process for scale up and transferred several products to the manufacturing facilities domestically and internationally.
- Served as technical liaison between formulation dept., process development dept. and manufacturing facilities.
- Lead pilot plant experiences and projects for constructing pilot and manufacturing facilities. Authorship of technical evaluation, safety issues, cost estimating and manufacturing procedures.
- Good hands-on experience and knowledge in utilizing state-of-the-art technology and equipment in preformulation/formulation and process development.
- Set up SOP systems for operation of R&D facilities under FDA and ISO-approval operations.

College of Pharmacy, University of Iowa, Iowa City, Iowa, Jan. 1990- 1995, Research and Teaching Assistant

- Worked on different biopharmaceutical projects sponsored by Alcon Laboratories, Inc. and Angelini Pharmaceuticals, Inc., Italy/U.S.A.
- Actively involved ophthalmic preformulation/formulation developments of ocular drug delivery system.

- Developed and performed high throughput pharmacological screening for dry eye drugs using cell culture method (in-vitro) and pharmacokinetics (in-vivo) study in ocular drug delivery using a bioanalytical HPLC assay.
- Successfully discovered a potential drug candidate for dry eye disease (FDA Clinical III).
- Performed animal experiments including corneal and sclera dosing, eye tissue dissection, blood sample collection, corneal permeability determination, and intraocular pressure measurement etc.

Illinois State University, Normal, Illinois, Jan. 1988-Dec. 1989, Research Associate

- Actively involved in isolation, purification and quantification of RNA/DNA from different rat tissues with different diets and ages.
- Five papers published from this study led scientists in this field to a better understand of the relationship between aging process and diet.

College of Pharmacy, China Pharmaceutical University, Aug. 1985-Dec. 1987, Assistant Professor and Research Associate

- Actively involved in teaching and research area related to the preformulation/formulation of solid dosage form of polysaccharide drugs from the traditional Chinese medicines.
- Prepared batch records and performed contract manufacture of batches for evaluating of taste-masking, bioavailability, stability, toxicity, clinical performance.
- Designed models for evaluating biological activities of polysaccharides.
- Evaluated the potentials of using polysaccharides as controlled released materials for anticancer drugs.

HONORS AND AWARDS:

- Awarded as an honored Distinguished Research Fellow at Shandong Institute of Pharmaceutical Research, Jinan, China (2014)
- Bausch & Lomb In Focus Recognition (2010)
- Adjunct Professor of Shandong University, China (2008)
- QiLu Friendship Award (Shandong Government, China, 2008)
- Awarded as an honored Distinguished Research Fellow at Shandong Institute of Pharmaceutical Research, 2008 (Jinan, China)
- Bausch + Lomb CSO Innovation Award, 2007 (Rochester, New York)
- National AWARD-Science Spectrum Trailblazer (2005, Baltimore)
- National EMERALD AWARD-Career Achievement in Industry (2004, Nashville, Tenn.)
- Commitment Awards (2001, Bausch + Lomb)
- President Awards (2001, Bausch + Lomb)
- Focus of Excellence (1995, 96, 97, 98, 99, 00, 01, 02, 03, 04, 05, 06 and 07 Bausch + Lomb)
- Member of the Delta Chapter of the Rho Chi Pharmacy Honor Society (1991)
- Award for the outstanding graduate student thesis (1985)

ORGANIZATIONS:

- American Association of Pharmaceutical Scientists (AAPS)
- The Association for Research in Vision and Ophthalmology (ARVO)
- Sigma Xi Society (American Chemistry Association)
- Parenteral Drug Association (PDA)
- American Chemical Society (ACS)
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HOBBIES:

Free Style Stir-Fry Cooking

Travelling

Basketball

U.S. PATENTS (including patent publications and applications from US and European Patent offices)

1. “Treatment of Contact Lenses with Aqueous Solution Comprising a Biguanide Disinfectant and A Complementary Phosphate-Borate Buffer”, Xia E., J. Roglskyl and L. Simpson (ReNu MPS).

U.S. Patent	6,143,244
World Patent	1999024541 A1
European Patent	1,049,763 B1

2. “Compositions Comprising Polyquaterniums in Combination with Polymeric Biguanides for Disinfecting Contact Lenses”, Xia E. and D. Heiler (ReNu MPS).

U.S. Patent	6,153,568
World Patent	1999024543 A1
European Patent	1030903 A1

3. “Treatment of Contact Lenses with Aqueous Solution Comprising Carbonate Salts for Enhanced Cleaning”, Xia E., L. Simpson and J. Denick,

U.S. Patent	6,309,658 B1
World Patent	1999043363
European Patent	1,030,692 B1

4. “Treatment of Contact Lenses with Aqueous Solution Comprising A Biguanide Disinfectant Stabilized by A Polomamine”, Xia E. and D. Heiler (ReNu MPS).

U.S. Patent	6,309,596 B1.
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5. “Treatment of Contact Lenses with Aqueous Solution Comprising Biguanide Disinfectant Stabilized by Tyloxapol”, Xia E.,

U.S. Patent	6,369,112 B1
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6. “Composition and Method for Inhibiting Uptake of Biguanide Disinfectants by Poly(Ethylene)”, Xia E., R. Smerbeck, J. Denick.,

U.S. Patent	6,514,528 B1
World Patent	2003011350 A2
European Patent	1414303 A2

7. “Composition and Method for Inhibiting Uptake of Biguanide Antimicrobials by Hydrogels”, Xia E., R. Smerbeck,

U.S. Patent	6,528,464 B1
World Patent	2003015835 A1
European Patent	1416976 A1

8. “Reversible Gelling System for Ocular Drug Delivery”, Xia E., R. Smerbeck,

U.S. Patent	6,703,039 B2
World Patent	2002045683 A2

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