

## **LORRAINE L. WEARLEY, Ph.D.**

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### **PROFESSIONAL EXPERIENCE**

2004 – Present: **Lorraine Wearley Consulting LLC**

#### **Consultant and Executive Coach**

- Providing consulting to the Pharmaceutical Industry and support services in the areas of product development, analytical, technical transfer, business development, regulatory affairs, patent litigation, team building and individual coaching.
- Clients have included: Johnson & Johnson, Bristol Myers Squibb, Novartis, Medpointe Laboratories, Winston & Strawn, Lord, Bissel & Brook
- Consulting networks include: SpyGlass Consulting Group, Duck Flats Pharma, Grovewell International, People and Process Solutions

1992 – 2004: **Johnson & Johnson, Family of Companies**

- **Vice President R&D Operations, Personal Products Company (PPC) Management Board Member** 2003 - 2004 Consumer & PPC Worldwide, Skillman, NJ
- **Vice President R&D Regulatory, Analytical, Product Development, PPC Management Board Member** 2000 – 2003, Consumer & Personal Care Research and Development (CPCR&D), Skillman, NJ
- **Vice President Women's Health R&D** 1997 – 2000 PPC, North Brunswick, NJ
- **Executive Director Product Development, Analytical, Research Services, Advanced Care Products Management Board Member** 1994 – 1997, Advanced Care Products, Ortho Pharmaceutical Co, North Brunswick, NJ
- **Director Product Development**, 1992 – 1994 Advanced Care Products, Ortho Pharmaceutical Co, North Brunswick, NJ

**Responsibilities:** Directed the development of Prescription and Over-the-Counter drug products for Women's Health and Dermatology. Led a lean, high performance team of 73 professionals (including, 18 Ph.D.'s, 1 M.D., 1 Attorney) in developing a pipeline of products, for each franchise. Directed a broad range of support functions (Analytical, Microbiology, Toxicology) for all of CPPWW. These functions provided key support for the Women's Health Skin, Wound, Oral, Baby, Kids and Sanitary Protection franchises. Managed a budget of \$11,000,000

## Accomplishments

- Established a leadership position for each Women's Health brand through consistent launch of innovative products and claims. Product forms include the full spectrum: tablets, liquids, creams, gels, suppositories, soft-gelatin capsules, films, lyophilized and confectionary products. Products developed based on physician insight and unmet consumer needs.
- Served as a critical member of PPC Board of Directors, providing scientific input on strategic planning, acquisitions and annual business plans. Provided leadership for roll-out of high performance team training to management and franchise teams supporting the PPC business.
- Revamped the Regulatory function, which supported all of the Consumer Products franchises, including toiletries, devices, and drug products. Hired leaders with professional credentials, and broad experience in Regulatory, as well as other functions. Improved morale and working relationship with teams. Created a Global Regulatory Community with annual meetings and global regulatory requirements accessible on-line. Ensured that the Regulatory strategy was determined with project teams early, so that Product Development cycle time was reduced and product approvals were rapid.
- Excellent track record in obtaining FDA approval in minimum amount of time. Average approval time was decreased by 2 mos over industry average. Initiated and completed thorough training of all functions in GMP's, GLP's, ICH Guidelines, SUPAC, and other FDA Guidances, so that assembly and internal auditing of FDA submissions occurred rapidly within days or weeks, rather than months. Built a relationship with FDA based on mutual respect.
- Provided smooth Technology Transfer and Validation of production processes and analytical methods at manufacturing sites (both J&J, as well as contract sites ). R&D team members assisted with Preapproval Inspections ( PAI's ) and troubleshooting at those sites, therefore, the Technology Transfer process served to establish future success.
- Spearheaded identification, acquisition and implementation of electronic document repository and publishing system. This DOCUMENTUM based system, allows electronic review, signature, publishing and storage of documents required for FDA submission and Release of Product for sale; which will comply with 21 CFR Part 11.
- Functional groups (Clinical, Analytical, Product Development, Regulatory) utilize qualified contract laboratories, manufacturing facilities and consultants to handle peaks in the workload. Staff encouraged to build internal and external relationships to meet business demands and keep themselves competitive. Staff longevity and high morale was accomplished through shared values, and frequent recognition of individual and team contributions.

- Gained Green Belt Certification for applying Six Sigma approach to Optimize Intellectual Property Strategy and Process

1989 – 1992: Principal Scientist, **Schering-Plough Corp, Kenilworth, NJ**

- Developed topical, aerosol metered dose inhalers ( MDI's ) and oral liquid prescription products for antifungals, protein-based immune response modifiers and anti-inflammatory drugs. Prepared and reviewed documents for CMC sections of NDA's.

1972 – 1985: Senior Group Leader, (last position held) **Searle R&D Division, Skokie, IL**

- Directed a group of 25 professionals (4 PhD's) providing analytical support for prescription products, including oral solid and controlled-release dosage forms. Established Analytical Method Validation guidelines utilized globally. Prepared and reviewed analytical documents for CMC sections of NDA's

## **EDUCATION**

Coaching Certification, Hudson Institute of Santa Barbara

Ph.D. in Pharmaceutics, Rutgers University, Thesis Title: "Factors Affecting Reversibility of Iontophoretic Transdermal Transport"

Engineering Management Program, Northwestern University

B.S. in Chemistry, Michigan State University

## **RELATED PROFESSIONAL ACTIVITIES**

2003-Present: Sleep Disorders Research Advisory Board for National Heart, Lung, Blood Institute of National Institutes of Health

1990-Present: Adjunct Professor, Rutgers University

1999-2001: AAPS Finance Committee

1997–2002 and

2004–Present: National Sleep Foundation Board of Directors, President 1998 - 2001

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1993-1994: American Association of Pharmaceutical Scientists (AAPS) Eastern Regional Meeting, Program, Overall Chairperson

## PATENTS

Controlled release composition comprising a sustained release layer and a fast release layer; Lin, S.Y.; Wearley, L. L.; Gole, D.J.; Posage, G.W.; Wilkinson, P.K.; Johnson and Johnson Consumer Companies, Inc.; EP1110541A1, 2001

Personal Lubricant Compositions; Ahmad, N.; Koll, G.E.; Lin, S.Y.; Toddywala, R.; Wearley, L.; Johnson and Johnson Consumer Products, Inc.; US005885591A, 1999

Stable Hydrated Cephalosporin Dry Powder for Oral Suspension Formulation; Johnson, D.A.; Wearley, L.; Galeos, R., Sequeira, J.A.; Schering Corporation EP0642344B1, 1997 and US005599557, 1997

## PUBLICATIONS

Wearley, L., Antonacci, B., Cacciapuoti, A., Assenza, S., Chaudry, I., Levine, N., Loebenberg, D., Norris, C., Parmegiani, R., Sequeira, J., Yarosh-Tomaine, T., Relationship Between Physiochemical Properties, Skin Permeability and Topical Activity of the Racemic Compound and Pure Enantiomers of a New Antifungal, Pharm. Res., 10 (1992) 136-140 .

Wearley, L., Recent Progress in Protein and Peptide Delivery by Noninvasive Routes, Critical Reviews in Therapeutic Drug Carrier Systems, CRC Press, Boca Raton, 8 (1991) 331-394.

Wearley, L., Tojo, K. and Chien, Y.W., A Numerical Approach to study the Effect of Binding on the Iontophoretic Transport of a Series of Amino Acids, J. Pharm. Sci., 79 (1990) 992-998.

Wearley, L. and Chien, Y.W. Iontophoretic Transdermal Permeation of Verapamil (III): Effect of Binding and Concentration Gradient on Reversibility of Skin Permeation Rate, Int. J. Pharm., 59 (1990) 87-94.

Wearley, L. and Chien, Y.W., Enhancement of the In-Vitro Skin Permeation of Azidothymidine (AZT) via Iontophoresis and Chemical Enhancer, Pharm. Res., 1 (1990) 34-40.

Wearley, L., Liu, J.C. and Chien, Y.W., Iontophoresis Transdermal Permeability of Verapamil II: Factors Affecting the Reversibility of Skin Permeability, J. Contr. Rel., 9 (1989) 231-242.

Wearley, L., Liu, J.C. and Chien, Y.W., Iontophoresis Transdermal Permeability of Verapamil II: Factors Affecting the Reversibility of Skin Permeability, J. Contr. Rel., 9 (1989) 231-242.

Wearley, L., Liu, J.C. and Chien, Y.W., Iontophoresis-Facilitated Transdermal Delivery of Verapamil I: In-Vitro Evaluation and Mechanistic Study, J. Contr. Rel., 8 (1989) 237-250.

Chien, Y.W. and Wearley, L., Aids and Chemotherapy, Drugs of Today, 1989, 25(1) 19-25.

Wearley, L., Karim, A., Pagone, F., Streicher, J. and Wickman, A., Food-Induced Theophylline Release/Absorption Changes from Controlled-Release Formulations: A Proposed In Vitro Model, Drug Development and Industrial Pharmacy, 14, 1988, 13-28.

Karim, A., Burns, T., Wearley, L., Streicher, J. and Palmer, M., Food-Induced Theophylline Absorption Changes from Controlled-Release Formulations: Part I, Clin. Pharm. Ther. 38, 1985, 77-83.

Wearley, L. and Anthony, G., Metronidazole, in Analytical Profiles of Drug Substances, Vol. 5, Florey, K. (Editor), Academic Press, 1976 pp. 328-344.

## **PRESENTATIONS**

Coaching with Confucian Values, Hudson Institute Coaches in Training, Nov. 2004.

Wearley, L., Evaluation of Iontophoretic Peptide Delivery Systems, (invited speaker) Insights into Evaluation of Topical and Transdermal Products, UMDNJ, Nov., 1992.

Wearley, L., Antonacci, B., Assenza, S., Chaudry, I., Levine, N., Loebenberg, D., Parmegiani, R., Norris, C., Sequeira, J., Yarosh-Tomaine, T., Relationship Between Physicochemical Properties, Skin Permeability and Topical Activity of a Racemate and Enantiomers of a New Antifungal, AAPS Meeting, 1991.

Wearley, L., Antonacci, B., Loebenberg, D., Norris, C., Parmegiani, R., Chaudry, I., Sequeira, J. and Yarosh-Tomaine, T., Correlation of Results Obtained in a Guinea Pig Dermatophyte Model with In Vitro Skin Permeation Data for Formulations of a New Antifungal, AAPS Meeting, 1991.

Wearley, L., Recent Progress in Protein and Peptide Delivery by Noninvasive Routes, Graduate Seminar, PMA Visiting Scientist Program, Temple University, 1991.

Wearley, L., Biotechnology and Pharmacy: Partners for the Future, Rho Chi Lecture Series, PMA Visiting Scientist Program, Temple University, 1991.

Wearley, L., Difficulties in Determining In Vitro/In Vivo Correlations of a Topical Antifungal, PDD Roundtable Discussion on Criteria in Optimizing Topical Drug Delivery, AAPS Meeting, 1991.

Garcia, C., Chaudry, I., DeCrosta, M., DeFillipo, K., Sequeira, J., Wearley, L., and Wycka, B., Comparative Studies of the Delron and Impaq Cascade Impactors and the Twin Impinger, American Association of Aerosol Research-Annual Meeting, 1991.

Wearley, L. and Chien, Y.W., Enhancement of the In Vitro Skin Permeability of Azidothymidine, AAPS Meeting, 1989.

Wearley, L. and Chien, Y.W., Effect of Binding and Concentration Gradient on the Reversibility of Skin Permeability after Iontophoresis Treatment, NERPA, 1989.

Wearley, L., Liu, J.C., and Chien, Y.W., Factors Affecting Reversibility of Skin Permeability After Iontophoresis Treatment, AAPS Meeting, 1988.

Wearley, L., Liu, J.C. and Chien, Y.W., Iontophoresis-facilitated Transdermal Delivery of Verapamil: In Vitro Evaluation and Mechanistic Studies, AAPS Meeting, 1988.

Wearley, L., Liu, J.C. and Chien, Y.W., Iontophoretic Transdermal Permeation of Verapamil (I): Factors Affecting Reversibility of Skin Permeability, NERPA, 1988

Wearley, L., Karim, A., Koch, R., Houswald, C. and Streicher, J., Animal Model for Studying Food-Induced Absorption Changes from Theophylline Controlled Release Products, 1st Natl. AAPS Meeting, 1986.

Weinrib, A., Chemburkar, P., Burns, T., Karim, A., Streicher, J. and Wearley, L., A Graphical Approach for Determining Theo-24 Dissolution Specifications, APhA/APS Annual Meeting, 1985.

Wearley, L., Karim, A., Pagone, F., Streicher, J. and Wickman, A., In Vitro Model for Explaining the Effect of Food on the Absorption of Theophylline from Oral Controlled Release Products, 12th International Symposium on Controlled Release of Bioactive Materials, 1985.

Wearley, L., Method Validation, A Management Perspective, AOAC Spring Workshop, 1983