JOHN TWIST, Ph.D. MBA

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Morgantown, WV 26505 Email: jntwist@mail.wvu.edu

CAREER SUMMARY

A senior level manager/scientist with over 35 years' experience in business management, applied statistics and the technical aspects of pharmaceutical dosage form development. Experienced in the drug development process from a pharmaceutical sciences perspective, modeling and simulation of business workflows, process improvement/optimization, unit operations for manufacturing drug products and technology transfer. Educating and consulting with scientists in the area of experimental design and data analysis/visualization, including stochastic modeling (Monte Carlo and dynamic simulation methods). Demonstrated ability of collaborating with cross-functional teams and managing high performing work groups. Continue to be significant individual contributor on the technical side of the business. Part Time Lecturer of Statistics at WVU (undergraduate and graduate level courses).

Experience at Mylan has been focused on supporting Product Development and Legal-IP groups with respect to patent analysis and litigation support related to formulation and polymorph patents. Implemented and currently operate/manage a Physical Pharmacy laboratory. Joined Product Development from 2007-2012 to fast-track a high value osmotic pump project and oversaw 6 bioequivalent OROS products, opioid buccal tablets and sustained release matrix tablets of a highly water soluble/high dose product. Eight original ANDA's filed; first Mylan experimental design based QbD ANDA submission (2008). Direct participation in FDA pre-approval inspections and providing responses to FDA Comment Letters and Information Requests.

Experienced in measurement system analysis (MSA), Design of Experiments (DOE), Statistical Process Control (SPC) methods and the ASTM E2810 stratified sampling standard.

CAREER HISTORY

VIATRIS (formerly MYLAN LABORATORIES), Morgantown, WV May 2004 to June 2022
Product Development R&D

Senior Research Fellow, R&D Product Development, 2008 to June 2022

January 2013 (to June 2022) reassigned to prior role as R&D liaise with Legal IP, Project Selection and Government Contract Teams. Work as an individual contributor: project selection team member, provide technical assessments/opinions for FDA information requests on projects pending ANDA approval, technical support of OROS platform with manufacturing Technical Services, tasked with gathering and presenting current information related to Abuse Deterrent Opioid formulations for ANDA development, provide non-clinical statistical support to R&D (small drug molecules and biologics), implementation of a Physical Pharmacy laboratory, coordinate hiring of additional scientific staff, and mentor junior scientists in formulation development.

2008 to 2013
Identify manufacturing technologies, new to Mylan, which increase internal capability and can provide non-infringing products- these include liquid fill encapsulation, hot melt extrusion, spray drying/congealing and push-pull bi-layer tablet osmotic pump technologies. Projects include potent DEA CII drug products. Research team consisted of 4-6 additional scientists.

Director, R&D Strategic Planning (R&D Administration), 2004-2007
Evaluate and monitor the intellectual property environment, with emphasis on formulation, polymorph, and process patents, for current and proposed development projects. Assist in the development of non-infringing formulation strategies for new products. Act as the key liaison between the Product Development Department and Legal Department on all legal matters related to development of new products. Participate on Product Selection Team (Phase 1) providing opinions on potential IP issues. Identify manufacturing technologies, new to Mylan, which increase internal capability and can provide non-infringing products- these include liquid fill encapsulation and technologies to support osmotic pump development (solvent based Wurster coating, bi-layer tableting and laser drilling).

PFIZER GLOBAL RESEARCH & DEVELOPMENT, Ann Arbor, MI / Morris Plains, NJ 1995-2003
Pharmaceutical Sciences.

Director of Business Operations, 1999-2003

Managed twelve direct reports with skills in project management, drug development experience, business administration, industrial statistics and web software development. Member of the site and worldwide pharmaceutical sciences leadership teams.

- Consulted with staff scientists/project teams and Pfizer global manufacturing services in the area of experimental design, data analysis and data visualization to efficiently address technical problems. Web based statistical tools were developed and network software applications established for routine analysis/graphing. Customized educational workshops and courses were developed and deployed.
- Coordinated pharmaceutical sciences activities for a compound project and served as a member of the Anaderm Therapeutic Area Management Team (topicals).
- Collaborated with pharmaceutical sciences leadership to monitor budgets in excess of $100 million and 450 headcount. Information was used to facilitate decisions regarding endorsement of development activities, single point of contact with corporate finance and recruitment based on business need.
- Managed individuals who created, maintained and communicated highly detailed project plans for all compound projects. Plans were used to generate bottoms-up resource estimates. Portfolio views and scenario analysis allowed senior management to make informed decisions on resource allocation, opportunities for workload sharing and ability to meet critical milestones. Dynamic simulation of business workflow identified constrained resources and allowed assessment of policy decisions on resource utilization.
- Developed a web-based metrics “dashboard” which linked all project and resource utilization information. This greatly simplified organizing and locating information for management and project teams.
- Educated both internal and external staff in pharmaceutical sciences workflow to ensure each person had a baseline understanding of business and improve collaboration with interface groups.

Senior Manager of Strategic Planning and Information Systems, 1996-1999
Managed and mentored two direct reports with skills in applied statistics.

- Served as an internal consultant to scientists and project teams in the area of design of experiments, statistical process control and data analysis/visualization.
- Analyzed drug substance and drug product stability data (SAS Proc GLM) to establish tentative specifications and expiration dating. Interacted with regulatory staff and participated in discussions with FDA reviewers.
- Developed and presented a comprehensive course in applied statistical, comprised of over 20 lectures, customized to the needs of pharmaceutical sciences/manufacturing staff.

Senior Research Associate, Technology Development and Assessment, 1995-1996
Managed four direct reports with skills in process technology.

- Characterized, optimized and transferred to manufacturing a hot melt extrusion process. The process dramatically enhanced the bioavailability of a poorly soluble drug. A comprehensive document fully describing the development was drafted and presented to FDA reviewers.
- Worked intimately with the following unit operations: fluid bed granulation, milling, blending, tableting and film coating.

KORSCH PROCESSING LABORATORIES, Somerset, NJ 1994-1995
Contract Manufacturing and Formulation Development.

Director of Contract Manufacturing and Development
Directed all aspects of operating a manufacturing facility and contract development. Managed thirteen direct reports in production and quality control.

- Facility handled blending and tableting operations for nutritional and OTC products. Other unit operations were contracted out. Authored numerous manufacturing SOPs.
- Performed formulation/process development activities for more than ten successful products.

BERLEX LABORATORIES, Wayne, NJ 1990-1994
Formulation and process development of ethical pharmaceuticals. Subsidiary of Schering AG.

Senior Research Pharmacist, 1993-1994
Managed three direct reports with skills in formulation development.

- Developed a sustained release prototype tablet (hydrogel system) using designed experiments.
- Characterized NCEs with respect to physical-chemical properties and excipient compatibility.

Research Pharmacist, 1990-1993
Managed two direct reports with skills in clinical supply manufacturing.

- Managed a GMP manufacturing pilot plant with high shear granulation, milling, drying, blending, tableting, film coating and encapsulation capabilities. Authored numerous manufacturing SOPs.
- Collaborated with manufacturing related to troubleshooting for commercial products.

BRISTOL-MYERS SQUIBB, New Brunswick, NJ 1987-1990
Formulation and process development of ethical pharmaceuticals. Subsidiary of Schering AG.

Research Investigator, Parenteral and Semi-Solid Products, 1988-1990
Manufacturing troubleshooting and process improvement of semi-solid products.

- Performed new equipment qualifications including a triple action mixer system for creams and ointments.
- Manufactured stability batches for re-formulation projects.
- Evaluated various polymers to reduce syneresis of commercial organogel.

Analytical Chemist (Part Time), Solid Dosage Forms, 1987-1988
Performed dissolution and assay testing using HPLC and spectrophotometry. Physical testing such as particle size analysis (sieve/laser diffraction), light microscopy and BET specific surface measurements.

PATHMARK PHARMACY, Supermarkets General Corporation, Woodbridge, NJ 1982-1995
Staff Pharmacist throughout New Jersey stores (part time).

EDUCATION

MBA 2000
Columbia Business School, New York, NY

Master of Science in Applied Statistics 1995
Rutgers University, New Brunswick, NJ

Doctor of Philosophy in Pharmaceutical Science 1989
Rutgers University, New Brunswick, NJ

Master of Science in Pharmaceutical Science 1987
Rutgers University, New Brunswick, NJ

Bachelor of Science in Pharmacy (NJ Pharmacist License 28RI-01704400) 1982
Rutgers University, New Brunswick, NJ

PATENTS/PUBLICATIONS

Patent: Disintegrable formulations of lanthanum carbonate, A. Works, J. Twist, O. Noe. EP 2389070 B1 granted July 2013. US 8,962,036 granted February 2015.

Patent Application: Sustained-release Oral Dosage Forms for Low Aqueous Solubility Compounds, A. Murty, J. Twist, B. Li. WO 2016123482.

Novel Application of Hot Melt Extrusion for the Manufacturing of Vaginal Films Containing Microbicide Candidate Dapivirine, G. Regev, S. Patel, B. Moncla, J. Twist, B. Devlin and L. Rohan. *AAPS PharmSciTech* 20: 239 1-11, 2019.

The Application of Mixture-Process Variable Experimental Design in Evaluating Direct Compression Formulations. C. Zhu, J. Twist, T. Simmons, R. Snee, J. Guess, J. Foster, A. Van Deusen.
Poster presented at 2018 AAPS Annual Convention November 2018. Two journal articles are in preparation which cover this work.

A Spoonful of Sugar; Taste Masking Strategies in Pharmaceutical Development- Part 2, D. Rossi and J. Twist, *American Pharmaceutical Review*, **11,** 53-54, 56-57, 2008.

A Spoonful of Sugar; Taste Masking Strategies in Pharmaceutical Development- Part 1, D. Rossi and J. Twist, *American Pharmaceutical Review*, **10** (6) 52-56, 2007.

X-Ray Powder Diffraction Metrics, G. Runger, K. Canter, J. Twist, D. Rossi, The 2006 International Conference on Bioinformatics and Computational Biology, Paper ID #: BIC4130.

Mixture and mixture-process variable experiments for pharmaceutical applications, C.M. Anderson-Cook, H.B. Goldfarb, C.M. Borror, D.C. Montgomery, K.G. Canter and J. Twist*, Pharmaceut. Statist*., **3**, 247-260, 2004.

Development of an enteric coating formulation and process for tablets primarily composed of a highly water-soluble, organic acid, G. Crotts, A. Sheth, J. Twist and I. Ghebre-Sellassie, *Euro. J. Pharm. and Biopharm.*, **51**, 71-76, 2001.

A model for alcohol-enhanced permeation through polydimethylsiloxane membranes, J. Twist and J.L. Zatz, *J. Pharm. Sci.*, **79**, 28-31, 1990.

The effect of solvents on solute penetration through fuzzy rat skin *in-vitro*, J. Twist and J.L. Zatz, *J. Soc. Cosmet. Chem.,* **40**, 231-242, 1989.

Interaction of vehicles with model skin membranes in the permeation process, Percutaneous Absorption, J. Twist and J.L. Zatz, Second Edition, Edited by R.L. Bronaugh and H.I. Maibach, Dekker, NY, pp. 147-173, 1989.

Membrane-solvent-solute interaction in a model permeation system, J. Twist and J.L. Zatz, *J. Pharm. Sci.*, **77**, 536-540, 1988.

Influence of solvents on paraben permeation through idealized skin model membranes, J. Twist and J.L. Zatz, *J. Soc. Cosmet. Chem.*, **37**, 429-444, 1986.

PROFESSIONAL AFFILIATIONS

American Association of Pharmaceutical Scientists (AAPS) and American Statistical Association (ASA) for over 30 years.

University of Charleston School of Pharmacy (2009-2019). Precepted over 30 students.

West Virginia University Pharmacy School and Chemical & Biomedical Engineering Department.

- Adjunct Faculty Status with Pharmacy and Biomedical Engineering (2018-present).
- Participate in WVU Career Fairs and seminar speaker at both Pharmacy and Engineering Departments.
- Capstone Mentor for Biomedical Engineering Students (5 senior undergraduates per group)
    - 2019-2020: Quantifying water channeling dynamics within osmotic pump tablets.
    - 2020-2021: Dynamic modeling of pharmacokinetics after administration of osmotic pump tablets. Key rates: drug release rate from tablet, absorption rate and elimination rate.
- May 2022: Committee member for Jordan Chapman (BMEG). Doctoral defense approved.
- August 2021 to Present: Part-Time Lecturer in Statistics (STAT-215 and STAT-511)

PROFESSIONAL REFERENCES

Grant Heinicke, Senior Director, Viatris (949) 444-8077 (Retired October 2022)

Thomas Reynolds, Research Fellow, Viatris (513) 522-9636

Cerasela Dinu, Professor Chemical and Biomedical Engineering, WVU (304) 293-9338