

Curriculum Vitae

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CITIZENSHIP: USA

CURRENT POSITIONS

- Principal Scientist, Ethicon Endo-Surgery, A Johnson and Johnson Company
- Adjunct Assistant Professor, Department of Pharmacology & Cell Biophysics, College of Medicine, University of Cincinnati
- Adjunct Faculty, Health Economics and Clinical Outcomes Research, Xavier University

EDUCATION

- University of Cincinnati, College of Medicine, PhD Neuroscience, 2013
Dissertation: *Surrogates, In-Vitro, and Clinical Investigations into the Safety and Effectiveness of Anesthesia*; Advisor: Hong-Sheng Wang
- Purdue University, BS Electrical Engineering, 1999

PROFESSIONAL EXPERIENCE

Ethicon Endo-Surgery (A Johnson and Johnson Company), 2003-Present

Principal Scientist - Sedation, 2010 - Present

Responsibilities and activities: develop and maintain knowledge of the medical and technical/analytical aspects relevant to the sedation franchise; lead scientific studies; develop new sedation related technologies; author clinical trial protocols and final reports; lead technical teams; provide analysis and data management; assess new medical device technologies; author data analysis software; and teach novel sedation medical device theory including literature studies, interacting with academic researchers and key opinion leaders, attending scientific advisory boards, attending scientific conferences and consulting with experts from other operating companies. Serve as the scientific representative on cross-functional teams; prepare clinical evidence reports; provide input into and oversight of preclinical testing protocols; and work with FDA on the Summary of Safety and Effectiveness Data (SSED) and clinical post approval study design.

Department of Pharmacology & Cell Biophysics, College of Medicine, University of Cincinnati, 2014-Present

Adjunct Assistant Professor, 2014 - Present

Responsibilities and activities: teach topics related to clinical pharmacology (including clinical Pharmacodynamics and clinical Pharmacokinetics) in various Pharmacology and Cell Biophysics courses, particularly courses in the department's MSSP (MS in Pharmacology with emphasis on Safety Pharmacology) program; collaborate with College of Medicine faculty on research especially related to novel drugs and devices; and present seminars about jobs in the private sector for students who have earned MS, PhD, and MD degrees in Pharmacology.

Health Economics and Clinical Outcomes Research, Xavier University, 2016-Present

Adjunct Faculty, 2016 - Present

Responsibilities and activities: teach topics related to health and clinical outcomes including literature and data reviews, systematic reviews, and meta-analysis which include teaching hypothesis development, structured research approaches, protocol development, and authoring and summarizing results. Tools taught include different literature database reviews, SAS, and SAS graphics.

Ethicon Endo-Surgery (A Johnson and Johnson Company), 2003-2010

Staff System Engineer, 2005-2010

Responsibilities and activities: led scientific studies; developed new sedation technologies; authored scientific content for clinical trials; led technical teams including international partners in Europe and Asia Pacific; performed analysis and data management; assessed new medical device technologies; authored data analysis software; taught novel sedation medical device theory; developed new proprietary monitoring technologies; worked with marketing to develop product requirements; and worked with the legal department in regards to intellectual property.

Senior System Engineer, 2003-2004

Responsibilities and activities: created a unique system requirement architecture; worked with international teams in Europe and Asia Pacific; managed technical teams; created large-scale system architectures; worked with clinical and regulatory groups for clinical submissions; developed physiological based drug control algorithms; worked with the legal department in relation to intellectual property; and reviewed/applied domestic and international standards targeting UL / CE approval.

Simplehomenet, 2006-2010

Chief Technical Officer, 2006-2010

Responsibilities and activities: developed electrical, software and mechanical engineering of home automation technologies; developed technical product strategies; managed product development; advised marketing and sales; and provided product support.

UMM, 2000-2002

Senior System Engineer, 2002

Responsibilities and activities: served as chief engineer on new products; provided technical management of teams; created and managed schedules; developed system architectures for products; analyzed and reviewed products for function, reliability, safety, and risk management; designed for six sigma practices; developed an ECG algorithm for near real time baseline wander correction; and designed circuits and software for products.

System Engineer, 2000-2001

Responsibilities and activities: developed system architectures; led small teams of five engineers; worked on optical detection systems and electromechanical devices; led design activities for complex electromechanical devices; and developed a predictive model for an optical system including the physical constructs, mathematical models, and the code development.

Software Engineer, 2000

Responsibilities and activities: developed software on a point of care blood analyzer; developed the software and software interfaces to a hospital information system for the blood analyzer; and managed schedules for relevant modules.

Aerotek, 1999

Software Engineer, 1999

Responsibilities and activities: engineered software for medical devices; verified software modules; and developed a software test suite including metrics, logic flows, and automated stub creation.

HONORS AND AWARDS

Johnson and Johnson Standard of Leadership Award 2006

Johnson and Johnson Standard of Leadership Award 2008

Johnson and Johnson Standard of Leadership Award 2009

Johnson and Johnson Standard of Leadership Award 2011

Johnson and Johnson Standard of Leadership Award 2013

MEMBERSHIP IN PROFESSIONAL SOCIETIES

American Society of Anesthesiologists

International Anesthesia Research Society

International Society of Anesthetic Pharmacology

International Society of Pharmacoepidemiology

TEACHING AND ADVISING

Ethicon Endo Surgery:

1. Trained sales team on clinical physiology, device operation, and sales tools.
2. Trained nurses on patient monitoring as recommended by the American Society of Anesthesiologists.
3. Trained nurses on pharmacokinetics and pharmacodynamics of sedatives and analgesics.
4. Taught classes on a novel sedation medical device, including theory and practice.
5. Taught classes on requirement design and product development.
6. Advised designers on physiological algorithm design.

University of Cincinnati:

1. Adjunct Faculty for Seminar, Xavier University, 2016
2. ACLS Education at University of Cincinnati 2015
3. Guest Lecturer for Safety Pharmacology of Biologicals, University of Cincinnati, 2014, 2015, 2016
4. Guest Lecturer at University of Cincinnati, 2011-2014
5. Mentored undergraduate student for summer program, Summer 2011-2012

PRESENTATIONS / SEMINARS

1. 2015 Invited Speaker at the Ohio Dental Society of Anesthesiology Annual Meeting, "The Pharmacology of Anesthetics and Analgesics Used in an Office Based Setting"
2. 2015 Invited Speaker at the Ohio Dental Society of Anesthesiology Annual Meeting, "The Science Behind Office Based Sedation and Anesthesia"
3. 2015 Invited Speaker at the American Dental Society of Anesthesiology Annual Meeting, "The Clinical Pharmacology of Drugs Used in Sedation"
4. 2015 Invited Speaker at the American Dental Society of Anesthesiology Annual Meeting, "Science of Sedation - A Clinical Application of Science"

5. 2015 Global Surgery Group Innovation Conference, Johnson and Johnson – “A novel index of hypoxemia for assessment of risk during procedural sedation”
6. 2014 Audio Interview for Article of the Month for Anesthesia and Analgesia - Part of GME program for Anesthesia and Analgesia (openanesthesia.org)
7. 2013 Invited Faculty Instructor, International Society for Pharmacoepidemiology Annual Conference
8. 2013 Excellence in Science, Johnson and Johnson, Hypoxemia and Cognitive Dysfunction
9. 2013 Nominated Speaker for Neuroscience Retreat, University of Cincinnati
10. 2011 University of Cincinnati Seminar – “Procedural Fear, Pain, and Anxiety: Investigations of Anesthesia and Concomitant Injury”
11. 2010 Physiology and Pharmacology Retreat – “Ionic Cellular Mechanisms for the Brugada Syndrome in Canine Myocytes”
12. 2010 Digestive Disease Weekly – “A Novel Patient Responsiveness Monitor for Minimal / Moderate Sedation”
13. 2008 Presented novel sedation medical device to Johnson and Johnson Global Management
14. 2006 Presented project status to executive global management for Ethicon Endo Surgery.

SKILL SETS

Human Clinical Study:

Protocol and final report ownership and development; design of clinical trials (20 subjects to approximately 9,000 subjects); clinical pharmacology including PK/PD modeling; biological computational modeling; post trial analysis; site initiation; data analysis; GCP; meta-analysis and retrospective studies

Animal Study:

Design of animal studies and IACUC approvals; Good Laboratory Practice; heart and brain isolation; brain slicing; staining and histology; in-vitro extracellular electrical recordings; LTP analysis; quantitative real-time PCR; western blot

Regulatory:

PMA / 510k experience from application to approval; Post Approval Study Designs; FDA panel experience; FDA appeal

Statistics and Data Analysis:

Descriptive Analysis; SQL; Access; ANOVA and derivatives; Non-Parametric Analysis; Image Analysis

Technical:

Algorithmic Development; System Architecture Development; Electrical Design Experience; Mechanical Design Experience including Hydraulic and Fluidics; Requirements Development; Interface Management; Intellectual Property Management; System Risk Management; V&V Planning; Product Concept Development

Software Development:

C / C++; Assembler; Pascal; Fortran; Java / Java Script; HTML / HTML Script; TCL/tk; Networked Environments (Wired, Wireless, Telemetry); Embedded Environments; Desktop Environments; Clustered Systems; Mesh Networks; Unix / POSIX Environments, RTOS, and Windows; software development of software > one million lines of code; Model Driven Architecture Approaches

Management:

Technical direction of teams of up to 25 people; oversight of international and domestic teams; vendor and partner relationships; presentations to clients / management; process development / excellence; Design for Excellence

Regulatory:

Worked with regulatory in the preparation of amendments, submissions, and panel preparation; worked with the FDA on final SSED and post approval study design.

Computer Applications:

Office suite; Requirements management tools (eg. Doors, TCSE); Electrical Cad and Simulation Tools (eg. SPICE); Mechanical Cad Tools (eg. Autocad); Mathematic Tools (eg. Matlab, R, SAS); Software Configuration Management (eg. PVCS, SVN); Issue Tracking Tools; UML Tools (Eclipse and ArgoUML); Software Development (eg. Visual Studio Suite, Eclipse); Graphic Suites (eg. GIMP, Blender, Photoshop); Physiological Simulation (CELLML, NEUROML, NEURON); Graphing (Sigmaplot); Typesetting (LATEX)

PUBLICATIONS

1. Pambianco, Daniel; **Niklewski, Paul J.** (Accepted for Publication). "Computer Assisted and Patient Controlled Sedation Platforms." *Gastrointestinal Endoscopy Clinics of North America*
2. Vargo, John J.; **Niklewski, Paul J.**; Williams, J. Lucas; Martin, James F.; Faigel Douglas O. (2016) "Patient Safety during Sedation by Anesthesia Professionals during Routine Upper Endoscopy and Colonoscopy: An Analysis of 1.38 Million Procedures." *Gastrointestinal Endoscopy*. [Corresponding Author]
3. **Niklewski, Paul J.**; Phero, James C; Martin, James F; Lisco, Steven J. (2015). "A Novel Index of Hypoxemia for Assessment of Risk During Procedural Sedation." *Anesthesia and Analgesia*. [Designated Article of the Month]
4. Wang, Hong-Sheng; Arvanitis, Demetrios A.; Dong, Min; **Niklewski, Paul J.**; Zhao, Wen; Lam, Chi Keung; Kranias, Evangelia G.; Sanoudou, Despina. (2011). "SERCA2a Superinhibition by Human Phospholamban Triggers Electrical and Structural Remodelling in Mouse Hearts." *Physiol Genomics*.
5. Dong, M.; **Niklewski, P.**; Wang H. (2010). "Ionic Mechanisms of Cellular Electrical and Mechanical Abnormalities in Brugada Syndrome." *Am J Physiol Heart Circ Physiol*.
6. Dong, Min; Yan, Sujuan; Chen, Yamei; **Niklewski, Paul**; Sun, Xiaoyin; Chenault, Kathryn; Wang, Hong-sheng. (2010). "Role of the Transient Outward Current in Regulating Mechanical Properties of Canine Ventricular Myocytes." *J Cardiovasc Electrophysiol*.

PATENTS

1. 7,338,470 Air-bubble-monitoring medication assembly, medical system and method
2. 7,935,081 Drug delivery cassette and a medical effector system
3. 7,970,631 Medical effector system
4. 8,146,591 Capnometry system for use with a medical effector system
5. 9,092,559 Drug delivery system with open architectural framework

ABSTRACTS

1. **Niklewski, Paul**; Martin, James (2013). "Hypoxemia and Cognitive Dysfunction" *Excellence in Science, Johnson and Johnson*
2. Vargo, John J; Faigel, Douglas O; **Niklewski, Paul J.**; Martin, James F; Williams, Jeffrey L; Jennifer L Holub (2013). "Safety and Risk Factors for Procedural Sedation in the 21st Century: A Review of Over 2 Million Patients from 2000-2011" *Digestive Disease Week*
3. Kim, Tae Kyun; **Niklewski, Paul**; Egan, Talmage D.; Martin, James; Obara, Shinju; Ogura,

Takahiro (2012). "A Novel, Non-invasive Method to Assess Clinical Sedation States: extending the MOAA/S score with truly noxious stimulation to identify general anesthesia." International Society for Anaesthetic Pharmacology

4. **Niklewski, Paul**; Egan, Talmage; Martin, James (2011). "A Computer-Assisted Personalized Sedation System" Society for Technology in Anesthesia
5. **Niklewski, Paul**; Russell, Lucille J.; Kesler, Julie (2010). "W1518: A Novel Patient Responsiveness Monitor for Minimal / Moderate Sedation." *Gastrointestinal Endoscopy* 71(5): AB348.
6. Weinstein, M. L.; Russell L. J.; Kesler, Julie; **Niklewski, Paul** (2010). "M1401: Level of Sedation and Patient / Clinician Satisfaction." *Gastrointestinal Endoscopy* 71(5): AB211.
7. **Niklewski, P.**; Dong, M.; Wang, Hong-Sheng (2010). "Ionic Cellular Mechanisms for the Brugada Syndrome in Canine Myocytes." *Biophysical Journal* 98 (3, Supplement 1): 360a-360a.
8. Dong, M.; Yan, S.; **Niklewski, Paul**; Chen, Yamei; Wang, Hong-Sheng (2010). "Role of the Transient Outward Current In Regulating Mechanical Properties of Canine Ventricular Myocytes." *Biophysical Journal* 98 (3, Supplement 1): 360a-361a.
9. Pambianco, D.; Vargo, J.; **Niklewski, P.** (2009). "Underreported Sedation Events and Treatment Response During Colonoscopy and EGDs." ACG 2009 Conference.
10. Vargo, J. J.; Pambianco, D. J.; **Niklewski, Paul** (2009). "Hypoxemia Risk Factors During Sedation in ASA I/II Populations for Midazolam- and Propofol-Mediated Sedation for Routine EGD and Colonoscopy." 2009 ACG Conference.

PATENT APPLICATIONS

1. 20130046280 Drug Delivery System with Procedure Stage Based Delivery Adjustment
2. 20130046279 User Interface Feature for Drug Delivery System
3. 20130046197 Docking Station for Patient Bedside Monitoring Units
4. 20110245579 Medical Effector System
5. 20110021978 Drug Delivery System Including a Drug-Container Holder and a Pump Assembly
6. 20100010433 Medical System which Controls Delivery of a Drug
7. 20090292226 Medical System and Method Employing a Drug Delivery Assembly
8. 20090292179 Medical System Having a Medical Unit and a Display Monitor
9. 20090283097 Medical Cannula Assembly for Use with a Patient
10. 20090177146 Apparatus and Methods for Controlling and Automating Fluid Infusion Activities
11. 20070060874 Apparatus and Methods for Controlling and Automating Fluid Infusion Activities
12. 20060081257 Single Use Drug Delivery Components
13. 20060042638 Apparatus for Delivering Oxygen to a Patient Undergoing a Medical Procedure
14. 20040107965 System and Method for Monitoring Gas Supply and Delivering Gas to a Patient

REVIEWS

Adhoc reviewer for:

Anesthesia & Analgesia

World Journal of Gastroenterology