

Michael Plishka | President

ZenStorming™, LLC

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Professional Experience Summary

Founder and President of ZenStorming, a Design and Innovation Consultancy.
Twenty+ years designing, developing and launching medical products

FOCUS ON THE CUSTOMER

Clinical Relationship Builder

Extensive experience in Sterile Environments

Trained clinicians and sales staff on device use in cadaver and mock labs

Established hospital based training programs for engineers

Market Research studies

Product Research = Product Requirements = New Product Directions

Product Complaint Support

Assembled Clinical Advisory Boards to guide product portfolio strategy

Instructional Videos and Label Copy

APPLIED CREATIVITY

Idea Generation

Innovator for Next Generation Products

Product Platform Development

Strategic Technology Planning

Technology Assessment

Intellectual Property Portfolio Development

Expedited Project Feasibility

3D Printing and Prototyping

Product Problem Solving

REGULATORY SPECIALISMS

Presenter at 2008 International Silicone Conference,

“Working with Medical Device Companies – The Essentials”

QSR Procedures (Design Controls, GMP, GLP, etc.)

Validation and testing protocols for new products and processes

Risk Assessment Process development

Authorship of 510 (k) submissions

Engineering Regulatory Compliance

Neuro Corn

PROFESSIONAL EXPERIENCE

ZenStorming Solutions, LLC

4/08 to Present

- Carefusion/BD – New Product Conception/Strategy/Design/Development, Development of Disruptive Innovation Portfolio, Technology Assessment, IP Development, Sales/Clinical Training, Mobile App Story-Boarding, Expert Witness Support
- Hollister – New Product Idea Generation - Brainstorming Moderation
- King Systems (Ambu) – Respiratory Products and Emergency Airway Access, New Product Design/Development
- Surgimatix – Endoscopic Suture Device Development, and Quality System Development
- Hines VA – Electrode Deployment Device Development, Grant Funding and Engineering Support
- AOK Inc. – New Product Development: Thoracic Access, Toy Robot Development
- Ferring Pharmaceuticals – Developed Marketing Awareness Campaign
- Testicular Cancer Society - Developed Marketing Awareness Campaign
- Baxter Healthcare – IP Portfolio Development
- EndoEvolution – Expert Witness (Ethicon EndoSurgery vs. EndoEvolution) Arbitration and Patent Case
- Hologic - Expert Witness (Ethicon EndoSurgery v. Hologic Inc and Suros Surgical Systems, Case No. 1:07-CV-00834)

Baxter Healthcare

6/06 to 4/08

Position: Engineering Specialist; Access Systems Business Unit

- Lead Innovator for generating IP for Next Generation Vascular Access Products resulting in multiple cross platform patent applications in heavily populated patent landscape
- Spearheaded development of resources that enabled manufacture of prototypes in half the time at a cost savings of 50%.
- Determined the feasibility of new IV Access product and benchmarked against key competitive products in six months
- Engineering Lead for Market Research Studies
- Developed relationships with clinicians which resulted in six new hospital sites for engineers to study clinician behaviors.
- Led Clinical Advisory Board Meetings in conjunction with Marketing.
- Drafted business unit plan for World Wide Technology/Product Planning Committees
- Mentor for younger engineers
- Company Representative in off-site college recruitment program.
- Direct Supervisory Responsibility for Junior Engineer

Cardinal Health (Allegiance Healthcare Corporation)

4/99 to 6/06

Position: Engineering Specialist; Special Procedures Business Unit

- Engineering Project Lead driving products from conception through launch while meeting aggressive timelines
- Physician Advisory Board Team Leader for new product development projects
- Technical Expert assessed and recommended new technologies and/or products for business development
- Developed patented, product platforms and line extensions that provided for 35% of all revenues in the Special Procedures business unit.
- Developed training materials and trained Sales Staff and Clinicians on new products in cadaver labs and lecture settings
- Developed and updated Quality System/Design Controls, minimizing documentation volume and time without sacrificing safety (Design Controls, Risk Analysis, GMP, GLP, etc.)
- Authored and performed validation and testing protocols for new products and processes
- Supported 510 (k) regulatory submissions
- Developed company-wide Technical Development Career track for non-degreed Designers/Technicians
- Direct supervisory responsibility for Designer and EDP (Engineering Development Program) Engineer
- Mentor for younger engineers
- Indirect managerial responsibility for cross-cultural Project Team
- Company Representative in off-site college recruitment program.

Manan Medical Products

3/95 to 4/99

Position: New Product Development Engineer

- Worked with clinicians to develop novel and patented catheter products
- Managed manufacturing scale-up through product launch.
- Developed advertising, labeling (instructions), packaging plans and manufacturing procedures for new products.
- Filed and successfully received 510(k) approval on new and modified products.
- Wrote and performed validation and testing protocols for products and processes.
- Head of Engineering Regulatory Compliance Team achieving ISO registration and passing FDA audit with no corrective action taken
- Developed Design Control and Hazard Analysis procedures as per QSR and ISO

Hines VA Hospital/Loyola Medical Center

3/91 to 5/94

Position: Biomedical Engineer

- Developed bi-polar surface electrode for use on perineum.
- Co-developed implantable "mesh" electrode for use on bladder wall.
- Co-designed supra-pubic indwelling catheter for use in bladder studies.
- Generated computer simulation of bladder in cooperation with University of Illinois.
- Co-authored papers which applied research to practical, diagnostic use.

INVENTIONS (Partial List)

US5730724 Drainage Catheter Apparatus
US5989241 Drainage Catheter Apparatus
US 7018343 Biopsy Needle and Device Containing the Same
D478987S Biopsy device
CA2413665 Multi-Use Surgical Cement Dispenser Apparatus And Kit For Same
CA2429357 Improved Paracentesis Device Having Multiple Detachable Components
WO03086201 Improved Biopsy Needle And Biopsy Device Containing The Same
WO03000121 Multi-Use Surgical Cement Dispenser Apparatus And Kit For Same
WO03022337 Improved Paracentesis Device Having Multiple Detachable Components
Curable Material Injection Device-Pending
Curable Material Mixing and Delivery Device -Pending
Paracentesis Device - Pending
Luer Activated Device –Three Patents Pending
Biopsy Devices – Two Pending

EDUCATION

Bachelor of Science Mechanical Engineering

University of Illinois at Chicago

Honors: Phi Eta Sigma for Honor Roll in multiple consecutive semesters

Master of Arts

Loyola University of Chicago

PUBLICATIONS

“Mind Opening Exercise” Illustration in "Lifespan Human Development" (Sigelman, Rider, De George-Walker, 2013)

Walter, J. S., Wheeler, J. S., Zaszczurynski, P., & Plishka, M. "Urodynamic measure of urethral cross-sectional area: Application for obstructive uropathy." *Neurourology and urodynamics* 13.5 (1994): 571-582.

Damaser, M. S., Walter, J. S., & Plishka, M. "Letter." *International Urogynecology Journal* 5.3 (1994): 191-191.

Walter, J. S., Wheeler, J. S., Morgan, C., Zaszczurynski, P., & Plishka, M. "Measurement of urethral compliance in females with stress incontinence." *Engineering in Medicine and Biology Society, 1992 14th Annual International Conference of the IEEE*. Vol. 4. IEEE, 1992.

Walter, J. S., Wheeler, J. S., Morgan, C., Zaszczurynski, P., & Plishka, M. "Measurement of total urethral compliance in females with stress incontinence." *Neurourology and urodynamics* 12.3 (1993): 273-276.

Walter, J. S., Wheeler, J. S., Cogan, S. F., Plishka, M., Riedy, L. W., & Wurster, R. D. "Evaluation of direct bladder stimulation with stainless steel woven eye electrodes." *The Journal of urology* 150.6 (1993): 1990-1996.

HONORS/SKILLS

Presentations:

- Presenter at 2008 International Silicone Conference, "Working with Medical Device Companies – The Essentials"

Awards:

- Received Foster G. McGaw Contribution for Ava-Tex™ Bone Cement Delivery System (2005).
- Received Karl D. Bays New Product Award for development of Temno Evolution Biopsy Device (2004).
- Received Karl D. Bays New Product Award for development of Safe-T-Centesis Drainage System (2003).
- Received Allegiance Innovation Award for development and launch of Ava-Tex™ Bone Cement Delivery System in nine months (2001).
- Received Technical Excellence Award from Technical Council in 2001 and 2003.

ITEMIZED PROJECT EXPERIENCE ADDENDUM

Innovation: Worked with clinicians to design the following:

- Biliary Catheters
- General Drainage Catheters
- Nephrostomy Catheters
- Guide Wire Introducers
- MRI Compatible Biopsy Needles
- Vertebroplasty Systems
 - Delivery System
 - Mixing System
 - Access System
- Repositionable Para/thoracentesis Catheters
- Drainage Systems
- Fully Automatic Breast Biopsy Device
- Catheter Fixation Disk
- Interventional Drainage Bag
- Laryngoscope
- Anesthesia Filters
- Endoscopic Suture Device
- Tissue/Fiduciary Markers
- Surgical Heating Systems
- Introducer Sheaths

Electrodes

- Perineal
- Implantable Woven Mesh

Vascular Access

- Luer Activated Devices

Clinical Procedural Attendance:

- Biopsy
- Vertebroplasty
- PICC Placement
- Kyphoplasty
- Angioplasty/Stent Placement
- Interventional Drainage Catheter Placement
- Interventional Diagnostics
- Vascular Access

Materials Knowledge: Partial list of materials used in product developed:

- Implant grade steels
- MRI Compatible Materials
- Polycarbonate
- Polyurethane
- PMMA
- ABS
- Polypropylene
- Silicones
- PEEK
- Nylon

Innovation Process:

- Improved Brainstorming Processes
- Technical Expert involved in cross-business innovation
- Independent Reviewer of Cross-business products
- IP Generation and Portfolio Management
- Key Opinion/Clinical User Boards

Process Engineering: Manufacturing of the following devices:

- Interventional Drainage Catheters
- Needles
- Hand Held Injectors
- Cement Delivery Tubes
- Hot and Cold Pads
- Drainage Bags
- Guide Wire Catheters
- Luer Activated Devices
- Tissue Markers

Anatomy/Physiology: Working knowledge in the following areas:

- Human physiology
- Spine Mechanics
- Interventional Visualization Systems
- Vascular Biology
- Modelling of Heat Transfer under Anesthesia

Coating/Impregnated Materials: Experience with the following coatings:

- Hydrophilic Coating
- Antimicrobial Silver Coatings
- Parylene & PTFE Coating
- Lubricious materials (Impregnated)
- Antimicrobials (Impregnated)