

## Michael Thomas Vincent Johnson, M.D.

406-209-3039

250 Badger Hill Trail

P.O. Box 106

Willow Creek, MT 59760

### Profile

- President of Philosopher's River llc
- Director of Clinical and Regulatory at Neuralynx, Inc. Brought the ATLAS Clinical Neurophysiology System to market with 510k and CE/MDD.
- Previously a Medical Device Project Manager at Quantel USA. Transferred to manufacture a ¾ million dollar, 2 year duration design project for a complex class II intense pulsed light – laser system for dermatology. Took project from specification through IEC 60601 CE marking and FDA 510(k) approval. See FDA database for k081095. Currently conducting clinical trials using this device.
- Quantitative motor neurophysiologist with extensive technical training and two decades of academic laboratory experience. Fully trained, board eligible neurologist with experience also in neurosurgery, intensive care, and general surgery.
- Biomedical consultant to industry for 15 years.
  - Consultant Medical Director.
  - FDA regulatory submission. Scientific technical writing.
  - Clinical protocol development, IRB applications. Clinical trial monitoring.
  - Marketing literature development. Scientific publication.
  - Reimbursement analyses. Medical cost/benefit modeling. Meta-analysis.
  - Internal Quality System inspections (Internal Quality Auditor Training, Montana State University, 2007). Experience in Internal Audits both to QSIT and ISO 9001.
- Regulatory/Quality Assurance
  - Submission of 510(k)s for Class I *combination devices*, Class III drug delivery devices, and Class II lasers and intense pulsed light devices for dermatology.
  - Produced an FDA mandated, ISO compliant, Quality System for small start up medical device companies (Quality Procedure Manual, Document control, Design control, CAPA, Complaint, Recall, MDR reporting, Training, Validation).
  - Statistical process validation using multivariate regression (Tagushi validation). A coating process comprising 46 inputs and 6 outputs was validated for three product lines.
- Clinical and basic research.
  - Invented, developed and assessed a computerized movement disorder quantification platform at various clinical sites, including NIH (Dr. Mark Hallett), Mayo Clinic (Dr. Eric Ahlskog), and University of Minnesota. Selected sites, developed protocols, consent forms, and documentation for the institutional review boards. Obtained SBIR phase I and II funding for this project.
  - Published clinical trials studying Parkinson's disease, quantitating motor responses to levodopa (Johnson et al., 1991; Johnson et al., 1994; Johnson et al., 1996) at several centers both academic and private (University of Minnesota, Mayo Clinic, Park-Nicollet Clinic).
  - Published extensively on the motor system, based on single unit and optical recording of cerebral and cerebellar motor neurons (Johnson et al., 1999a;

- Johnson et al., 1999b; Johnson et al., 2000; Johnson et al., 2001). Designed and conducted single neuron recording experiments on primates characterizing the representation of movement parameters in various motor areas. Pioneered the optical recording of the frontal motor cortices of alert behaving primates.
  - Skilled in the management of scientists and engineers. Educator to residents, students, and technical staff.
  - Expertise includes psychophysics, applicable to quantitative measurement of pain and occult cognitive processes.
- Medical device research and development.
  - Employed as Senior R&D Research Scientist for 4 years at EMPI, Inc. Continued biomedical device R&D consulting while in academia for a decade. Author of several biomedical device patents.
  - Invented and followed biomedical devices through clinical trials to FDA approval. Products included a proton scavenging iontophoretic drug delivery device and a stimulator for female urinary incontinence.
  - While in industry, awarded grants (Small Business Innovation in Research I and II, totaling \$300,000) and commendations from governor of Minnesota. Awarded EMPI Founder Award.
  - Presented new product concepts to management, performed product evaluation, and researched the market. Evaluated potential product acquisitions.
- Extensive experience and formal training in biostatistics.
  - Conversant with SAS, Systat, GBstat, Statview, Matlab.
  - Frequent user of ANOVA and linear regression methodologies.
  - Knowledgeable of statistical pitfalls and their diagnostics (skewed distributions, collinearity of independent variables)
- Excellent presentation skills, both written and verbal. Over a hundred pages, first authored, in peer reviewed international neurology and neuroscience journals. Invited to speak at international neuroscience meetings.

## Education

University of Minnesota, Minneapolis, MN	Residency	1994	Neurology
University of Minnesota, Minneapolis, MN	M.D.	1983	Medicine
University of Minnesota, Minneapolis, MN	B.A.	1978	Psychology

## Professional Experience

July 2012 to present	President of Philosopher's River llc
July 2011 – July 2012	Director of Clinical and Regulatory, Neuralynx, Inc.
Dec 2006 – July 2011	Medical Device Manager, Big Sky Laser Technologies, now Quantel USA.
June 2006 – Dec 2006	Founded Philosophers River Consultancy: Regulatory and Statistical consulting.
Oct 2004 – June 2006	Vice President of Quality Assurance, Regulatory Affairs, and Clinicals. Bacterin, Belgrade, Montana

- May 2002 – Oct 2004 Consultant, founder of SKUNKWORKS, a research and development partnership. Minneapolis, Minnesota.
- July 1994-May 2002 Assistant Professor / Research Associate, Department of Neuroscience, University of Minnesota  
Pioneered the use of optical recording of neuronal activity in the frontal motor cortices of alert behaving primates. Designed and managed an optical and multi-electrode laboratory.  
Designed and conducted studies characterizing the representation of multiple kinematic parameters in the cerebellum and motor cortex during visuomotor behavior. Published extensively concerning visuo-motor transforms, visuo-spatial transforms, information channel limits to visual processing and movement.
- July 1991-July 1994 Resident, Department of Neurology, University of Minnesota  
Dr. Richard Price MD  
Managed and supervised a team of residents, interns, and students in the neurology programs of four hospitals as Chief Resident.  
Conducted quantitative clinical studies on the motor performance of Parkinsonian subjects designed to detect subtle drug effects.  
Winner of the Shapiro Award for outstanding neurologic research.
- July 1990-Jan 1991 Internship, Department of Medicine, Hennepin County Medical Center  
Dr. David C. Anderson MD
- July 1986-July 1990 Senior Research Scientist, EMPI Inc.  
Donald Maurer PhD, CEO  
Invented and conducted research & development for two product lines: female urinary incontinence devices ([http://www.empi.com/b/b3\\_1.htm](http://www.empi.com/b/b3_1.htm)) and iontophoretic electrodes ([http://www.empi.com/b/b4\\_1.htm](http://www.empi.com/b/b4_1.htm)). Both are profitable components of EMPI's product line.  
Exploratory work in neurologic quantification, wound healing, feedback-controlled electrical muscle stimulation.  
Awarded Small Business Innovation Research Grant I leading to SBIR II with commendation from the state of Minnesota (Governor Carlson).
- July 1985-July 1986 Resident, Department of Neurosurgery, University of Minnesota  
Dr. Shelley Chou, MD PhD
- July 1984-July 1985 Intern, Department of Surgery, University of Minnesota  
Dr. John Najarian, MD
- July 1983-July 1984 Fellow, Electroencephalography, Department of Neurology, University of Minnesota  
Dr. Fernando Torres, MD

### **Society Memberships and Honors**

Phi Beta Kappa; Shapiro Award (Neurological Residency), Society for Neuroscience, Society for Quality Assurance (int).

### **Selected Publications**

Johnson MTV. Summa Thesis. Detection of amplitude modulated three-component signal in noise. August 1978.

Johnson MTV, Kipnis AN, Lee MC, Loewenson RB, Ebner TJ. Modulation of the stretch reflex

during volitional sinusoidal tracking in Parkinson's disease. *Brain* 114: 443-460, 1991. PMID: 2004250

Johnson MTV, Kipnis AN, Lee MC, Ebner TJ. Independent control of the reflex and volitional EMG modulation during sinusoidal pursuit tracking in humans. *Exp Brain Res* 96: 347-362, 1993. PMID: 8270027

Johnson MTV, Mendez A, Kipnis AN, Silverstein P, Zwiebel F, Ebner TJ. Acute effects of levodopa on wrist movement in Parkinson's disease: Kinematics, volitional EMG modulation and reflex amplitude modulation. *Brain* 117: 1409-1422, 1994. PMID: 7820576

Johnson MTV, Kipnis AN, Coltz JD, Gupta A, Silverstein P, Zwiebel F, Ebner TJ. Effects of levodopa and viscosity on the velocity and accuracy of visually guided tracking in Parkinson's disease. *Brain* 119:801-813, 1996. PMID: 8673492

Mason CR, Johnson MTV, Fu Q-G, Gomez JE, Ebner TJ. Temporal profile of the directional tuning of the discharge of dorsal premotor cortical cells. *Neuroreport* 9:989-995, 1998. PMID 9601655

Johnson MTV, Coltz JD, Hagen MC, Ebner TJ. Visuomotor processing as reflected in the discharge of premotor and primary motor neurons. *J Neurophysiol* 81:875-894, 1999. PMID: 10036299

Johnson MTV, Coltz JD, Ebner TJ. Encoding of target direction and speed during visual instruction and arm tracking in dorsal premotor and primary motor cortical neurons. *Eur J Neurosci* 11:4433-4445, 1999. PMID: 10594670

Coltz JD, Johnson MTV, Ebner TJ. Cerebellar Purkinje cell simple spike discharge encodes movement velocity in primates during visuomotor tracking. *J Neurosci* 19:1782-1803, 1999. PMID: 10024363

Johnson MTV, Ebner, TJ. Processing of multiple kinematic signals in the cerebellum and motor cortices. *Brain Res Rev*, 33:155-168, 2000. PMID: 11011063

Coltz JD, Johnson MTV, Ebner TJ. Population code for tracking velocity based on cerebellar Purkinje cell simple spike firing in monkeys. *Neurosci Lett*, 296:1-4, 2000. PMID 11099819

Johnson MTV, Mason CR, Ebner TJ. Central processes for the multiparametric control of arm movements. *Current Opinion Neurobiol*, 11:684-688, 2001. PMID: 11741018

Ebner TJ, Johnson MTV, Roitman A, Fu Q. What do complex spikes signal about limb movements? *The Cerebellum, Recent Developments in Cerebellar Research*, vol 978: 205-18 *Annals of NY Acad Sci*, 2002. PMID:12582054

Roitman AV, Pasalar S, Johnson MT, Ebner TJ. Position, direction of movement, and speed tuning of cerebellar Purkinje cells during circular manual tracking in monkey. *J Neurosci* 40: 9244-57, 2005. PMID: 16207884

Johnson M, Martinson M. Efficacy of electrical nerve stimulation for chronic musculoskeletal pain: A meta-analysis of randomized controlled trials. *Pain* 130:157-165, 2007. PMID:17383095

Martinson M, Johnson, M. Cost-effectiveness of Treatments for Low Back Pain. *Practical Pain Management*, 2011; April: 23, 32-37, 91.

## Invited Talks

- 1994 Neurology Research Conference, Shapiro Award, Minneapolis, MN. Defect in the coordination of volitional and reflexive control systems in parkinsonism.
- 1997 Human Science Frontiers, Annual Conference, Minneapolis, MN, Visuomotor processing as reflected in the discharge of premotor and primary motor neurons.
- 1998 ATR Symposium, Kyoto, Japan, Encoding of target direction and speed during visual instruction and arm tracking in dorsal premotor and primary motor cortical neurons.
- 1999 European Behavioral Brain Society Meeting, Rome, Italy, Processing of multiple kinematic signals in the cerebellum and motor cortices.
- 2000 Neuroscience Colloquium, Minneapolis, MN, Visuomotor Transform: Multiplex and Cinemplex.

## Patents

- 2007 application "Medical device including a bioactive in a non-ionic and an ionic form and methods of preparation thereof.
- 2006 application "Method by which the ratio of freebase and freebase salt may be controlled to tailor the temporal elution profile from a medical device".
- 2005 application 20070167979 "Wound drain removal device"
- 2005 application "Angiogenic composition of demineralized bone".
- 2005 application "Tactile stimulator with kinematic inputs".
- US 4,964,411 "Evoked EMG signal processing" (referenced by 10 US patents)
- US 4,881,526 "Electrode and stimulation system for control of urinary incontinence" (referenced by 30 US patents)
- US 4,973,303 "PH buffered electrode for medical iontophoresis" (referenced by 18 US patents)
- US 5,263,489 "Relative electromyographic muscle reflex activity during motion"
- D 348,934 "Incontinence electrode"
- E 33.12-0100 "External loading in neurological motor deficient quantification"

## Abstracts

- Johnson MTV, Kipnis AN. Topography of the reflex evoked agonist-antagonist EMG activity as reflected in the dynamic compliance of the wrist. American Academy of Clinical Neurophysiology, 1987.
- Johnson MTV, Kipnis AN, Lee MC, Ebner TJ. Modulation of the stretch reflex during sinusoidal tracking in parkinsonism. Soc Neuroscience Abstracts, 6, 1989.
- Johnson MTV, Kipnis AN, Lee MC, Ebner TJ. Defect in the coordination of volitional and reflexive control systems in parkinsonism. First International Congress of Movement Disorders Abstract, 1990.
- Johnson MTV, Kipnis AN, Ebner TJ. Independence of reflex and volitional EMG modulation during sinusoidal tracking in normals. Soc Neuroscience Abstracts, 8, 1991.
- Johnson MTV, Amrami K, Kipnis AN, Mendez A, Poppele R, Ebner TJ. Stretch reflex modulation during sinusoidal tracking in cerebellar ataxia. Soc Neuroscience Abstracts, 10, 1993.
- Johnson MTV, Mendez A, Kipnis AN, Silverstein P, Zwiebel F, Ebner TJ. Acute effects of levodopa on wrist movement in Parkinson's disease: kinematics, volitional EMG modulation, and reflex amplitude modulation. Soc Neuroscience Abstracts, 11, 1994.
- Johnson MTV, Mendez A, Kipnis AN, Silverstein P, Zwiebel F, Ebner TJ. Acute effects of levodopa on wrist movement in Parkinson's disease: kinematics, volitional EMG modulation, and reflex amplitude modulation. Fifth International Congress of Movement Disorders Abstract, 1994.
- Johnson MTV, Kipnis AN, Aris R, Ebner TJ. Nonlinear dynamics of visually-guided sinusoidal tracking in normals and parkinsonism. Soc Neuroscience Abstracts, 12, 1995.
- Coltz JD, Johnson MTV, Ebner TJ. Relationship of cerebellar Purkinje cell discharge to movement parameters during visuomotor arm tracking. II. Complex spikes. Soc Neurosci Abstracts, 13, 1996.
- Johnson MTV, Coltz JD, Hagen MC, Ebner TJ. Evidence for visuo-motor processing in the

directional firing of motor cortical neurons. Soc Neurosci Abstr, 13, 1996.

Ebner TJ, Johnson MTV, Coltz JD. Relationship of cerebellar Purkinje cell discharge to movement parameters during visuomotor arm tracking. I. Simple spikes. Soc Neurosci Abstr, 13, 1996.

Johnson MTV, Coltz JD, Ebner TJ. Encoding of target direction, speed, and velocity in the discharge of premotor and primary motor neurons. Soc Neurosci Abstr, 14, 1997.

Coltz JD, Johnson MTV, Ebner TJ. Cerebellar Purkinje cell simple spike discharge encodes movement velocity vectors in primates during visuomotor arm tracking. Soc Neurosci Abstr, 15, 1998.

Johnson MTV, Coltz JD, Ebner TJ. Differences in discharge of Purkinje cells and motor cortical neurons in primates during the performance of a visuomotor tracking task. Soc Neurosci Abstr, 16, 1999.

Johnson MTV, Chen G, Ebner TJ. Intrinsic optical signals in the monkey motor cortices during the performance of a visuomotor task. Soc Neurosci Abstr, 17, 2000.

Roitman A, Johnson MTV, Ebner TJ. Kinematic analysis of manual tracking: Interception and pursuit. Soc Neurosci Abstr, 18, 2001.