

Gerald Hunsberger Jr.

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Biomedical Engineer | Electrochemistry Consultant | Implantable Medical Device Development

Biomedical engineering professional specializing in electrochemistry, implantable medical devices, and ex vivo electrophysiology assay development. Extensive experience leading electrochemical characterization, verification and validation, custom test method development, and design control activities for neuromodulation and bioelectronic medical technologies.

SKILLS:

Electrochemistry & Neural Interface

Electrochemical characterization (EIS, CV, Q_{inj}), Electrode impedance analysis & stability assessment, Implantable neural interface architecture & optimization, Electrode material development (IrOx, Pt, PEDOT), Neural stimulation and bioelectronic system development

Electrophysiology & Assay Development

Ex vivo electrophysiology assay development, CAP, ENG, EMG, ganglia recordings, eCAP signal processing & dose-response modeling, Directional neuromodulation techniques, KHFAC and DC block

Systems Engineering & Design Controls

Requirements development, traceability (RTM, DHF), V-Model execution, Verification and Validation strategy and test method development, Risk management (ISO 14971), Design Controls (ISO 134865), DOE, root cause investigation, CAPA and reliability testing

Risk & Compliance

Risk management (ISO 14971, FMEA), Hazard analysis & risk control verification, Regulatory integration within design controls (ISO 13485)

Modeling & Engineering Tools

COMSOL Multiphysics, LTspice circuit modeling, CAD-based fixture & test system design, JIRA

WORK EXPERIENCE:

Founder & Principal Consultant

(07/2026-Present)

Ex Viva LLC

Upper Merion, PA

Independent medical device engineering consultant specializing in electrochemistry and implantable technologies.

- Electrochemical testing and characterization of implantable electrodes (CV, EIS, voltage transient testing).
- Verification and validation strategy for active implantable medical devices.
- Ex vivo electrophysiology assay development and experimental test method design.
- Custom test method and fixture development.
- Design control and risk management support.
- Technical consulting for neurotechnology and bioelectronic medical devices.

Principal Biomedical Engineer

(2019-2026)

Galvani Bioelectronics – Neural Interfaces

Upper Providence, PA

Systems and Requirements Engineering

- Lead requirements generation, decomposition, and ongoing maintenance for neural interface systems, ensuring full traceability across design, verification, and clinical use
- Facilitate cross-functional design reviews and alignment across R&D, quality, regulatory, and clinical teams

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- Contribute to Design History File (DHF), risk analyses, and technical documentation supporting Class III implantable devices

Design & Development

- Lead engineer for neural interface design improvements across materials, electrochemistry (Qinj, CV, EIS), and mechanical/electrical modeling (COMSOL, LTspice)
- Design and qualify (IQ/OQ/PQ) custom test fixtures supporting verification, reliability testing, and root-cause investigations
- Design and execute DOE-based preclinical and bench studies generating the data used to establish device requirements, design limits, and verification criteria

Verification & Validation Leadership

- Manage a team executing risk-based (ISO 14971) verification & validation for Class III implantable systems (ISO 14708, EN 45502, IEC 60601)
- Author test plans, protocols, reports for neural interface and GB-1 connector interface
- Establish and manage an ISO 13485 compliant in-house test facility: equipment qualification, budgeting, QMS compliance, audits, and SAP inventory management
- Maintain CRO partnerships for GLP/ISO-aligned preclinical verification and bio-functional testing.

Clinical Engineering

- Provide Clinical engineering for US trials: device surveillance, data collection, clinical troubleshooting, returned-device evaluation, and real-time failure analysis
- Provide operating room engineering support during implant procedures: deliver surgeon training, procedural guidance, and implant troubleshooting

Quality, Reliability & Failure Analysis

- Lead US neural interface failure analysis of clinical return goods: identify failure modes, perform root-cause investigations, and support CAPA and reliability improvements

Regulatory Support

- Assist in the writing of regulatory applications and responses to FDA and other regulatory bodies

Biomedical Engineer

(2016-2019)

Galvani Bioelectronics – Advanced Concepts

Upper Providence, PA

- Led a multidisciplinary team of engineers and scientists, and delivered against project goals including the invention of a novel biomarker for assessing the dose response of perivascular nerve stimulation
- Supported multiple engineering projects work streams for the Advanced Concepts Neural Interface Bioelectronics portfolio
- Owned Ex Vivo neuromodulation and physiological output measurements (ganglia recordings, CAP, ENG, EMG, tension, pressure) on multiple autonomic pathways (sensory, parasympathetic, sympathetic) for evaluation and optimization of neural interface design
- Developed and patented novel techniques to achieve directional neuromodulation
- Developed and patented novel techniques to assess electroceutical dose response in vivo (eCAP signal processing, Access Resistance, Strain)
- Developed custom amplification circuits with saturation protection and signal envelope extraction for data acquisition
- Responsible for developing models for ex vivo assessment of KHfAC and carousel DC block
- In-house neural interface prototype manufacturing
- Applied electrodeposition coatings (PEDOT, Platinum, Iridium Oxide) and conducted advanced electrochemical characterization.

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Investigator

(2015-2016)

GlaxoSmithKline – Bioelectronics, Disease Biology

Upper Merion, PA

- Supported the Bioelectronics Respiratory portfolio through ex vivo compound action potential (CAP) recordings across sensory and autonomic pathways (rodent, canine, human)
- Led bronchopulmonary selectivity assessments of electrical stimulation using isolated airway and perfused lung models
- Contributed to preclinical bioelectronic medicine development across multiple novel disease targets
- Evaluated and optimized neural interface designs and stimulation paradigms to achieve selective and unidirectional fiber activation

Investigator (2013-2015), Senior Scientist (2009-2013), Scientist (2006-2009), Associate Scientist (2005-2006)

GlaxoSmithKline – Respiratory Drug Performance Unit (DPU)

Upper Merion, PA

- Designed and validated electrophysiology and cell-based assay platforms (whole-cell patch clamp, automated ion-channel systems, FLIPR) to characterize NaV and GPCR target performance
- Performed multi-species ex vivo airway and vascular testing to quantify small molecule and biologic dose response, potency, selectivity, and safety margins
- Applied quantitative pharmacology (IC_{50} , pA_2/Kb , kinetic analysis) to guide structure–activity optimization and reduce off-target risk

EDUCATION:

Drexel University

Bachelor of Science in Biomedical Engineering, cum laude

Concentration in Biomechanics

Cumulative GPA: 3.6/4.0

Minor in Mechanical Engineering

SELECTED PUBLICATIONS & PATENTS:

- Named inventor on 5 issued patents and 6 pending applications related to neuromodulation and electrochemical sensing
- Author/co-author on 11+ peer-reviewed publications in neural interfaces, electrophysiology, and small molecule drug development

REFERENCE:

Available upon request