# Eric J. Vanderploeg, Ph.D.

## www.linkedin.com/in/ericjvanderploeg

Dynamic R&D leader and strategic thinker with demonstrated success advancing interdisciplinary programs from discovery through late-stage preclinical development across biotech, pharma, and medtech sectors. Extensive expertise in preclinical development for multiple therapeutic areas, including deep technical and regulatory knowledge of cell therapy, biologics, and combination products. Committed to advancing innovative programs that meaningfully impact the lives and health of patients.

### **QUALIFICATIONS AND EXPERTISE**

- **Preclinical Strategy & Execution:** 15+ years leading the design and execution of nonclinical development programs, including pharmacology, PK/PD, and IND-enabling studies across diverse modalities (cell therapy, biologics, combination products, ASOs) and therapeutic areas (T1D, liver disease, musculoskeletal, fibrosis)
- Translational Model Development: Expertise developing translational in vivo models aligned with human disease biology, including substantial experience with NHPs, to guide programmatic decisions and meet regulatory requirements
- Regulatory Authoring & Strategy: Proven success preparing regulatory submission packages and study reports leading to productive interactions across agency branches (CBER, CDER, and CDRH) for early development programs, including novel modalities
- External Partnership Oversight: Established and managed highly collaborative CRO/CDMO relationships for nonclinical development and manufacturing activities, ensuring scientific rigor, timeline adherence, and regulatory compliance
- Product & Process Development: Success directing internal and external process and product development activities for iPSC derived cell therapy (T1D) and implantable biomaterials technologies
- Cross-Functional Leadership: Skilled at partnering with CMC, clinical/regulatory, and business colleagues to integrate nonclinical data into development strategy, clinical design, and investor/board communications
- **Due Diligence & Portfolio Strategy:** Led scientific teams in evaluating external assets, performing technical assessments of preclinical and regulatory readiness

#### PROFESSIONAL EXPERIENCE

## **Confluence Biotechnology Consulting**

Winchester, MA

#### Founder and Principal

**2019 - Present** 

• Independent consultant specializing in preclinical development activities, with expertise in biologics, cell therapy, and combination products in biotechnology and pharma

# Vice President, Head of Preclinical

2022 - 2024

- Led the Preclinical Department (6 direct and indirect reports) overseeing the development activities for a regenerative medicine cell therapy program addressing severe liver disease
- Directed the nonclinical in vivo program, including efficacy, safety, and biodistribution studies (PK/PD), as well as animal model development in both small and large species
- Developed nonclinical regulatory strategy and authored submission materials for FDA and ex-US filings, such as pIND and Scientific Advice meetings
- Managed both internal and external efforts for preclinical in vitro and in vivo biomarker assay development to support therapeutic progress
- Key member of senior leadership team managing interdisciplinary projects in a matrixed environment
- Accountable for developing and maintaining departmental budget while meeting key programmatic objectives

### **Sigilon Therapeutics** (acquired by Eli Lilly in 2023)

Cambridge, MA

## Sr Director / Vice President of Preclinical Development, Diabetes Research 2020 - 2022

- Led preclinical development team (7 direct and indirect reports) demonstrating potency and in vivo efficacy of a novel, encapsulated stem cell derived beta islet technology
- Oversaw internal process development program for bioreactor-based iPSC differentiation, managing both direct and matrixed teams to ensure efficient execution
- Managed key CDMO partnerships, directing tech transfer, process development, and scale-up activities to support program advancement
- Provided department-level programmatic and technical updates to strategic partner to ensure alignment on R&D strategy

Boston, MA

### Senior Director, BMP Program

2016 - 2019

- Led interdisciplinary R&D team (9 direct and indirect reports) in developing a nextgeneration recombinant bone morphogenetic protein (BMP) combination product for bone repair in orthopedic applications through late-stage preclinical development
- Provided scientific and strategic leadership for all preclinical program activities
   (pharmacology, toxicology, assay development, design controls, CMC, regulatory)
- Authored regulatory documents and led in-person discussions for multiple pIND meetings with CDER and CDRH FDA reviewers
- Oversaw product & process development activities leading to successful pre-GMP/GMP campaigns for a biologic drug substance & drug product and a medical device implant
- Responsible for all scientific/technical aspects of extensive asset out-licensing effort
- Led technical due diligence for multiple acquisition/partnering opportunities for pipeline development in orthobiologics space
- Member of Design Review and Design Controls team for a successfully commercialized surgically implanted Class II medical device

## **Director, Biomaterials Research**

2013 - 2016

- Directed biomaterial carrier development efforts internally and with external collaborators and CDMOs to invent and develop a biodegradable implant for localized delivery of a novel osteoinductive protein therapeutic, resulting in five issued patents
- Developed and managed preclinical in vivo pharmacology program to evaluate efficacy
  of protein therapeutic combination product with academic and CRO partners
- Led early activities to establish and stand-up new laboratory and office infrastructure for a satellite R&D location in Boston, MA

# Pfizer, Inflammation and Remodeling Research Unit

Cambridge, MA

# **Principal Scientist / Sr Principal Scientist**

2011 - 2013

- Successfully directed internal research efforts and managed multiple external collaborations to develop and evaluate novel biomaterials in orthopedic *in vivo* models
- As a Research Project Leader, implemented an aggressive strategy to provide a robust data package on a very tight timeline allowing for a clear Go/No-Go decision utilizing cross-functional collaboration and matrix management across the organization
- Served as biology or project lead on preclinical and clinical stage programs for therapeutic antibody and ASO modalities in inflammation and fibrosis disease areas
- Scientific lead for due diligence supporting acquisition of assets for tissue homeostasis and remodeling therapeutic area (i.e. chronic wound healing)

## Wyeth Research, Tissue Repair (acquired by Pfizer)

Cambridge, MA

## **Senior Research Scientist**

2009 - 2011

- Led a team to develop biomaterial carriers for localized delivery of protein biotherapeutics across multiple musculoskeletal disease areas
- Designed and implemented in vitro and in vivo screening paradigms for efficient characterization and selection of candidate technologies

# **Massachusetts Institute of Technology**

Cambridge, MA

#### Postdoctoral Research Fellow

2006 - 2009

Center for Biomedical Engineering

- Developed technologies to utilize peptide binding motifs for TGF-β delivery and natural ECM molecules as signals to promote chondrogenic differentiation of mesenchymal stem cells in 3D hydrogel scaffolds
- Awarded the Arthritis Foundation Postdoctoral Fellowship

#### **Graduate Research Fellow**

1999 - 2006

Woodruff School of Mechanical Engineering Parker H. Petit Institute for Bioengineering and Bioscience Georgia Tech/Emory Center for the Engineering of Living Tissues

- Designed and built a novel bioreactor system to induce phenotypic specialization of engineered cartilage tissues via mechanobiology pathways
- Awarded NSF Graduate Research Fellowship and ARCS Foundation Fellowship

### **EDUCATION**

2006	D. Mechanical Engineering, Georgia Institute of Technology, Atlanta, GA	Ph.D
2003	Mechanical Engineering, Georgia Institute of Technology, Atlanta, GA	M.S.
1999	Mechanical Engineering, Calvin College, Grand Rapids, MI	B.S.

### **GRANTED PATENTS**

- 1) Wilson, **Vanderploeg**, Lee, Davis, Seeherman, Wozney. "Porous Carrier Matrix", U.S. Patent 11,529,438 issued Dec 20, 2022.
- 2) Welch, **Vanderploeg**, Wilson, and Wozney. "Protein delivery with porous metallic structure", U.S. Patent 10,646,347 issued May 12, 2020.
- 3) **Vanderploeg**, Seeherman, Wilson, Wozney, and Brown. "Matrix for enhanced delivery of osteoinductive molecules in bone repair", U.S. Patent 10,300,172 issued May 29, 2019.
- 4) **Vanderploeg**, Seeherman, Wilson, Wozney, Brown, and Kambouris. "Systems and methods for improved delivery of osteoinductive molecules in bone repair", U.S. Patent 10,130,678 issued Nov 20, 2018.
- 5) DeGasparo, Van Garderen, Bohner, Seeherman, and **Vanderploeg**. "Method for producing porous calcium deficient hydroxyapatite granules", U.S. Patent 10,131,543 issued Nov 20, 2018.

#### **RESEARCH PUBLICATIONS**

- 1) Seeherman HJ, Wilson CG, **Vanderploeg EJ**, Brown CT, Morales PR, Fredricks DC, Wozney JM. "A BMP/Activin A Chimera Induces Posterolateral Spine Fusion in Nonhuman Primates at Lower Concentrations Than BMP-2". J Bone Joint Surg Am. Aug 18;103(16):e64 (2021).
- 2) Seeherman HJ, Berasi SP, Brown CT, Martinex RX, Juo ZS, Jelinsky SA, Cain MJ, Grode J, Tumelty KE, Bohner M, Grinberg O, Orr N, Shoseyov O, Eyckmans J, Chen, CS, Morales PR, Wilson CG, **Vanderploeg EJ**, Wozney JM. "A BMP/activin A chimera is superior to native BMPs and induces bone repair in nonhuman primates when delivered in a composite matrix", Sci Transl Med. 11 eaar4953 (2019).
- 3) Kopesky PW, Byun S, **Vanderploeg EJ**, Kisiday JD, Frisbie DD, Grodzinsky AJ. "Sustained delivery of bioactive TGF-β1 from self-assembling peptide hydrogels induces chondrogenesis of encapsulated bone marrow stromal cells", *J Biomed Mater Res A*. 102(5): 1275-85 (2014).

- 4) **Vanderploeg EJ**, Wilson CG, Imler SM, Ling CH, Levenston ME. "Regional variations in the distribution and colocalization of extracellular matrix proteins in the juvenile bovine meniscus", *J Anat.* 221(2): 174-86 (2012).
- 5) Kopesky PW, **Vanderploeg EJ**, Kisiday JD, Frisbie DD, Sandy JD, Grodzinsky AJ. "Controlled delivery of transforming growth factor β1 by self-assembling peptide hydrogels induces chondrogenesis of bone marrow stromal cells and modulates Smad2/3 signaling", *Tissue Eng Part A*. 17(1-2): 83-92 (2011).
- 6) Miller RE, Grodzinsky AJ, **Vanderploeg EJ**, Lee C, Ferris DJ, Barrett MF, Kisiday JD, Frisbie DD. "Effect of self-assembling peptide, chondrogenic factors, and bone marrow-derived stromal cells on osteochondral repair", *Osteoarthritis Cartilage*. 18(12): 1608-19 (2010).
- 7) Kopesky PW, Lee HY, **Vanderploeg EJ**, Kisiday JD, Frisbie DD, Plaas AH, Ortiz C, Grodzinsky AJ. "Adult equine bone marrow stromal cells produce a cartilage-like ECM mechanically superior to animal-matched adult chondrocytes", *Matrix Biol.* 29(5): 427-38 (2010).
- 8) Connelly JT, **Vanderploeg EJ**, Mouw JK, Wilson CG, Levenston ME. "Tensile loading modulates bone marrow stromal cell differentiation and the development of engineered fibrocartilage constructs", *Tissue Eng Part A*. 16(6): 1913-23 (2010).
- 9) Kisiday JD, **Vanderploeg EJ**, McIlwraith CW, Grodzinsky AJ, Frisbie DD. "Mechanical injury of explants from the articulating surface of the inner meniscus", *Arch Biochem Biophys*. 494(2): 138-44 (2010).
- 10) Kopesky PW, **Vanderploeg EJ**, Sandy JS, Kurz B, Grodzinsky AJ. "Self-assembling peptide hydrogels modulate in vitro chondrogenesis of bovine bone marrow stromal cells", *Tissue Eng Part A*. 16(2): 465-77 (2010).
- 11) Wilson CG, **Vanderploeg EJ**, Zuo F, Sandy JD, Levenston ME. "Aggrecanolysis and *in vitro* matrix degradation in the immature bovine meniscus: mechanisms and functional implications", *Arthritis Res Ther*. 11(6): R173 (2009).
- 12) Sui Y, Lee JH, DiMicco MA, **Vanderploeg EJ**, Blake SM, Hung HH, Plaas AH, James IE, Song XY, Lark MW, Grodzinsky AJ. "Mechanical injury potentiates proteoglycan catabolism induced by interleukin-6 with soluble interleukin-6 receptor and tumor necrosis factor alpha in immature bovine and adult human articular cartilage", *Arthritis Rheum*.60(10): 2985-96 (2009).
- 13) **Vanderploeg EJ**, Grodzinsky AJ. "Can the meniscus affect the nature of a chondrocyte?", *Osteoarthritis Cartilage*. 17(8): 969-70 (2009).
- 14) **Vanderploeg EJ**, Wilson C., Levenston ME "Articular chondrocytes derived from distinct tissue zones differentially respond to *in vitro* oscillatory tensile loading", *Osteoarthritis and Cartilage* 16(10): 1228-36 (2008).
- 15) **Vanderploeg EJ**, Imler SM, Brodkin KR, Garcia AJ, & Levenston ME "Oscillatory tension differentially modulates matrix metabolism and cytoskeletal organization in chondrocytes and fibrochondrocytes", *Journal of Biomechanics* 37(12): 1941-1952 (2004).
- 16) Connelly JT, **Vanderploeg EJ**, & Levenston ME "The influence of cyclic tension amplitude on chondrocyte matrix synthesis: experimental and finite element analyses", *Biorheology* 41(3-4): 377-387 (2004).