**Overview:**The Keck Graduate Institute (KGI) School of Pharmacy is proud to partner with Profusa.Inc.to offer the first Profusa-KGI Biopharmaceutical Industry Fellowship. These two 2-year Medical Affairs Fellowships will provide an opportunity to learn the skills and experiences necessary to excel as a pharmacist in all aspects of Medical Device development, a key function in any biotechnology company. The fellowship will be based out of the Profusa offices near San Francisco, California.

**Education and Experience:**

The successful candidates must be PharmD graduate from an ACPE accredited institution. Substantial background knowledge in a related field is a plus. All candidates must be legally authorized to work in the USA.

**PharmD Fellowship**

Medical Affairs

**DESCRIPTION**

Profusa is establishing a PharmD fellowship Program looking for enthusiastic, detail-oriented individuals to join the Medical Affairs team. The fellows will be exposed to all aspects of Medical Device Development with focus on Medical Affairs matters including clinical intelligence, strategic clinical study design, clinical study preparation and conduct in relation to regulatory submission needs, data analysis/reporting and publication, Medical Advisory Board interactions, KOL (Key Opinion Leader) mapping and device vigilance recording. The fellows will also be involved defining user needs and medical gaps supporting medical market analyses. They will interface with cross-functional teams internally and CROs, clinicians, thought leaders, and IRB organizations externally.

Profusa is developing medical device products in the field of biosensing and in vivo diagnostics for multiple analytes including oxygen and glucose. Profusa is actively pursuing device development studies, safety and efficacy studies as well as supporting Investigator Initiated studies. Overall, evidence generation and reporting is particularly important serving as input for regulatory/reimbursement submissions, manuscript preparations, clinical evaluations, product iterations and other deliverables related to product lifecycle management. The Fellows will work collaboratively within the Medical Affairs team and other Profusa team members to achieve these goals.

**RESPONSIBILITIES**

* Provide clinical Intelligence and clinical development support, including work on clinical studies and clinical outcome measures clinically relevant to HCPs, regulatory authorities and payors
* Studying and understanding clinical treatment trends and how in vivo sensing could improve clinical outcomes and treatment strategies
* Establishing a clinical competitive analysis process to better understand competitor landscape and progress. Understanding current solutions from other companies and incorporating best practices to optimize support systems and mobile technology offering
* Payor landscape mapping, including payor attitudes and trends toward Profusa products, clinical outcome measures and expectations, in order to optimize clinical and market development strategy
* Assist with development of study design, protocols, informed consents, case report forms, monitoring plans, agreements and other study-specific documents essential to the execution of clinical investigations
* Support managing aspects of investigators/sites/CROs relations to ensure device availability, ensure optimal compliance and performance to the protocol, regulatory requirements, safety reporting, discrepancy reporting, ethical practice, and post-market surveillance
* Support data management and statisticians in timely analysis and dissemination of study data
* Support product iterations by bringing insights and learnings from users to Profusa’s R&D and Products teams. Assist in technical support in clinical studies.
* Optimization and coordination of human factors and regulatory requirements for FDA submissions from a clinical/medical risk perspective. Assist in quality and regulatory activities such as document writing and review, submissions.
* Establishing a medical information system to meet the needs of internal and external stakeholders.
* KOL mapping and establishing clinical intelligence capture and report mechanism, including optimized literature search, congress reports and KOL interactions, including MSL (field) data analysis, in order to inform and optimize a medical strategy
* Establishing a patient and provider clinical support system which incorporates medical education, publications and payor support infrastructure as part of “comprehensive clinical systems offerings” versus product only information.
* Collaborate with strategic marketing and inform team on context around market research versus emerging trends
* Lead publication strategy and presentation of clinical data and findings.
Required to travel
* Medical congress coverage relevant to product development, including clinical competitive intelligence analysis and engaging stakeholders to address -including but not limited to- clinical study design, clinical treatment trends, real world study design and surrogate analysis to determine acceptable clinical outcome measures
* May visit clinical sites (in conjunction with CRO, if applicable) for site evaluation, initiation, monitoring, or close-out
* The Profusa-KGI Fellows will have academic responsibilities at the Keck School of Pharmacy and Health Sciences, which may include precepting students, publishing abstracts and posters and representing the fellowship program to pharmacy students

**REQUIREMENTS**

* Doctor of Pharmacy degree from an accredited US institution
* Demonstrated leadership ability/capacity
* Rotations in industry, medical information or other medical strategy environment
* Interest in Medical Device development
* Interest in clinical trial design in medical devices or pharmaceutical industry, or combination of experience and education/training preferable
* Willing to learn and apply US/EU/ROW device regulations, Good Clinical Practice requirements
* Technical writing skills with the intent to write clinical protocols, study reports, publications
* Skills to analyze data, present data
* Demonstrated ability to work independently tackling complex project
* Comfortable in managing multiple priorities in a fast-paced environment
* Excellent verbal communication, listening, presentation, organizational and relationship-building skills required

**Application Process:**

Candidates must submit all the following application materials. **The KGI School of Pharmacy and Health Sciences will be accepting applications until Thursday, September 28th, 2018.**

* Letter of Intent (why you are a great fit for this opportunity).
* Updated curriculum vitae (CV).
* Three (3) letters of recommendation emailed directly from letter writer to Fellowship Director (these can follow your application).
* Official pharmacy school transcript mailed or emailed to:

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