

About Ascendis Pharma

Ascendis Pharma is applying its innovative platform technology to build a leading, fully integrated biopharma company focused on making a meaningful difference in patients' lives. Guided by our core values of patients, science and passion, we use our **TransCon®** technology to fulfill our mission of developing new and potentially best-in-class therapies that address unmet medical needs.

Ascendis Pharma (NASDAQ: ASND) is based in Palo Alto, California & Hellerup, Denmark and focuses on the oncology and endocrine rare disease spaces.

About Keck Graduate Institute

Founded in 2018, the Keck Graduate Institute (KGI) Biopharmaceutical Industry Fellowship Program aims to provide exceptional biopharmaceutical industry training for Doctor of Pharmacy (PharmD) graduates with a broad exposure to the areas fundamental to drug discovery, development, and commercialization. This program will prepare fellows for a career in the pharmaceutical industry by focusing on developing a deep understanding of how companies operate. Each position affords significant experience in a corporate setting, enabling fellows to hone their business and clinical skills. The program also aims to foster professional development, provide intensive, hands-on training, and expose fellows to a variety of industry and academia-based opportunities.

Contact Information

Ascendis Pharma, Inc.

1000 Page Mill Rd
Palo Alto, CA 94304

<https://ascendispharma.us>

Bernard Tyrrell

Associate Dean for Pharmacy and Industry Relations and
Professor of Practice for Administrative Sciences;
Certificate Coordinator for Medical and Clinical Affairs, School
of Pharmacy and Health Sciences

Keck Graduate Institute

535 Watson Drive
Claremont, CA 91711

909.607.0447 | bernard_tyrrell@kgi.edu



Ascendis Pharma Biopharmaceutical Industry Fellowship Program

2023-2025 Recruitment Brochure
(GCP & PV Regulatory Compliance)



Fellowship Mission

To develop strong, confident, and competent biopharmaceutical industry leaders through the following:

- Professional development to promote learning agility, scholarship, enhance leadership, critical thinking, and team-building skills
- Networking to establish both personal and professional relationships among colleagues, alumni, industry professionals, and healthcare providers
- Community service to contribute and remain connected within the community

Good Clinical Practice (GCP) & Pharmacovigilance (PV) Regulatory Compliance Fellowship

Recruiting for one (1) position for 2023-2025 – **Strong Preference for Hybrid Position** in Palo Alto, CA headquarters, but open to Remote requests

SUMMARY

The GCP & PV Regulatory Compliance Fellowship provides two (2) years of comprehensive practical hands-on biopharmaceutical training and fosters an environment of learning within a fast-growing biopharmaceutical company. The fellow will be paired with leaders in the GCP & PV Regulatory Compliance functional area and will have the opportunity to support Quality Assurance initiatives, provide Quality Assurance oversight to various clinical trial and study teams, and to work cross-functionally with all departments. The collaborative environment will offer the fellow an enduring network and exposure to all aspects of the drug development process.

Fellows will spend 90 percent of their time on duties specific to Ascendis Pharma and 10 percent of time on academic development activities with the KGI School of Pharmacy and Health Sciences. All fellows will be eligible for adjunct faculty status and will have the opportunity to earn a Teaching Certificate.

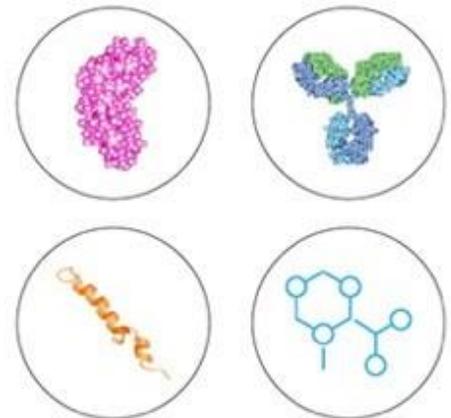
Learning Objectives:

- Support and participate in GxP audit activities
- Assist in developing standard operating procedures (SOPs), policies, and systems needed to comply with regulatory requirements
- Ensure accurate data entry of GCP and GVP audit reports, investigation reports, associated corrective and preventive actions (CAPAs), and deviations in the Quality Management System
- Assist in GxP Inspection Readiness Activities in support of global regulatory agency inspections and partner/vendor audits.
- Assist in the development and management of GxP risk assessments, CAPAs, deviations, trending analysis, change controls, etc.
- Develop standards for excellence in GCP audits, investigation documentation, inspection preparation and responses, CAPAs, and effectiveness checks to optimize effective and consistent performance within QA and for R&D clinical trial stakeholders
- Facilitate identification of root cause analysis and development of CAPAs; track actions and confirm effectiveness; ensure reporting of potential or confirmed violations to regulatory authorities.

— Eve Kwan,
Senior Director, GCP and Pharmacovigilance
Regulatory Compliance



"I am so pleased and excited that Ascendis Pharma chose to participate in this fellowship program. I believe it is the ideal setting for the development and growth of recent pharmacy graduates, and a mutually beneficial way to introduce them to the Biotechnology industry. We hope that with exposure to the different stages of drug development, manufacturing, and commercialization that we gain a champion for compliance in industry and a potential future colleague. Our team feels fortunate to have gained a collaborative and capable candidate in Daniel Tran, and for this reason, we look forward to continuing our partnership with KGI in the future."



Application Process

The KGI-Ascendis Biopharmaceutical Industry Fellowship provides a unique opportunity to prepare PharmD's for successful careers in industry. Candidates are encouraged to review the application requirements and deadlines, as admission to this program is competitive.

Ascendis Pharma – Diversity, Inclusion & Equal Opportunities

Ascendis Pharma is proud to be an equal opportunity workplace and we believe that diversity and inclusion among our workforce is critical to our success as a global company.

Individuals seeking employment at Ascendis Pharma are considered without regards to age, ancestry, color, gender (including pregnancy, childbirth, or related medical conditions), gender identity or expression, genetic information, marital status, medical condition, mental or physical disability, national origin, protected family care or medical leave status, race, religion (including beliefs and practices or the absence thereof), sexual orientation, military or veteran status, or any other characteristic protected by federal, state, or local laws. All employment is decided on the basis of qualifications, merit and business need.



Requirements for Eligibility

A successful candidate must be a PharmD graduate from an ACPE accredited institution before July 1st of the fellowship term.

Available Position:

- Good Clinical Practice (GCP) & PV Regulatory Compliance Fellow – 1 position

Application Materials

Candidates must submit all the following application materials to kgifellowships@kgi.edu:

- Letter of intent
- Two (2) letters of recommendation submitted via email directly from each reference
- Curriculum Vitae (CV)
- Unofficial pharmacy school transcripts

**Additional materials that the candidate feels would be useful to the interview committee may be submitted*

Deadline

Candidates are required to submit all required application materials by **Monday, October 31st, 2022 by 11:59 PM (PST)**

- Letters of recommendation may be submitted by **Monday, November 14th, 2022 by 11:59 PM (PST)**
- Interviews will be conducted on a rolling basis. Early application submission is encouraged.

Please address letters of recommendation & the letter of intent to:

Bernard Tyrrell, RPh, MBA
Associate Dean for Pharmacy & Industry Relations

Keck Graduate Institute
535 Watson Drive
Claremont, CA 91711



Informational Webinars

Please join us for an overview of the Ascendis Pharma & KGI Biopharmaceutical Industry Fellowship Program. We will elaborate on the application process and provide a Q&A session. Please register [here](#).

- **Webinar #1: Wednesday, September 28th, 2022 at 6-7PM (PST)**
- **Webinar #2: Tuesday, October 11th, 2022 at 5:30-6:30PM (PST)**