



Job Description

Full name	Recruiting for candidate in process
Job Title	TMTT Clinical Science Fellow- 2-year fellowship
Job Location	Irvine, CA
Name / Title of Manager	Clinical Science Manager (TBD) Medical Affairs, Transcatheter Mitral and Tricuspid Therapies (TMTT)
Start date	November/December 2021
PharmD Class of	2021 and prior- must have your PharmD degree prior to starting job

Position Summary

KGI and Edwards Lifesciences are proud to announce a 24-month fellowship with the Edwards Lifesciences Transcatheter Mitral and Tricuspid Therapies (TMTT) division. TMTT is passionate about developing breakthrough solutions for patients suffering from structural heart disease. The Clinical Science Fellowship is a unique opportunity to play a role in the growth of new cutting-edge transcatheter mitral and tricuspid heart valve therapies. The fellowship is designed to provide pharmacists with broad exposure to clinical science within the field of structural heart disease therapies, including medical writing and clinical trial design. This is also an opportunity for the Fellow to learn about the life cycle of regulated devices, product development processes, and global regulatory approval pathways. The position will be based in Irvine and the Fellow is expected to collaborate with various members of the TMTT Clinical Science team on diverse projects.

Key Responsibilities

- Support Clinical Scientists in developing and amending pre- and post-market clinical trial protocols
- Partner with Clinical Scientists in writing clinical evaluation plans (CEPs), clinical evaluation reports (CERs), post-market clinical follow-up (PMCF) plans and reports, study reports (e.g., annual progress reports, clinical study reports), and regulatory responses
- Provide scientific support by interpreting safety and effectiveness results data and by effectively and clearly describing research results, product use, and other medical information in various formats (e.g., scientific documents, PowerPoint slides)
- Maintain current, in-depth knowledge of TMTT products and existing and emerging structural heart disease therapies
- Summarize key clinical evidence from published literature
- Collaborate effectively with TMTT cross-functional teams, including Research & Development, Clinical Affairs, Safety, Regulatory Affairs, Quality Assurance, Biometrics, and Global Health Economics & Reimbursement



- The Edwards Lifesciences-KGI Fellow will have academic responsibilities at the KGI School of Pharmacy and Health Sciences which may include precepting students, publishing abstracts and posters, and representing the fellowship to pharmacy students

Knowledge, Skills and Experience

A successful candidate must be a PharmD graduate from an accredited institution. Background knowledge in structural heart disease, medical writing, and/or clinical trials is a plus. All candidates must have the right to work in the USA.

Desired Skills:

- Ability to take direction and work both independently and as part of a team.
- Ability to manage competing priorities in a fast-paced environment.
- Ability to interact professionally with all organizational levels and functions where appropriate.
- Excellent oral and written communication skills.
- Demonstrated analytical skills, problem-solving skills, and scientific mindset.
- Must be assertive, persistent, detail-oriented, and comfortable interacting with others in a collaborative environment.
- Experienced with literature reviews and various publication databases (e.g., PubMed) is highly desired.
- Working knowledge of the use of MS PowerPoint, MS Word, MS Excel, and Adobe Acrobat. Working knowledge of the use of reference management software (e.g., EndNote) is a plus.
- Understanding of US FDA, MDR, Good Clinical Practice requirements and ICH guidelines is a plus.
- Knowledge of policies, procedures and guidelines relevant to medical writing styles and techniques is a plus.
- Adhere to all EHS rules and requirements and take adequate control measures in preventing injuries to themselves and others as well as to the protection of environment and prevention of pollution under their span of influence/control.

Edwards Lifesciences is committed to creating a diverse environment and is proud to be an equal opportunity employer. All qualified applicants will receive consideration for the fellowship without regard to race, color, religion, gender, gender identity, national origin, disability, age, sexual orientation or veteran status.

Application Process:

Candidates must submit all the following application materials to:

KGI Fellowship Director Prof. Bernard Tyrrell Bernard_tyrrell@kgi.edu and Ashley Gonzalez Ashley_Gonzalez@kgi.edu

Office phone 909-607-0447.



We will be accepting applications from Friday October 8th to Monday October 25th, 2021 at 5:00 pm PT.

Applications materials need to include the following:

- Letter of Intent.
 - Updated curriculum vitae (CV).
 - One letter of recommendation emailed directly from letter writer to Fellowship Director.
 - Unofficial pharmacy school transcripts emailed to Fellowship Director.
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