

Denise Harville Steps into Senior Clinical Research Associate Role at PPD

Driving Excellence in Clinical Research Standards and Compliance





New York City, New York Feb 10, 2025 (<u>Issuewire.com</u>**)** - Knoxville, Tennessee – Denise Harville, a dedicated registered nurse, is making waves in the clinical research field as Senior Clinical Research Associate (SR CRA I) at Thermo Fisher/PPD, a global leader in providing comprehensive drug development and regulatory consulting services. Having joined the team in November 2022 as part of the clinician to CRA program. Denise is committed to ensuring that clinical studies are conducted with the utmost compliance to study protocols, regulatory requirements, and sponsor expectations.

In her role, Denise is responsible for critical monitoring and site management tasks. She conducts site visits, including selection, initiation, monitoring, and close-out visits, all in strict alignment with Good Clinical Practice (GCP) and International Conference on Harmonization (ICH) guidelines. Her collaborative approach allows her to work closely with study sites to develop and track subject recruitment plans, administer protocol-related training, and maintain effective communication to manage project expectations effectively.

Denise's astute evaluation of study site practices ensures the quality and integrity of clinical trials, as she promptly escalates any quality concerns. She expertly manages study progress by tracking regulatory submissions, patient enrollment, data collection, and query resolution. With a keen eye for detail, Denise guarantees that proper documentation is maintained in the Trial Master File (TMF) and the Investigator's Site File (ISF) in accordance with GCP standards.

In addition to her core responsibilities, Denise contributes to special projects, delivers insightful presentations to contract research organization (CRO) staff, and plays a vital role in mentoring new team members through training and orientation programs, both virtually and onsite. Her multifaceted expertise enhances the capabilities of her team and contributes to the overall success of clinical research initiatives.

Denise's educational journey began at Roane State Community College, where she earned an Associate of Applied Science in Registered Nursing in 2001. She furthered her education with a Bachelor of Science in Health Sciences, with a minor in Gerontology, from Excelsior University in 2014. Committed to advancing her expertise in healthcare leadership, she achieved a Master of Science in Health Administration with a perfect 4.0 GPA, receiving The Graduate Excellence Award in 2023.

A lifelong learner and active member of Sigma Theta Tau, Nursing Leadership and Honor Society, and the Managed Care Nursing Association, Denise is passionate about advancing the nursing profession. Her experience as a Legal Nurse Consultant provides her with a unique perspective that bridges healthcare and legal domains.

With a steadfast commitment to patient safety and clinical excellence, Denise Harville is poised to make a significant impact in the clinical research landscape.

Learn More about Denise Harville:

Through her online profile, https://todaysnurse.org/nurse/4149821



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