

Dr. NAVEEN V

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📍 1/24, Anna Nagar, Bommahalli, Karimangalam, Dharmapuri -635111, Tamil Nadu

PROFESSIONAL SUMMARY

Doctor of Pharmacy (Pharm.D) graduate with hands-on experience in regulatory affairs, clinical research, and clinical pharmacy. Skilled in preparing and reviewing regulatory submissions, ensuring compliance with IMDR, ISO 13485, and CDSCO standards. Experienced in supporting clinical trials, monitoring patient safety, and maintaining accurate documentation. Known for attention to detail, strong organizational skills, and commitment to improving healthcare quality and ensuring regulatory compliance.

WORK EXPERIENCE

Regulatory affairs executive - Medical Device, Morulaa Health Tech Pvt. Ltd. 03/2025 – 11/2025
Chennai

- Managed end-to-end regulatory submissions via CDSCO (MD Sugam); prepared Final and submitted Final client dossiers.
- Ensured compliance with IMDR, ISO 13485, and ISO 14971; maintained up-to-date regulatory knowledge.
- Facilitated import license approvals; coordinated with authorities and internal stakeholders.
- Handled query responses and submission tracking on the CDSCO portal.
- Supported internal and external audits; ensured readiness and compliance alignment.
- Collaborated with R&D, QA, and Legal to integrate regulatory needs across product lifecycle.
- Conducted regulatory risk assessments and gap analysis for new products.

Clinical Research Coordinator (Internship), CLINSOLVE 06/2024 – 08/2024
Chennai

- Followed clinical research protocols and conducted study visits in compliance with ICH/GCP and FDA regulations.
- Screened patient records, databases, and physician referrals to identify prospective candidates for research studies.
- Enhanced patient safety by meticulously monitoring and documenting adverse events during clinical trials.
- Followed informed consent processes and maintained records.

Clinical Pharmacist (Internship), Maruthi Medical Center 12/2023 – 05/2024
Erode

- Enhanced patient care by conducting thorough medication therapy management and providing appropriate recommendations.
- Reduced medication errors by diligently reviewing prescriptions for accuracy, drug interactions, and therapeutic duplications.
- Conducted comprehensive medication reconciliation reviews during transitions of care to reduce risk of adverse drug events.

EDUCATION

Doctor of Pharmacy, JKKMMRF'S Annai Sampoorani Ammal College of Pharmacy
GPA: 72.6%

Higher Secondary Certificate, Shanthy Nikethan Hr. Sec School
GPA: 75.5%

SKILLS

- Adverse event reporting
- Good Clinical Practice (GCP)
- Knowledge of EU MDR and Indian CDSCO Regulations
- Narrative writing
- Regulatory Documentation & Submission
- Final Client Dossier preparation
- Product registration & license renewal
- Good Manufacturing Practice (GMP)
- Knowledge of Good Documentation Practices (GDP)
- Patient counseling
- Variations, renewals, and post approvals changes
- Document Formatting

PROJECTS

A Comparative Study of the net Cost- Benefit Analysis of Intravenous Push Versus Intravenous Piggyback Antibiotics Administration Technique., Authors: Mr. A. Srinivasan, Dr. N.Senthilkumar, Manoj Kumar S, Nanthish N, Naveen V, Omarali Thangal V. *GIS Science Journal*. 2024;11(11):592-605. 11/2024
GIS Science Journal

PUBLICATIONS

Progress in ATTR-CM: A Detailed Exploration of Pathophysiology, Diagnostics, and Treatment Approaches., Authors: Naveen V, Felic S, Abishek P. *International journal of Innovative Science and Research Technology*. Volume 9, Issue 11, Nov 2024. ISSN No: 2456-2165. 11/2024
International journal of Innovative Science and Research Technology

A Review on Current Understanding, Clinical Manifestations, and Therapeutic Approaches of Anxiety Disorders., Authors: Naveen V, Felic S, ASWIN A, KC AP. *Journal of Pharma Insights and Research*. 2024 Oct 4;2(5):173-81. 10/2024
Journal of Pharma Insights and Research

Precision Medicine: Scope, Integration, and Future Directions., Authors: Felic S, Naveen V. *Int J Pharm Pharm Res*. 2024 Oct;30(10):127. ISSN: 2349-7203. 10/2024
Int J Pharm Pharm Res

Microbiota and hypertension: exploring the gut-heart connection- a review., Authors: Felic S, Ezilkkavia S, Naveen V. *Int J Pharm Res Appl*. 2024 Jan Feb;9(1):1652-1660. 02/2024
Int J Pharm Res Appl