Sue Bhadare

Virginia, USA
Freelance Clinical Consultant

Sue Bhadare is a successful expert in drug development with over 25 years of experience, specializing in plasma products and interfacing with the FDA. Her consulting services include clinical trial operations, CRO management, clinical and regulatory strategy, protocol development, clinical trial conduct, FDA consultation, and Pre-IND and Orphan Drug registration activities. She is a graduate of Nottingham University and has been based in the US since 1998.

Through her tenure with such plasma product companies as Baxter, BioProduct Laboratories, Octapharma, Omrix, as well as founding and operating her own CRO, CROfessionals, a niche plasma product development company, she has gained in-depth, hands-on knowledge in all aspects of these unique clinical trials.

Sue's wide-ranging experience includes Orphan Drugs, Primary Immunodeficiency Diseases (PIDD), Alpha-1 Antitrypsin Deficiency (AAT), hemostasis in surgery (fibrin sealants), albumin therapy, Fresh Frozen Plasma (FFP) treatment, Plasminogen Deficiency, treatment with hyper immune immunoglobulins, Human Immunodeficiency Virus (HIV), deficiencies in coagulation factors VIII (hemophilia A), IX (hemophilia B), VIIa, X, and XIII, von Willebrand Disease, Immune (Idiopathic) Thrombocytopenic Purpura (ITP), and diabetic foot ulcers. She has also worked with anti-viral therapy, tinnitus, topical pain relief, and gene therapy trials in Critical Leg Ischemia (CLI).

Having owned and operated her own CRO for over 10 years, Sue is well qualified to evaluate and select CROs for smaller companies, providing ongoing CRO management as needed throughout the entire clinical process.

Sue Bhadare has attended over 30 CBER meetings in the last 25 years, either leading them or defending clinical strategies. She has extensive experience in clinical and regulatory development with an emphasis on Pre-IND meeting preparation and follow-up activities. Moreover, she has presented and supported multiple successful End of Phase II Meetings at CBER, as well as IDE meetings at CDRH. She has managed the filing process for numerous INDs and BLAs, leading to successful product licensure. She has also produced clinical sections of multiple regulatory submissions, including Orphan Drug Designations and approvals.