Sue Lesly

Sue can be reached through
cdginc@clinicaldevice.com

SUMMARY

Diverse clinical research experience. Involved in all aspects of clinical trial performance including: Monitoring, Site Recruitment, Site Management, CRA & CRO management, protocol development, CRF & source document design, development of study specific procedures & internal clinical SOPs, and preparing reports for FDA & regulatory submissions. Experienced in Phase II, III, IV drug studies & Pilot, Pivotal and Post Market device studies. *Have held the following roles: CRA, Project Manager, CRA Manager, Study Director.*

EXPERIENCE

Most Recent Study Assignments in drug and device, as follows:

• Chugai Bio	Diabetic Gastroparesis, Phase II IBS, Constipation Predominant, Phase II
• Cyberonics	Chronic Refractory Depression, Pilot Anxiety, Pilot Headache, Pilot Chronic Refractory Depression, Pivotal Cost Utilization / Depression, Post Market Epilepsy, Post Market Alzheimer's (Europe), Pilot
• CTSS	Osteoarthritis, Phase IV Depression, Phase IV OCD, Phase III Dermatology, Phase III
• Inspire	Respiratory, Phase II
• Pharm-Olam	Premature Ejaculation, Phase IIb
• Plethora	Post Radical Prostatectomy Erectile Dysfunction, Phase IIb
• Cargill	Hypertension, Food Additive Diabetes, Food Additive
• Onyx	Chronic Myelogenous Leukemia, Blast Phase, Phase II Chronic Myelogenous Leukemia, Chronic Phase, Phase II Chronic Myelogenous Leukemia, Accelerated Phase, Phase II Acute Myeloid Leukemia, Phase III Advanced-Stage Myelodysplastic Syndrome, Phase II
• Leptos	Obesity (Europe and US), Pilot
• LaJolla Pharma	Systemic Lupus Erythematosus, Phase II
• ZLB Behring	Primary Immunodeficiency Disorder, Phase IV
• OrthoAccel	Orthodontics / Celeract Device, Pivotal
• BrainsGate	Stroke / Neurostimulation, Pivotal
• MethylGene / Pharmion	Relapsed or Refractory Hodgkin's Lymphoma, Phase II Relapsed or Refractory Non-Hodgkin's Lymphoma, Phase II

(Other studies include arthritis, diabetes, dermatology, IBS, hypertension, ophthalmic, seasonal rhinitis, and radiological device)

9/2006 – present **Independent Consultant**
Assignments in drug, device and food additives. Lead CRA and Project Management. (Overlap with prior position is intentional. Continued as a consultant for Leptos from 9/06 until 1/07.)

7/2005 – 1/2007 **Manager, Clinical Operations**
Leptos Biomedical
San Francisco, CA
Full responsibility of the title for Pilot Obesity studies in Europe and US.

6/2000 – 3/2005 **Senior CRA and Study Director**
Cyberonics, Inc
Houston, TX
Study Director for Cost Utilization Study and two Epilepsy Post Market Studies. Participated in PMA for depression and attended panel meeting. Managed contract and in-house CRAs. Assisted in some capacity with all active studies.

11/1999 - 5/2000 **CRA Divisional Manager**
CTSS
Research Triangle Park, NC
Contract position to assist in hiring and training entry level CRAs for PPD and Quintiles. Supervised entry level CRAs and managed their developmental needs.

04/1993-10/1999 **Clinical Research Staffing Manager**
Specialty Medical Services
Dallas, TX
Assigned to various studies with client companies to staff and manage monitors for Phase IV studies. Scheduled CRAs and assisted Project Managers with staffing appropriately for changing needs as each study progressed. Planned CRA training.

01/1990-4/1993 **Manager of Pharmacy, Southwest Region**
Kimberly Quality Care, Pharmacy Division
Dallas, Texas
Managed Dallas Regional Office to oversee Pharmacy offices for IV dispensing for Home Health delivery in eleven states. Managed staff & budget.

9/1987-1/1990 **Human Resources Consultant and Training Specialist**
Quest International Human Resources Consulting
Las Colinas, TX
Worked on various HR and Training assignments for clients in the Drug and Device Clinical research business.

PRIOR EXPERIENCE

Fifteen years prior experience in HR Management and Physician Relations. Details available upon request.

EDUCATION

West Texas State University, Canyon, TX **Bachelor of Science in English and Psychology**

RELATED TRAINING

• Good Clinical Practices	Radiant Research	9/2007	Online Training and Test
• Good Clinical Practices	CIPIE	2/2007	Minneapolis, MN
• Applied Regulations	Clinical Design Group	10/2002	Houston, TX

• Project Management for Clinical Trials	Clinical Design Group	9/2002	Boston, MA
• Medical Device, PMA Workshop	RAPS	3/2002	San Francisco, CA
• FDA Medical Device Seminar	RAPS	3/2002	San Francisco, CA
• ACRP Advanced CRA Training	ACRP	2/2002	Houston, TX
• Clinical Design	Clinical Design Group	1/2002	San Diego, CA
• Good Monitoring Practices	Clinical Design Group	8/2001	Boston, MA
• GCP/ICH Training	Quintiles	7/2001	San Diego, CA
• Federal Regulations for Clinical Trials	FDLI	3/2001	Washington DC
• Randomization of Subjects	Synergos	2/2001	Houston, TX
• Protection of Human Subjects	NIH	2/2001	Washington DC
• Monitoring for Device	Quintiles	10/2000	Houston, TX
• The Role of the CRA, Advanced	Synergos	5/2000	Houston, TX
• Medical Terminology	Synergos	5/2000	San Antonio, TX
• Intermediate CRA	PPD thru CTSS	12/1999	RTP, NC

COMPUTER SKILLS

Microsoft Word ~ Excel ~ Access ~ Outlook ~ Power Point ~ Project Management