

# LINDA L. LYNCH, PHD

12011 NW State Hwy 92, Kearney, MO 80521

(816) 520-3873

drlindalynch@aol.com

## MEDICAL WRITER – PHARMA/BIOTECH/HEALTHCARE

**Multiple Therapeutic Areas/ Published Author / FDA Regulatory Compliance / Training Curriculum Development/ CME & Patient Education Materials/ AMWA Certified / Technical Writer**

Dynamic catalyst and professional, successful in developing summarizing clinical reports for biomedical and pharmaceutical research projects and teams. Multiple therapeutic pharmaceutical background. Consistently improved efficiency, profitability, and exceeded quotas. Strong working knowledge of Federal Code of Regulations, ICH and GCP guidelines.

- **Edited and wrote seven journal articles published in the same issue of a medical journal for clients**
- **Managed over 100 IRB submissions and accompanying reports and paperwork for two years**
- **Developed multiple medical documents, abstracts and summaries for submission ,publication and presentation**
- **Developed and wrote educational courses for CME**

**Special Skills:** Summarizes research study reports and documents. Writes edits, reviews manuscripts, reports, protocols, presentations, biostatistical reports for regulatory submission. Critiques others' written materials. Develops literature reviews employing documented sources. Designs protocols, case report forms and investigator brochures. Participates in the design, writing and review of all project-related documents including: budgets and proposals, change orders, and study content documents including: protocols, case report forms, statistical analysis plans, study reports and monitoring documents. Assists in establishing and defining clear and measurable project operating guidelines. Develops SOPs that are compliant with state, federal and International Conference on Harmonization (ICH) statutes. Develops instructional materials and curriculum following stated objectives.

**PhD** Science (2001) Summa Cum Laude, University of Missouri; **MS** Distance Education, University of Nebraska; **BS** Animal Science, **BS** Education, University of Arizona.

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### SELECTED ACCOMPLISHMENTS

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**Edited and wrote seven journal articles published in the same issue of a medical journal.** Radiology residents were asked to develop journal submissions with faculty, reporting on updates with newer radio logic techniques. Assisted in writing and editing all submissions with 100% acceptance. Missouri Medicine March 2005.

**Managed over 100 IRB submissions and accompanying reports and paperwork for two years.** Launched a research department with no assistance. Developed new researchers by assisting with all needs including medical writing needs. Developed all documents for several protocols, investigator initiated studies.

**Developed multiple medical documents, abstracts and summaries for submission ,publication and presentation** Numerous opportunities presented as COO Research to assist researchers to report, publish and develop written materials. Assisted in writing and formatting medical posters, and power point presentations.

**Developed and wrote a series of 18 educational online courses for CME.** Research related training needed to develop new researchers. Developed a series of online courses for new researchers, to introduce to research techniques. Completed the curriculum and paperwork to approve for CME and CEU.

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### CAREER HISTORY

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**Director of Clinical Research**, Maricopa Integrated Health Systems, 2006 - 2007. Directed a staff including CRA's biostatisticians, and writers and managed a budget of \$1.5M. Launched department of Biomedical Research. Developed clinical and academic trials, monitored studies, written regulatory submissions, medical writing, IRB, training development for new researchers.

**Biomedical Editor/Writer**, Incredible English, 2005 - 2006. Developed medical presentations, manuscripts, abstracts and numerous medical writing/editing assignments, including for CME, CEU, and patient education. Limited technical writing.

**Operations Officer for Research**, Saint Luke's Hospital, 2003 - 2005. Led development of Biomedical Research department. Developed and monitored research. Liaison to medical research community. Staff of CRA's and \$2M budget. Located and assisted in acquisition of 2 Endowed Chairs for Research.

Previously served as **Operations Manager**, Lynch Farms, LLC; **Specialty Hospital Pharma Rep**, Wyeth; **Key Pharmaceutical Rep**, Pitman - Moore (Animal Health subsidiary of Johnson & Johnson).

