Tracy L. Franklin

Biostudy Solutions, LLC
4008 Caesar Court, Wilmington, NC 28405
(910) 795-0379
tracy@biostudysolutions.com

Professional Experience

Operations Manager/Publishing Specialist **(2015 to Present)**
Biostudy Solutions, LLC, Wilmington, NC

- Supervise and assist lower level staff.
- Handle day-to-day office management and tasks.
- Project management.
- Prepare quotes and workorders for report projects.
- Review monthly invoices.
- Human Resource.
- IT assistance.
- Assist in bookkeeping duties.
- Fulfill all requirements of Clinical Document Coordinator for Biostudy Solutions, LLC.

Clinical Document Coordinator **(2012 - 2015)**
Biostudy Solutions, LLC, Wilmington, NC.

- Project management.
- Compile integrated reports for Module 5 ANDA and Phase 1 reports per CTD and eCTD specifications.
- Developed and maintained QC checklists, SOPs, Power Point presentations and training modules.
- Research, updating, development and implementation new processes and standards for electronic report formatting (eCTD) of Module 5 for ANDA submissions in accordance with current FDA/ICH/CDER/CBER and Regulatory guidelines.
- Format FDA-directed documents using internal publishing templates, specifications, and style guide. Created hypertext links and bookmarks of Adobe Acrobat.pdf file; provide electronic submission publishing documents using leading industry tools including Microsoft Office Suite, Adobe Acrobat, and Authoring templates.
- General bookkeeping.
- Assist in research.

Clinical Document Coordinator **(2007 – 2012)**
AAIPharma, INC, Wilmington, NC.

- Carried out full-scope of responsibilities associated with tracking project timelines, scheduling final report dates and delegating project tasks.
- Compiled integrated reports for Module 5 ANDA and Phase 1 reports per CTD and eCTD specifications.
- Developed and maintained QC checklists, SOPs, Power Point presentations and training modules.
- Researched, updated, developed and implemented new processes and standards for electronic report formatting (eCTD) of Module 5 for ANDA submissions within the Clinical Research Unit in accordance with FDA/ICH/CDER/CBER and Regulatory guidelines.
- Scanned, converted and formatted FDA-directed documents using internal publishing templates, specifications, and style guide. Created hypertext links and bookmarks of Adobe Acrobat.pdf file; provided electronic submission publishing documents using leading industry tools including Microsoft Office Suite, Adobe Acrobat, and Authoring templates.

Education

Katharine Gibbs College – Providence, RI

Affiliations

Regulatory Affairs Professionals Society, member.