

Alani Jenkins

☎ (215) 555-6841 ✉ alani.jenkins@example.com 💼 linkedin.com/example/alanijenkins 📍 Philadelphia, PA 19103

SUMMARY

Product safety and pharmacovigilance leader with 12 years of experience evaluating safety data for marketed and investigational medicines. Combines **biomedical science** training, medical writing expertise, and practical knowledge of drug development, post marketing safety, global health authority requirements, and benefit risk assessment. Leads **safety evaluation strategy**, data retrieval, complex analysis, **medical scientific interpretation**, report writing, proactive safety reviews, and signal tracking. Partners with Medical Safety Officers, clinical, regulatory, epidemiology, and business teams on **Safety Management Team** activities and decision ready regulatory content. Mentors safety scientists through novel analyses and unclear processes, creating practical structure without limiting scientific judgment. Clear communication, thoughtful planning, and steady stakeholder partnership support sound decisions across competing priorities and timelines.

EXPERIENCE

Associate Director, Safety Science

January 2023 - Present

Northstar Biopharma

Philadelphia, PA

Leads integrated safety evaluations for marketed and development stage therapies, partnering with Medical Safety Officers and cross functional teams on evidence review, **benefit risk decisions**, regulatory content, Safety Management Team governance, and scientist mentorship.

- Led integrated safety evaluations using clinical, case, literature, and aggregate evidence for benefit risk conclusions.
- Escalated medically meaningful patterns through proactive reviews and multidisciplinary assessment with documented follow up.
- Authored complex safety reports and regulatory sections using quality control practices for decision ready narratives.
- Prepared **Safety Management Team** presentations, **signal tracking** updates, minutes, and action records across safety functions.
- Mentored safety scientists through novel analyses without established workflows, preserving traceability and scientific rigor.
- Influenced clinical, regulatory, epidemiology, and business partners through clear evidence and uncertainty discussions.

Senior Safety Scientist

July 2020 - December 2022

Crescent Therapeutics

King of Prussia, PA

Managed safety analyses for assigned therapies, translating adverse event and literature findings into surveillance conclusions, regulatory content, Safety Management Team materials, and practical guidance for newer scientists.

- Managed adverse event and literature analyses supporting surveillance and periodic benefit risk evaluation.
- Developed evaluation plans, retrieved datasets, and drafted reports for **Medical Safety Officer** signal discussions.
- Reviewed clinical and **regulatory documents**, coordinating evidence based revisions with cross functional authors.
- Prepared **Safety Management Team presentations** and data packages covering trends, emerging issues, and follow up.
- Coached newer scientists on **medical writing**, evidence synthesis, standard procedures, and global safety expectations.
- Balanced concurrent assessments through structured **planning**, priority setting, and early risk communication.

Safety Scientist

June 2017 - June 2020

Meridian Life Sciences

Wilmington, DE

Evaluated clinical and post marketing safety information for prescription medicines, producing concise scientific interpretations, aggregate reporting content, signal records, and cross functional presentations under global pharmacovigilance procedures.

- Evaluated clinical and **post marketing safety** information for surveillance and aggregate reporting.
- Integrated case narratives, clinical data, and literature into concise safety assessment sections.
- Applied **pharmacovigilance** procedures and global safety requirements during adverse event research.
- Analyzed safety datasets in Excel and presented scientific findings through PowerPoint discussions.
- Maintained **signal tracking** records, action histories, and evidence summaries for recurring safety reviews.
- Advanced independent judgment through targeted clinical consultation and progressively complex evaluations.

Drug Safety Associate

June 2014 - May 2017

Arbor Clinical Safety

Newark, DE

Reviewed adverse event information across clinical development and marketed products, supporting case assessment, medical writing, controlled documentation, reporting timelines, and safety discussions with scientists and physicians.

- Reviewed adverse event information for completeness and medical relevance across product programs.
- Drafted case and safety summaries from source documents under controlled quality procedures.
- Researched medical terminology, product information, and literature for scientist and physician assessments.
- Tracked safety deliverables against reporting **timelines**, escalating information gaps and compliance risks.
- Prepared Word, Excel, and PowerPoint materials for recurring safety reviews and scientific discussions.
- Built practical knowledge of serious adverse event reporting, clinical safety, and global regulatory concepts.

Clinical Safety Research Coordinator

Harborview Research Institute

June 2012 - May 2014

Baltimore, MD

Coordinated safety documentation for investigator led clinical research, supporting adverse event follow up, protocol records, ethics documentation, investigator communication, and scheduled oversight reviews.

- Coordinated safety documentation and adverse event follow up across active research protocols.
- Reviewed study records and source information before escalation to investigators and oversight personnel.
- Prepared clinical observation and safety event summaries that supported clear **medical writing**.
- Maintained protocol, safety, and ethics documentation for scheduled research governance reviews.
- Resolved documentation questions with investigators and study staff within protocol timelines.
- Built practical knowledge of clinical operations, research ethics, medical terminology, and safety reporting.

PROJECTS

Proactive Safety Review Program 📅 2024

Created a repeatable review framework for marketed and development stage therapies, connecting aggregate evidence, signal tracking, stakeholder discussion, and documented benefit risk interpretation.

Safety Management Team Reporting 📅 2022

Developed presentation and action tracking practices that gave safety teams clearer evidence summaries, meeting records, follow up ownership, and timeline visibility.

LEADERSHIP & AWARDS

- Pharmacovigilance Scientific Writing Mentor, recognized for guiding scientists through complex safety reports and clear evidence based narratives.
- Safety Science Peer Review Lead, selected to support consistent scientific review and constructive feedback across safety deliverables.
- Clinical Safety Documentation Contributor, recognized for dependable follow up across research protocols and oversight records.

EDUCATION

Master of Science in Biomedical Sciences

2012

Drexel University GPA: 4.0

Philadelphia, PA

Coursework: Pharmacology, Clinical Research, Medical Sciences, Research Ethics

Bachelor of Science in Biological Sciences

2010

University of Maryland, Baltimore County GPA: 4.0

Baltimore, MD

Coursework: Cell Biology, Human Physiology, Biochemistry, Molecular Biology

CERTIFICATIONS

- Drug Safety and Pharmacovigilance Certificate 📅 2015
- Good Clinical Practice Training 📅 2026

TECHNICAL SKILLS

- **Microsoft Office:** Microsoft Word, Microsoft Excel, Microsoft PowerPoint
- **Safety Analysis:** Adverse event analysis, Aggregate data review, Literature review
- **Pharmacovigilance:** Signal detection, Signal tracking, Case assessment
- **Medical Writing:** Safety reports, Regulatory sections, Case narratives
- **Clinical Safety:** Clinical trial safety, Protocol review, Adverse event follow up
- **Regulatory Safety:** Health authority requirements, Regulatory responses, Safety submissions
- **Drug Development:** Investigational medicines, Marketed medicines, Product safety
- **Benefit Risk:** Benefit risk assessment, Risk characterization, Medical interpretation
- **Safety Governance:** Safety Management Teams, Meeting minutes, Action tracking
- **Quality Systems:** Quality control, Standard operating procedures, Documentation traceability
- **Data Management:** Data retrieval, Dataset review, Evidence summaries
- **Scientific Collaboration:** Medical Safety Officers, Clinical teams, Epidemiology teams

SKILLS

- Pharmacovigilance
- Drug development
- Safety data analysis
- Cross functional teamwork

- Benefit risk assessment
- Clinical safety
- Medical interpretation
- Safety Management Teams
- Medical writing
- Post marketing safety
- Risk management
- Microsoft Office
- Signal tracking
- Regulatory documents
- Scientific communication

PROFESSIONAL AFFILIATIONS

- Pharmacovigilance Scientific Writing Mentor, supports practical coaching on safety narratives and evidence synthesis.
- Safety Science Peer Review Lead, coordinates focused review of scientific content and documentation quality.

LANGUAGES

- English (Native)
- Spanish (Intermediate)

ADDITIONAL INFORMATION

Work Status : Authorized to work in United States. No sponsorship required.

REFERENCES

AVAILABLE ON REQUEST