

Bernice Simon

Data Manager, Biospecimen Operations

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PROFESSIONAL SUMMARY

Results-driven Data Manager with over three years of clinical data management experience in the pharmaceutical and biotechnology industries. Experienced in managing complex clinical trials, working within cross-functional teams, and delivering clean, analyzable data for clinical studies. Strong background in data processing systems, data pipeline engineering, automation, technical troubleshooting, and client relationship management. Builds innovative tools and high-quality data solutions that improve speed, accuracy, and scalability.

CORE SKILLS

Clinical Data Management: Database lock (DB lock), CRF/eCRF design and review, query review, reconciliation workflows, UAT coordination, audit support, regulatory compliance.

Data Processing & Pipelines: Custom local and cloud-based pipelines, JSON-based configuration files, biomarker data platforms, data validation, log parsing.

Programming & Automation: Python, R, Bash, Power Automate, automated data checks, QC reporting, CRON jobs.

Tools & Systems: GitLab, Git, GitHub, Jira, Confluence, Asana, Smartsheet, RAVE, Veeva, IBM, Linux/Ubuntu, macOS, Windows, Microsoft Excel, Word, Outlook, PowerPoint, LibreOffice, Teams, Slack, Zoom.

Collaboration & Leadership: Cross-functional team leadership, mentoring and onboarding, client relationship management, technical documentation and writing, project coordination.

PROFESSIONAL EXPERIENCE

Data Manager, Biospecimen Solutions — QuartzBio

Buckeystown, MD (Remote)

Feb 2023 – Present

- Designed and built reusable packages that automatically generate expected sample schedules and study configuration plans, replacing a manual, error-prone workflow and reducing turnaround from several weeks to roughly two days per study.
- Lead data management activities for complex clinical trials across portfolios including Arcus, Takeda, Blueprint, and GSK, ensuring data integrity, accuracy, and regulatory compliance.
- Manage project timelines, deliverables, and internal and external team communications, including coordination for UAT, database lock, and CRF reconciliation.
- Run local vSIM pipelines in Linux environments to create and troubleshoot internal JSON configuration files, validate data outputs, and ensure proper syncing of biomarker datasets across multiple studies.
- Troubleshoot configuration-related pipeline errors using system logs, custom-built scripts, and exploratory analysis, applying version control via GitLab to manage and resolve issues efficiently.
- Piloted the Data Mapper proof of concept with the SolveBio API to transform vSIM data using EDP templates, collaborating closely with engineering and data product teams.
- Provided technical evaluations and hands-on feedback on AI tools such as Zipstack/Unstruct to assess integration feasibility for expected samples scheduling.
- Served as the primary technical mentor for new team members, conducting onboarding sessions, technical walkthroughs, and training in custom workflows and Linux-based toolsets.
- Developed custom R functions to enhance the flexibility and scalability of data checks across portfolios, including flagging systems for consent date discrepancies, duplicate detection, and assay result interpretation.

Lead Administrative Services Coordinator & Operations Technician — Thermo Fisher Scientific (NCI-CAR/DMID)

Germantown, MD

Jun 2022 – Nov 2022

- Applied Agile methods and user-experience research to streamline efficiency projects, including new SOPs for weighing, QC checking, and shipping of chemical shipments, reducing technician time under the hood by 30%.
- Wrote Power Automate automations to scan in thousands of biospecimens per day and extract shipping lists from email, cutting processing time by 20%.
- Managed federal contract budgeting, reorganization, and integration of a new budgeting management system under Microsoft Dynamics NAV (Navision), along with procurement activities.
- Participated in forecasting meetings to determine prioritized purchases for upcoming months and the contract year, targeting women-owned, veteran-owned, and small-business suppliers.
- Designed PTO and on-call Excel trackers in Microsoft Teams to simplify labor tracking against the federal budget tracker.
- Used inventory management systems (inTrak and Global Trace) for data entry, sample tracking, and sample management while maintaining cGMP, SOP, and FDA compliance.
- Prepared samples, clinical agents, and biospecimens for courier deliveries and shipments in a BSL-2 laboratory, handling specimens at temperatures ranging from ambient to -196°C.

Laboratory Scientist, Chemistry — Thermo Fisher Scientific

Silver Spring, MD (Remote)

Sep 2019 – Jun 2022

- Wrote and maintained advanced Excel formulas to process and organize over 1 million chemical compound containers, saving hundreds of hours of manual checks.
- Created chemical warning-label templates for hundreds of hazardous compounds and assisted in writing SOPs for laboratory and computer procedures.
- Trained new and temporary employees in computer and laboratory operations.
- Processed, received, and shipped chemical orders from WRAIR in support of multiple government divisions and facilities.
- Validated and maintained chemical structures and data in the Core Laboratory Information Management System (CoreLIMS), observing OSHA, GLP, and GMP regulations.
- Stored, handled, and disposed of compounds in accordance with OSHA, EPA, and MDE regulations, accounting for compound stability, hazards, and potential interactions.

EDUCATION

B.S., Chemistry — University of Maryland, Baltimore County

A.S., Chemistry and Biochemistry — Montgomery College