Amanda Albers

Clinical Research Associate

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Education

Master of Science, Clinical Research Management – Regulatory Science
ARIZONA STATE UNIVERSITY | Tempe, AZ | 2021

Bachelor of Applied Science (B.A.Sc.), Nutrition Sciences, Minors: Biology, Chemistry
INDIANA UNIVERSITY | Bloomington, IN | 2014
Phi Eta Sigma, Alpha Lambda Delta (PES/ALD) Honor Society, IU Women's Rugby Team

Professional Experience

MIRAVISTA DIAGNOSTICS · Indianapolis, IN · 1/2015 – Present
A CLIA and CAP certified mycology reference laboratory with an exclusive focus on developing and processing diagnostic tests for serious fungal infections, with recent expansion into IVD product development.

Production Supervisor, 1/2021 – Present

Responsible for the integration and scheduling of all lab activities, including manufacturing, product transfer activities, inventory management, and engineering needs, while maintaining lead role in new product transfers and manufacturing of complex processes such as purifications, biotinylations, and IVD manufacture. Coordinated and executed label control rework, manufacturing documentation revisions, specification system rework, and QC document creation. Outlined and utilized a tracking and trending of GDP compliance and GMP to better identify improvement opportunities.

- Reworked packaging specifications of all antibody-based materials to optimize usage by 30% and decrease packaging costs by 15%.
- Aided in the implementation of an ERP system to better track inventory status, usage, movement, and costing.
- Named SME for all training activities and material manufacture, including all LDT and IVD materials, with additional role of Audit support.
- Assisted in the expansion of all consumable supply specifications under change control to combat supply chain issues.
- Increased order fulfillment lead time from 8 weeks to 12 weeks with no manufacturing freezes or delayed orders, including custom orders.
- Named production lead of Blasto Human Ab LDT product transfer.

Production Associate scientist III, 1/2020 – 12/2020

Formulation of materials for clinical, research, and IVD use, which include buffers, reagents, purified antibodies, detector-labeled antibodies, lab developed test kits, and IVD kits with a team role of planning, scheduling, and execution. Schedule and perform equipment validations and preventative maintenance as needed.

- Developed an inventory system of all raw materials and revised all manufacturing BOMS to improve mapping of material needs and timelines.
- Created a new system for document management to aid in FDA and CLIA readiness.
- Served as team lead for updating clinical LDT and research only IVD kit configurations, with lead role in product transfer documentation, such as Specifications, QC Test Methods, Manufacturing Instructions, IFUs, and DMRs.
- Increased lead time of material order execution from 1 week to 8 weeks, despite issues in supply chain.

Research Associate Scientist, 1/2016 – 12/2019

Developed and outlined methodology of research aimed at improvement and development of diagnostic products, taking a team lead role directing cross-functional team meetings and interdepartmental collaboration to move products forward. Developed ELISA and LFA IVDs from feasibility to CE marking status, with contributions to design control activities, such as tracking and trending, troubleshooting, verification, validation, and documentation. Present findings and updates in both company-wide all staff meetings and management team meetings. Coordinated and executed training of production manager and employees on various buffer, diluent, and material synthesis.

- Coordinated, performed, and managed ten research studies with outside organizations, including Indiana University, Vanderbilt, CDC, and several veterinary facilities.
- Led development team for five ELISAs taking lead role in assay performance, data analysis, and validation documentation.
- Served as Lead Auditor for one Internal Audit and assisted in four additional audits covering FDA, ISO, and Canadian regulations for Medical Devices.
- Developed and wrote 90% of protocols executed per year (125-175).
- Named Team Lead for development of Histoplasmosis Canine Serum Antigen EIA and Development Lead for Lateral Flow Device for Histoplasmosis Human Urine Antigen.
- Approved Internal Inspector for EIA kits, LFA devices, and other production materials.

Research Assistant, 01/2015 – 1/2016

Played a key role in conducting research aimed at improvement and development of diagnostic products, ensuring compliance with all clinical protocols. Prepared correspondence, documentation, and presentation materials on findings. Managed specimen processing, storing, shipping, and sample set preparation, including blinding, diluting, treating, randomizing, as well as preparation of solutions, reagents, and media. Performed equipment function verification and preventative maintenance activities, entering controlled data for various pieces of laboratory equipment.

- Performed three studies with outside organizations, taking the lead role in test performance and data analysis.
- Contributed to research studies with various universities, independent research facilities, national research centers, and veterinary facilities.

Credentials

Certifications

Qualified Internal QMS Auditor – MiraVista Diagnostics (2016 – 2020)

Qualified Internal Inspector for Materials and IVD Devices – MiraVista Diagnostics (2015 – 2018)

Professional Development

Management Training Sessions – Indiana University (2017) | **Women's Leadership Conference** (2015, 2021)

Publications

Bloch KC, Myint T, Raymond-Guillen L, Hage CA, Davis TE, Wright PW, Chow FC, Woc-Colburn L, Khairy RN, Street AC, Yamamoto T, **Albers A**, Wheat LJ. Improvement in Diagnosis of Histoplasma Meningitis by Combined Testing for Histoplasma Antigen and Immunoglobulin G and Immunoglobulin M Anti-Histoplasma Antibody in Cerebrospinal Fluid. Clin Infect Dis. 2018 Jan 6;66(1):89-94. doi: 10.1093/cid/cix706. PMID: 29020213; PMCID: PMC5850023.

Myint T, Chow FC, Bloch KC, Raymond-Guillen L, Davis TE, Wright PW, Woc-Colburn L, Khairy RN, Street AC, Yamamoto T, **Albers A**, Wheat LJ, Hage CA. Detection of (1,3)-β-d-Glucan in Cerebrospinal Fluid in Histoplasma Meningitis. J Clin Microbiol. 2018 Sep 25;56(10):e00663-18. doi: 10.1128/JCM.00663-18. PMID: 30021828; PMCID: PMC6156302.

Janelle Renschler, **Amanda Albers**, Hanna Sinclair-Mackling, and Lawrence Joseph Wheat (2018) Comparison of Compounded, Generic, and Innovator-Formulated Itraconazole in Dogs and Cats. Journal of the American Animal Hospital Association: July/August 2018, Vol. 54, No. 4, pp. 195-200.