



## About AOA Dx Inc.

AOA Dx is developing the next frontier in early-stage cancer detection through its pioneering work in proprietary multi-omic biomarker technology. AOA Dx is developing AKRIVIS GD™, an early-stage liquid biopsy test for ovarian cancer.

## Senior IVD Product Development Scientist

The **Sr. Product IVD Development Scientist** will be a critical contributor in advancing AOA Dx's diagnostic assays through late-stage Cancer-focused IVD development, including analytical validation, design verification and validation (V&V), design transfer, and regulatory submission.

This role will serve as a technical contributor and leader towards the transition of R&D assays into robust, manufacturable, clinically validated products that meet FDA and global regulatory requirements. The ideal candidate brings experience in IVD product development, cross-functional skills, and working with teams.

### Responsibilities:

#### Late-Stage Assay Development & Validation

- Drive planning, design, and execution of analytical validation and design V&V studies for IVD assay development.
- Drive validation strategies aligned with FDA, CLIA, CAP, and ISO 13485 expectations.
- Ensure rigorous documentation, traceability, and adherence to design control requirements.

#### Regulatory Submission

- Work closely with R&D leadership and Regulatory Affairs in the preparation of data packages for FDA submissions (e.g., 510(k), PMA, De Novo) and CLIA LDT validations.
- Lead the translation of scientific data into regulatory-ready documentation, summaries, and justifications.
- Drive regulatory discussions, audits, and technical inquiries.

#### Cross-Functional Contributor

- Collaborate across R&D, Clinical, Regulatory, Quality, Operations, and Program Management in alignment on timelines, risks, and deliverables.
- Partner with Manufacturing/Operations to ensure smooth design transfer, scale-up, and reproducibility.
- Drive late-stage development as part of cross-functional strategic planning and commercial readiness.

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#### Technical Oversight & Mentorship

- Provide scientific and technical leadership to scientists and research associates within the late development team.
- Guide experimental design, data analysis, and technical troubleshooting for complex assay challenges.
- Foster a culture of quality, accountability, and continuous improvement.

#### Program and Project Ownership

- Develop and manage project plans, including timelines, resource allocation, and risk mitigation strategies.
- Communicate progress and challenges to internal stakeholders and leadership with clarity and transparency.

#### Qualifications:

- PhD or master's degree in molecular biology, Biochemistry, Analytical Chemistry, Biomedical Engineering, or related field
- 3+ years of experience in IVD development, including V&V, analytical validation, and late-stage product development
- Proven experience supporting FDA regulatory submissions (510(k), PMA, De Novo) or CLIA LDT development
- Strong working knowledge of design controls, risk management (ISO 14971), quality systems (ISO 13485), and documentation standards
- Demonstrated ability to manage complex cross-functional projects
- Experience in design transfer, manufacturing scale-up, or sustaining engineering for IVDs
- Familiarity with clinical trial design or clinical laboratory operations
- Experience with multi-omics or biomarker-based diagnostics is a plus
- Preferred experience developing cancer-based IVD assays
- Preferred experience with mass spectrometry, immunoassay, proteomics, or other complex diagnostic platforms
- Preferred experience in a fast-paced biotech start-up

The salary range for this position is \$130,000 to \$160,000 per year, which factors in various geographic regions. The actual compensation and seniority level for this position will be determined based on relevant experience and qualifications.

AOA Dx offers competitive benefits, including unlimited PTO, group health, dental, and vision insurance, 100% employee sponsored life and disability benefits, monthly cell phone reimbursement, and a 401k plan with employer match.

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# AOA

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For consideration, please apply via LinkedIn:  
<https://www.linkedin.com/jobs/view/4386940021/>

Location: Denver, CO: In-Person

AOA Dx is an equal opportunity employer and welcomes candidates from all backgrounds to apply.

*We foster an environment where all people are afforded the freedom to pursue their passions without regard to race, color, religion, national or ethnic origin, gender (including pregnancy), sexual orientation or expression, age, disability or veteran status or any other characteristics protected by law.*

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