

DAVID CHEISHVILI, PhD

Molecular Diagnostics, Epigenetics & Biotech Product Development

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I am a molecular diagnostics scientist and biotech product developer with more than 20 years of experience in molecular biology and epigenetics, including more than 10 years in translational diagnostics, biomarker development, targeted NGS, and diagnostic assay validation. My work focuses on turning promising science into practical products: defining the assay, building the laboratory and bioinformatics workflow, validating performance, preparing CAP/CLIA-aligned documentation, and supporting commercialization.

I have led cancer-detection and biological-age programs, developed products that combine genetic and epigenetic information, supported international partnerships, and helped a high-complexity molecular laboratory achieve and maintain CAP accreditation.

WHAT I BRING TO A PROJECT

End-to-end development

From biomarker selection and assay design to validation, documentation, launch, and post-launch improvement.

Molecular diagnostics

DNA methylation assays, targeted NGS, liquid biopsy, cfDNA, qPCR/PCR, pyrosequencing, and bisulfite-based workflows.

Quality and compliance

CAP/CLIA-aligned documentation, SOPs, validation plans, quality systems, proficiency testing, internal audits, and inspection readiness.

Product translation

Ability to connect scientific evidence, laboratory feasibility, clinical use, customer needs, and commercial positioning.

Bioinformatics

Analysis of methylation, SNP, sequencing, and public datasets; pipeline review, QC, troubleshooting, and interpretation.

Scientific leadership

Diagnostic clinical validation, cross-functional coordination, international collaborations, grant support, and scientific communication.

SELECTED PRODUCT DEVELOPMENT & COMMERCIALIZATION

epiAge

Biological age assessment

Led development and launch of a targeted NGS DNA methylation assay for biological-age assessment in saliva and blood, including assay optimization, performance review, interpretation, and product support.

epiLiver / HCC program

Early cancer detection

Led clinical validation of a high-throughput DNA methylation test for hepatocellular carcinoma and served as clinical trial lead for NCT03483922, connecting assay development with clinical evidence.

MetaGen Panel

Integrated genetics and epigenetics

Created a product concept that combines SNP-based genetic information with epigenetic profiling, translating two complementary data types into a single, more informative customer report.

epiCervix and related oncology assays

Methylation biomarkers

Developed and validated DNA methylation markers and haplotype-based approaches for cervical cancer detection, while contributing to additional plasma-based oncology programs.

COMMERCIAL AND OPERATING EXPERIENCE

Beyond R&D, I have worked on product strategy, technical and investor materials, partner discussions, international contracts, digital commercialization, and scientific communication. I understand that a diagnostic product must be scientifically credible, operationally reproducible, clearly explained, and commercially usable.

20+ years

molecular biology and epigenetics

40+ papers

peer-reviewed research and translational studies

h-index 25

1,953 citations as of June 2026

3 patent filings

cancer detection and epigenetic aging

SELECTED LEADERSHIP AND RESEARCH EXPERIENCE

Founder | Biotech Insight Solutions | 2024-present

Independent consulting in molecular diagnostics, assay development, bioinformatics, validation strategy, laboratory quality systems, and scientific product development.

Scientific and Innovation Leadership / CAP Technical Consultant | HKG epiTherapeutics | 2017-2026

Directed epigenetic diagnostic programs, validation work, bioinformatics, quality documentation, and commercialization. Supported CAP accreditation, proficiency testing, inspection readiness, and international business development.

Co-Founder | MTL Epitherapeutics | 2019-2026

Developed and commercialized DNA methylation-based oncology assays and established collaborations with clinical laboratories and academic groups.

Postdoctoral Fellow and Research Associate | McGill University | 2011-2017

Investigated epigenetic mechanisms and biomarkers in cancer, metastasis, osteoporosis, and therapy response; developed translational approaches linking discovery research to clinical applications.

TECHNICAL AND REGULATORY SCOPE

Assays & platforms

DNA methylation, targeted NGS, Illumina MiSeq, cfDNA/liquid biopsy, qPCR/PCR, pyrosequencing, bisulfite methods, and methylation arrays.

Quality systems

CAP/CLIA-aligned validation, SOPs, QA programs, proficiency testing, internal audits, HIPAA/PHI policies, and inspection preparation.

Bioinformatics

Methylation and SNP analysis, RNA-seq, ChIP-seq, WGBS, GEO/TCGA/ENCODE/SRA, IGV, R, Python, Bash/Linux, and statistical review.

Product development & communication

Diagnostic clinical validation, biomarker-study leadership, grant and investor materials, partner-facing technical content, commercialization strategy, and scientific communication.

EDUCATION, AFFILIATIONS AND SELECTED CREDENTIALS

- PhD and MSc in Biochemistry and Molecular Biology, Hebrew University of Jerusalem
- Affiliate Member, Gerald Bronfman Department of Oncology, McGill University
- Inventor on three patent filings covering cervical cancer detection, non-invasive cancer detection, and epigenetic aging
- Publications in Nature Communications, Communications Medicine, Scientific Reports, Aging, International Journal of Cancer, Clinical Cancer Research, and Human Molecular Genetics
- Languages: English, Hebrew, Russian, and Georgian; working proficiency in French

Available for consulting, advisory, product development, diagnostic validation, laboratory quality systems, and scientific leadership projects.

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