

# Nidhi Menon

[in menonnidhi](#) | [nidhimenon.info](#) | [nmenon4@vt.edu](#) | [+1 202 215 6612](#)

## SUMMARY

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Results-oriented Biomedical Engineer and R&D leader with extensive experience in *in vitro* diagnostic (IVD) product development, medical device design, and translational medicine. Successfully led the development and launch of a rapid diagnostic platform, combining technical innovation, regulatory compliance, and strategic leadership to drive product commercialization and company growth.

## WORK EXPERIENCE

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### Head of R&D, HueDx, Inc., Philadelphia, PA

Aug 2023 - present

- Directed end-to-end development of an at-home quantitative diagnostic test for Luteinizing hormone, taking the product from concept through commercialization,, and driving the first revenue milestone for HueDx, Inc..
- Led preclinical and clinical validation of the HueDx diagnostic platform as Principal Investigator, ensuring full compliance with 21 CFR and ICH guidelines.
- Developed and implemented ISO13485-compliant QMS protocols and SOPs, strengthening regulatory readiness and operational efficiency.
- Served as lead scientific and technical strategist, building and managing external partnerships to accelerate innovation in rapid diagnostic assay development.

### Senior Biomedical Engineer, HueDx, Inc., Philadelphia, PA

Jun 2021 - Aug 2023

- Designed and engineered HueDx's first flagship smartphone-based quantitative diagnostic platform for colorimetric assays, leading to the company's first revenue-generating product.
- Developed and executed validation protocols and analytical methods aligned with CLSI guidelines to support FDA 510(k) submissions.
- Partnered with the software engineering team to integrate the diagnostic platform with the Hue-Cloud and HueReader app, enabling assay quantification, and reducing development time by over 75%.
- Co-inventor on multiple patents and contributor to successful grants and peer-reviewed publications, advancing the company's innovation pipeline.

### Graduate Researcher, Virginia Tech, Blacksburg, VA

Aug 2015 - Apr 2021

- Spearheaded a lead author publication featured on the front cover of a high-impact journal, quantifying the transcriptomic changes (RNA-Seq with NGS), as well as chemoresistance of matrix-encapsulated 3D breast cancer spheroids.
- Designed and fabricated silicone elastomer-based (PDMS) microfluidic platforms to investigate tumor and immune cell interactions, as well as pseudomonas-neutrophil interactions in the context of sepsis.
- Managed cross-functional collaboration to develop an innovative FRET-based biosensor for cell-surface receptors with direct implications in point-of-care diagnostics.
- Engaged with Clinicians to procure whole blood samples of healthy and septic patient volunteers. Isolated PBMCs from whole blood for sensor characterization.

- Supervised and motivated young researchers in a preliminary drug development process to screen over 400 endophytic fungal extracts and identify novel and potent anti-breast cancer drug candidates.

## Undergraduate Research Fellow, West Lafayette, IN

Aug 2012 - May 2015

- Collaborated with a multidisciplinary research team to design and optimize genetic constructs for reliable protein expression using GeneDesigner as part of the International Genetically Engineered Machine (iGEM) program.
- Applied Taguchi Statistical Methods and JMP software to execute robust Design of Experiments (DOE) for genetic construct optimization.
- Presented research to over 500 attendees at international iGEM Jamborees (University of Toronto and MIT), earning a Gold Medal and the Purdue Summer Undergraduate Research Fellowship in recognition of technical innovation.

## Research Intern, Vaccine Development, TIFR, Mumbai, India

Jun 2014 - Aug 2014

- Investigated the enzymatic function and reaction kinetics of GAPDH in the malarial parasite (*Plasmodium yoelii*) as a potential vaccine target.
- Designed and executed protein purification experiments to analyze GAPDH distribution across soluble and insoluble parasite fractions.
- Gained hands-on experience with *in vivo* murine models, acquiring skills such as parasite inoculation, tail pricking, and retro-orbital blood collection.

## EDUCATION

2015 - 2021 Ph.D. (Translational Biology, Medicine and Health) at **Virginia Tech, Blacksburg, VA**

2011 - 2015 Bachelor's Degree (Biological Engineering) at **Purdue University, West Lafayette, IN**

## PUBLICATIONS

Menon, Nidhi, Ha X Dang, et al. (2020). "Heparin-based hydrogel scaffolding alters the transcriptomic profile and increases the chemoresistance of MDA-MB-231 triple-negative breast cancer cells". In: *Bio-materials Science* 8.10, pp. 2786-2796. URL: <https://doi.org/10.1039/C9BM01481K>.

Menon, Nidhi, David Beery, et al. (2024). "Development of a smartphone enabled, paper-based quantitative diagnostic assay using the HueDx color correction system". In: *PloS one* 19.10, e0311343. URL: <https://doi.org/10.1371/journal.pone.0311343>.

Full list can be found on  [Google Scholar](#)

## SKILLS

|                              |                                                                                                                                   |
|------------------------------|-----------------------------------------------------------------------------------------------------------------------------------|
| Product Development          | In Vitro Diagnostics (IVD), Point-of-Care Devices, Assay Design, Prototyping, Manufacturing partnerships and Commercial Launch    |
| Biomedical Engineering       | Microfluidics, Biomaterials, Immunoengineering, Translational Medicine                                                            |
| Regulatory & Quality Systems | ISO13485, US FDA 21 CFR (800-1299), QMS Implementation, SOP Development, 510(k) Submissions, FDA Registrations for exempt devices |
| Research & Validation        | Preclinical and Clinical Studies, Experimental Design, Data Analysis, Statistical Methods                                         |
| Software & Tools             | JMP, MATLAB, ImageJ, SolidWorks, GraphPad Prism                                                                                   |
| Leadership & Collaboration   | Cross-functional Team Management, Strategic Partnerships, Technical Communication                                                 |