

Keshav Kotteswaran

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Education

M.S. in Bioengineering | *Northeastern University* | Boston, MA | **GPA: 3.76/4.00** | December 2025

Concentration in Biomedical Devices and Bioimaging · Nanomedicine Graduate Certificate

B.S. in Bioengineering | *Northeastern University* | Boston, MA | **GPA: 3.56/4.00** | May 2024

Concentration in Biomedical Devices and Bioimaging · Minor in Business Administration

Experience

Project Manager | **Epic Systems** | Madison, WI | September 2024-August 2025

- Led the full-cycle implementation of biomedical device integration for Operating Rooms and Cath Lab. Built system records and executed validation testing for HL7 messaging protocols, ensuring 100% reliability for data monitoring
- Deployed streamlined Perioperative workflows, reducing average surgery turnover time by 3 minutes per case. Against industry benchmarks for OR time, this efficiency yields a projected annual cost avoidance of ~\$1.8 million.
- Demoed client-facing product presentations to clinical stakeholders, facilitating consensus on key design decisions
- Utilized agile and waterfall methodologies to manage project and sprint timelines
- Utilized statistical modeling to visualize block utilization inefficiencies and used Visio to convey new workflow designs. Identified bottlenecks in third-party software that drove a 15% improvement in "First Case On-Time Starts."

Systems Engineering Design Verification Co-op | **Insulet Corporation** | Acton, MA | July 2023-December 2023

- Conducted Design Verification for 50+ system requirements of the Omnipod 5, tracing every test case back to ISO 14971 risk controls and IEC 62304 software lifecycle standards.
- Spearheaded end-to-end Systems Integration Testing for critical device-to-cloud telemetry. Validated the integrity of insulin delivery logs transmitted between the PDM and the secure cloud backend, ensuring HIPAA compliance.
- Architected a Test Capacity Optimization framework that streamlined resource allocation across 70+ unique test specifications. Prioritized high-risk features and reduced regression testing cycle time by 30%.

Analytical Development Co-op | **Acorda Therapeutics** | Waltham, MA | July 2022-December 2022

- Optimized assay throughput by transitioning testing methodologies from HPLC to UPLC. Leveraging sub-2µm particle column technology, achieved a 9x reduction in run time while maintaining ICH Q2(R1) validation standards.
- Followed GMP and GDP guidelines in lab setting for all test runs including ACI-8 analysis on novel drug formulations in accordance with ISO 10993 standards
- Analyzed properties of Spray-Dried Dispersions for drug delivery using Andersen Cascade Impaction (ACI-8). Validated that particle size distributions consistently met the target Mass Median Aerodynamic Diameter of 1–5 µm with less than 5% standard deviation to ensure optimal alveolar deposition.

DBS Intern | **CSC** | Wilmington, DE | June 2020-September 2020

- Created a clean reference database of international ticker suffixes (e.g., .US, .IN, .CA, .HK), standardized symbol formats, and wrote a small AWS Lambda job to validate/ingest CSVs to storage (S3) for easy lookup
 - Mapped how database services connect in AWS (Lambda → S3 → CloudWatch)
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Projects

Capstone: Modifying NIH 3T3 Cells | *Northeastern University* | Boston, MA | May 2023-April 2024

- Targeted wound healing efficiency by engineering NIH 3T3 fibroblasts to overexpress PDGFR-beta, utilizing a Lipofectamine LTX transfection protocol to drive cellular response.
 - Designed a fluorescence-based chemotaxis assay (Boyden Chamber) seeded with 50,000 cells per well, creating a standard curve to rigorously quantify migration limits against wild-type controls.
 - Validated a ~25% increase in invasion velocity toward serum chemoattractants in the modified phenotype using EVOS microscopy, demonstrating the potential for accelerated tissue repair applications.
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Skills

Regulatory: FDA 21 CFR Part 11/820, ISO 13485 (Medical Devices), IEC 62304, cGMP/GDP, IQ/OQ/PQ Validation, HIPAA, Agile, Waterfall, Root Cause Analysis (Fishbone/5 Whys), Risk Management (ISO 14971).

Software: Epic (OpTime/Anesthesia), Visio, AWS (Lambda, S3), Python, SQL, Tableau, MATLAB, SolidWorks