

# Keshav Kotteswaran

kotteswaran.k@northeastern.edu | 302-897-6913 | [www.linkedin.com/in/keshav-kotteswaran/](https://www.linkedin.com/in/keshav-kotteswaran/)

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## Education

**M.S. in Bioengineering** | *Northeastern University* | Boston, MA | **GPA: 3.63/4.00** | 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

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## Experience

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

- Built and validated biomedical device integration records for anesthesia workstations. Led verification testing for HL7 messaging protocols, ensuring data accuracy for vital signs and anesthesia parameters flowing to Epic flowsheets.
- Performed Systems Integration Testing for device interfaces and documented verification results per FDA 21 CFR Part 11 requirements. Maintained traceability and supported regulatory audits with verification documentation.
- Conducted root cause analysis on device interface failures using troubleshooting methodologies. Collaborated with vendors to resolve HL7 messaging errors and validated corrective actions through regression testing.
- Designed Perioperative workflow configurations using statistical analysis to identify integration bottlenecks.
- Validated workflow changes and maintained data integrity while improving First Case On-Time Starts by 15%.

**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 to S3 to 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), Risk Management (ISO 14971)

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