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

Experience

Project Manager | **Epic Systems** | Madison, WI | September 2024-August 2025
- Designed statistical analysis framework to identify integration bottlenecks in perioperative workflows, implementing process improvements that increased First Case On-Time Starts by 15%
- Maintained Systems Integration Testing documentation per FDA 21 CFR Part 11 requirements in SharePoint, supporting 3 regulatory audits with complete traceability records and verification deliverables
- Led root cause analysis (5-Why, Fishbone) investigations on 9 device interface failures, collaborating with vendors to resolve data transmission errors and validating corrective actions through regression testing protocols
- Coordinated cross-functional teams of 18 IT analysts on $2M EHR implementation using Agile and Waterfall methodologies, delivering all project milestones on schedule while managing competing priorities in MS Project
- Created Visio workflow diagrams and technical documentation to support client presentations, facilitating stakeholder alignment on system design decisions across 26 clinical leaders and 3 separate workgroups

Systems Engineering Design Verification Co-op | **Insulet Corporation** | Acton, MA | July 2023-December 2023
- Executed Design Verification testing for 50+ system requirements of the Omnipod 5 insulin delivery device, maintaining traceability matrices in electronic QMS linking test cases to ISO 14971 risk controls, IEC 62304 software standards, and FDA 21 CFR Part 820.30 Design Control requirements
- Led end-to-end Systems Integration Testing for device-to-cloud telemetry protocols, validating data integrity of insulin delivery logs transmitted between PDM and secure cloud backend within regulated QMS environment
- Investigated product anomalies through structured root cause analysis and FMEA methodologies, documenting findings and presenting corrective action recommendations to engineering leadership
- Developed Test Capacity Optimization framework applying risk-based prioritization per ISO 14971, streamlining resource allocation across 70+ test specifications and reducing regression cycle time by 30%

Analytical Development Co-op | **Acorda Therapeutics** | Waltham, MA | July 2022-December 2022
- Validated 5 drug formulations using HPLC and UPLC analytical methods, executing 85+ sample runs per ICH Q2(R1) standards
- Executed biocompatibility testing of spray-dried drug formulations using Andersen Cascade Impaction (ACI-8), validating particle size distributions met target MMAD specifications of 1–5 μm with <5% standard deviation
- Maintained GMP/GDP compliance across 60+ laboratory test runs, documenting results in accordance with ISO 10993 biocompatibility standards
- Compiled particle dispersion data in Excel and authored presentation reports for cross-functional stakeholders

Projects

Capstone: Modifying NIH 3T3 Cells | ***Northeastern University*** | Boston, MA | May 2023-April 2024
- Executed plasmid isolation and lipofection protocol using Lipofectamine LTX to transfect PDGFRbeta into NIH 3T3 fibroblasts, verifying successful transfection via GFP fluorescence imaging on EVOS FL microscope
- Designed Boyden Chamber chemotaxis assay with 50,000 cells/well seeding density, generating standard curves from fluorescence plate reader data and conducting T-tests to compare migration between wild-type and modified cells
- Performed statistical analysis in Excel using linear regression to convert fluorescence readings to cell counts, calculating percent invasion and standard error across experimental conditions

Skills

Regulatory: FDA 21 CFR Part 11/820, ISO 13485, ISO 14971, cGMP/GDP, IQ/OQ/PQ, CAPA, Design Controls
Technical: HPLC/UPLC, ACI-8, MATLAB, Tableau, SolidWorks, Excel, MS Project, Visio, SharePoint