

NICK KAISER

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Summary

Experienced pharmaceutical data and process scientist, passionate about bringing innovative therapies to patients in need through more effective applications of digital automation, statistics, modeling, and visualizations.

Education

Brown University

Ph.D. in Biomedical Engineering

Providence, RI

Sep. 2014 – May 2019

Boston University

B.S. in Biomedical Engineering

Boston, MA

Sep. 2006 – May 2010

Technical Skills

Scientific: Cell Therapy Processes and Analytics, Mammalian Cell Culture, CAR-Ts, HSCs, qPCR, FACs, Biomaterials

Statistics/Modeling: Design of Experiments (DOE), Response Surface Modeling, Multivariate Linear Regression, Hypothesis Tests, Correlational Analyses, Data Wrangling, Statistical Process Control (SPC), Comparability

Process Development/Regulatory: ICH Q8 and Q11, BLA and MAA filings (CTD 3.2.S.2.6 and 3.2.P.2.3), Process Characterization, Tech Transfers, Quality by Design (QbD), Risk Assessments, GxP Documentation

App and Pipeline Development: Data Wrangling, Package Development, Data Warehouses, Database Connectors

Technologies/Software: JMP, R (tidyverse, Shiny), Quarto, Python, VS Code, Posit Workbench, git, Linux, Bash

Experience

Novartis

Associate Director, Data Science

Senior Expert, Data Science

Cambridge, MA

Oct. 2023 – Present

Oct. 2021 – Oct. 2023

- Designed, built, and deployed postgresQL database for process development data on internal Kubernetes cluster. Further, developed a Shiny app with Spotfire dashboard for distributing data and visualizations to the development team.
- Developed an internal R package (harpde) for cleaning, harmonizing, and analyzing manufacturing datasets.
- Implemented an automated service utilizing harpde to retrieve, clean, and store clinical manufacturing data from a GxP database via a REST API on a weekly basis.
- Collaborated cross-functionally with data scientists to build data tools that make full use of newly established data pipelines. Integrated development data pipelines with cross-functional sources (including clinical, QA, and operations).
- Successfully resolved three root cause investigations through effective application of process knowledge and diverse clinical datasets.
- Provided statistical leadership and guidance on topics including process characterization, critical quality attribute (CQA) reporting, statistical process control (SPC) for pre-commercial processes, and comparability across manufacturing sites, process versions, and disease indications.
- Fostered a culture of data and statistical excellence in a diverse team of researchers, scientists, and engineers.

bluebird bio

Senior Scientist, Process Development

Scientist II, Process Development

Scientist I, Process Development

Cambridge, MA

Apr. 2021 – Oct. 2021

May 2020 – Apr. 2021

June 2019 – May 2020

- Directly supported BLA and MAA authorship, submission, and approval of two commercial hematopoietic stem cell therapies (Skysona and Zynteglo).
- Designed and led the execution of late-stage process characterization of the transduction and cryopreservation unit operations via DOE studies leveraging both full and small scale models.
- Mentored and managed a team of five talented process scientists in performing process characterization and authoring process development filing sections.
- Led the analysis and authorship of filing sections addressing the comparability of the cell therapy manufacturing process across the process and analytical development history.
- Trained both junior and senior staff in the use of JMP and DOE for both early and late-stage development applications.

Brown University

Ph.D. Candidate

Providence, RI

Aug. 2014 – May 2019

- Led the design, development, and optimization of a novel tunable collagen fiber scaffold platform for cardiac tissue engineering applications.
- Fabricated engineered cardiac tissues composed of stem cell derived cardiomyocytes in collagen and fibrin copolymer hydrogel scaffolds and characterized these tissues using a DOE approach paired with chemical, histological, and mechanical assays.
- Managed individuals and teams of undergraduate students working on multiple projects simultaneously, including the development of a mechanical stimulation bioreactor and empirical validation of compressible vessel flow characteristics using a novel physical modeling method.
- Independently designed, fabricated, and iteratively improved custom lab apparatuses through the application of CAD, laser cutting, and 3D printing technologies.

Histogenics, Inc

Process Development Engineer

Woburn, MA

Feb. 2014 – Aug. 2014

- Led the development and optimization of a lyophilization process to manufacture a tunable, porous collagen tissue scaffold for an autologous cellular cartilage product.
- Designed and executed DOE studies to identify and optimize critical process parameters.
- Designed bench top assays to characterize collagen scaffold material density, thickness, and pore attributes.

Organogenesis

Product Development Engineer

Canton, MA

July 2012 – Feb. 2014

- Developed dermis tissue products composed of collagen hydrogels seeded with neonatal fibroblasts and keratinocytes.
- Applied DOE and QbD to efficiently optimize analytics and ensure compatibility with the commercial process.

Allergan Medical

Associate Biomedical Engineer

Medford, MA

May 2011 – July 2012

- Supported R&D and marketing teams with the testing of implantable medical devices in vitro and in preclinical models.
- Performed advanced image and mechanical analyses of tissues and devices to study the in vivo resorption characteristics of silk scaffold materials.

BARD Davol (now BD)

Product Development Intern

Canton, MA

May 2010 – June 2011

- Designed and executed novel experimental procedures for in vitro and in situ tissue scaffold characterization.
- Authored reports and constructed presentations to communicate effectively with a variety of audiences including R&D, marketing, and executive teams.

Publications

Kaiser, N.J., Kant, R.J., Minor, A.J., Coulombe, K.L.K., *Optimizing Blended Collagen-Fibrin Hydrogels for Cardiac Tissue Engineering with Human iPSC-derived Cardiomyocytes*, ACS Biomaterials Science & Engineering, 2018

Kaiser, N.J., Munarin, F., Coulombe, K.L.K., *Custom Engineered Tissue Culture Molds from Laser-etched Masters*, Journal of Visualized Experiments, 2018

Munarin, F., Kaiser, N.J., Kim, T.Y., Choi, B.R., Coulombe, K.L.K., *Laser-Etched Designs for Molding Hydrogel-Based Engineered Tissues*, Tissue Engineering Part C, 2017

Kaiser, N.J., Coulombe, K.L.K., *Physiologically inspired cardiac scaffolds for tailored in vivo function and heart regeneration*, Biomedical Materials, 2015

Post-Graduate Open Online Courses

Machine Learning with Python - From Linear Models to Deep Learning, Regina Barzilay and Tommi S. Jaakkola, MITx via edX, in progress

Probability - The Science of Uncertainty and Data, John Tsitsiklis and Patrick Jaillet, MITx via edX, completed May 2024

Mathematics for Machine Learning: Linear Algebra, David Dye, Samuel J. Cooper, and A. Freddie Page, Imperial College London via Coursera, completed Jan. 2024

Data Science: Foundations using R, Roger D. Peng, Jeff Leek, and Brian Caffo, Johns Hopkins University via Coursera, completed Jan. 2022