DANIEL MORALES

530.651.3945 | danmorales209@gmail.com | Rancho Cordova, CA

Technologies

HTML5 /CSS3
JavaScript / jQuery / React
BootStrap / Materialize
NodeJS / Express.js
NPM
Sequelize / Mongoose ORMS
MySQL
MongoDB
Matlab
SolidWorks
Git / GitHub
Heroku
C++
Java

SKILLS

Validation
Commissioning / Qualification
DQ/IQ/OQ/PQ
cGMP, GDP, GLP
Microsoft Office
Visual Studio / VS Code
Source Control

EDUCATION

UC Davis; B.S., Biomedical
Engineering.
UC Davis College of Continuing
Education – Full Stack Web Developer
Bootcamp

LINKS

linkedin.com/in/damorales209/
github.com/danmorales209
danmorales209.github.io/

BIOGRAPHY

I am a full-stack web developer with a passion building dynamic applications and determining how to integrate the best technologies to solve problems.

I have over four years of experience working with cross-functional teams in a cGMP pharmaceutical production facility testing equipment and automated systems, and have always sought to use all available technologies to organize, analyze, and present data.

After obtaining a BS in Biomedical Engineering, I began taking programming and computer science courses to deepen my understanding of computers and programming, including course on structured programming, object-oriented programming, and data structures, as well as web development.

Most recently I have nearly completed UC Davis' Full Stack Web developer Bootcamp, where I have gained a much broader understanding of both front-end and back-end technologies, including JavaScript, CSS3, HTML5, ReactJS NodeJS, Express, MySQL, and MongoDB, as well as paradigms including creating and using RESTful APIs and MVC design for applications.

EXPERIENCE

Engineer II | Hyde Engineering + Consulting | 2017 – present
- Generate lifecycle documents for equipment, facilities, and utilities, including requirements traceability matrices, criticality assessments, and user requirement specifications.
- Generate and execute commissioning and qualification protocols for new and modified equipment as part of tech transfer, including clean steam, process air, media preparation and hold vessels, portable product pool tanks, buffer preparation tanks, temperature controlled rooms and equipment, and automated bulk drug substance dispensing unit.
- Participant in preliminary risk analysis and root-cause analysis for automated bulk drug substance dispensing unit.
- Generate and execute airflow visualization studies to meet ISO Grade 5 cleanliness requirements.
- Monitor, query, and trend automated process parameters using Siemens BAS and OSIsoft PI software packages.

Validation Engineer | VERSA Engineering and Technology | 2015 – 2017
- Generate and execute test protocols (IQ, OQ, PQ, Automation Qualification) for upstream and downstream equipment, facilities, and utilities.
- Temperature mapping using Kaye Validator 2000, Kaye ValProbes, and disposable Sensitech TempTales and applicable software.
- Autoclave validation and cycle development using biological indicators and thermocouples.
- Fixed tank sterility studies using biological indicators and thermocouples.
- Cleaning validation of automated cleaning recipes and manual cleaning procedures, including clean and dirty hold expiry studies.
- Creation and submission of samples and projects using Labware LIMS
- Investigate and resolve deviations and discrepancies to validation protocols and executions.
- Utilize TrackWise for support of controlled change records.

Student Researcher | UC Davis | 2013 – 2014
Solution preparation; pipetting; use of centrifuges; autoclaving; Western Blot preparation and execution; biological waste disposal; lab stocking and preparation; modeling using MatLab.

Lab Assistant | INTERTEK | 2011 – 2012
Solution, mobile phase, and control phase preparation using standard lab glassware; inventory; disposal of biohazard wastes; all in compliance with FDA GLP regulation.

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PROJECT EXPERIENCE

My MES | UC Davis College of Continuing Education | 2019

Currently developing a web-based manufacturing execution system using React to display and manage the front end, and NodeJS, Express, and MongoDB to server the back-end logic. The application seeks to enable real-time tracking of inventory, equipment, and orders. The server provides user authentication utilizing JSON Web Tokens and bcrypt. Target completion date is early June 2019. Developed requirements for page views and functionalities, interactions and relationships between MongoDB collections, and implementing the user authentication in both the front-end and back-end.

My Grade Book | UC Davis College of Continuing Education | 2019

Created an online grade book portal using JavaScript, MySQL, NodeJS, ExpressJS, Firebase, and Sequelize. Web portal allows for creating / editing assignment grades for students, and calculation of letter grades as data is updated. The web application interacts with the server via a custom API. Responsible for setting up relations in SQL database, sever routes for accessing the API, and displaying student grades graphically from the landing page. Responsible for managing the codebase on Github.

Too Much Food | UC Davis College of Continuing Education | 2019

Created recipe search and restaurant search web application utilizing jQuery AJAX to query Edeman API for recipe data and Zomato API for restaurant data. Recipe results. Wrote custom sorting algorithm to sort recipe results based upon required amount of searched ingredient. Responsible for managing the codebase on Github.

Actemra SC / IV Drug Transfer Project – Genentech | 2017 – 2018

- Represented Commissioning and Qualification team for multiple integrated design teams to ensure new and existing systems implementation and design met all stakeholders needs.
- Generate and execute commission and qualification documentation and testing
- Became an SME on site bulk drub substance bulk dispensing unit
- Manage small teams to coordinate testing of complex systems across diverse groups of stakeholders.
- Mentored and trained junior engineers and consultants in best practices for generation of documentation and execution of testing.
- Identified gap between site user requirements and system alarming strategies, and worked with system owners to reconcile
- Helped develop strategy to leverage testing during SAT, FAT, and Commissioning for later qualification phases.

Ambient GMP Warehouse Temperature Mapping - Study at Genetech | 2016 – 2017

- Developed and executed testing procedure to ensure all GMP warehouse storage areas met "Ambient Conditions".
- Performed first mapping and analyzed data to compare results against existing Building Automation System temperature sensors for accuracy and compliance.

Harvest Transfer Line Clean Hold Expiry – Clean hold study at Genetech | 2016 – 2017

- Developed and executed testing procedure to validate clean hold period on upstream equipment through depth filters to pool tanks.
- Worked with manufacturing, automation, and engineering to identify and isolate potential areas of bioburden contamination and to solve deviations and discrepancies as they were encountered during execution.

Cell Saver – Senior Design Capstone Project | 2014 – 2014

- Designed, tested and validated a method to seed human mesenchymal stem cells onto decellularized porcine submucosa using a hexagonal stencil and GFP – expressing stem cells.
- Critical aspects of design criteria were modeled using Matlab.
- Design of prototype was achieved using SolidWorks and fabricated to design specifications.