

MIGUEL ESCOBAR

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CORE COMPETENCIES

React JS, Handlebars, JavaScript
HTML, CSS, Tailwind, Bootstrap
New Product Development
Medical Device Statistics & Packaging

Node.js, Express, Apollo, GraphQL, REST API
MongoDB, Mongoose, MySQL, Sequelize
Fluent in Spanish

PROFESSIONAL EXPERIENCE

Medline, Inc.

April 2021 – Present

Medline, LP., is one of the world's leading manufacturers and distributors of medical devices.

Senior Verification &
Validation Engineer
April 2021 – Present

Member of the Research & Development organization holding a position of responsibility in the Design V&V Laboratory supporting 24 medical device divisions within Medline.

- Develop and implement process improvements for the laboratory (e.g., statistical sampling plan procedures, TMV procedures, training plans, etc.).
- Author and review DHF documentation such as design verification plans, protocols, technical justifications, data analyses, and reports.
- Interpret data and evaluate product performance to verify product requirements and design inputs.
- Collaborate with design and development teams to develop product requirements based on user needs, regulatory strategy, and applicable standards.
- Perform product failure and out of calibration equipment investigations. Determine root causes, assess impact to data based on risk, identify mitigating factors, and support solution implementation.
- Lead test method development activities, including test fixture design, equipment acquisition, and hardware/software validation.
- Teach Quality organization about topics relevant to medical devices (e.g., medical device statistics, new testing standards, etc.).
- Test and evaluate new and existing products.

ICU Medical, Inc.

Nov 2017 – March 2021

ICU Medical is one of the world's leading infusion therapy companies.

Engineer II – Sustaining and
Packaging
July 2020 – March 2021

Member of the Consumables Operations organization holding a position of responsibility in the on-market product support and packaging activities for IV consumables and IV solutions.

Engineer I – Sustaining and
Packaging
Nov 2017 – July 2020

- Lead and managed projects for on-market products and packaging from development to completion across several manufacturing sites.
- Authored DHF documentation such as Design & Development plans, design verification plans, protocols, technical justifications, data analyses, and reports.
- Served as technical lead for on-market product projects such as EU MDR.
- Balanced multiple projects of varying priority.
- Worked alongside suppliers in the development of components and materials for both on-market product and packaging changes.
- Compiled technical review presentations and meeting minutes for the DHF.

- Communicated with manufacturing sites to ensure understanding of validation process and successful builds/testing.
- Oversaw sample builds and testing at manufacturing sites.
- Updated BOMs, specifications and drawings in Agile documentation system.
- Authored Technical Data Sheets for new and on-market products.
- Developed and maintained project hopper for team's future packaging project ideas.
- Trained new hires on all Sustaining & Packaging Engineering job responsibilities.

Fresenius Kabi
Aug 2017 – Oct 2017

Fenwal, a Fresenius Kabi company, is one of the world's leading manufacturers of automated blood collection machines and disposables.

Sr. Engineer
Aug 2017 – Oct 2017

Member of the Disposable R&D organization holding position of responsibility in the design and development activities for automated blood collection technologies.

- Authored protocols & reports to support the identification, qualification, and implementation of new plastic material and filter replacements on existing on-market disposable kits for the automated blood collection systems.
- Developed design specifications for disposable kits used in automated blood collection systems.
- Performed mechanical and biological laboratory testing on disposable kits to support regulatory submissions and new product development verification.

ICU Medical, Inc.
August 2014 – May 2017

ICU Medical is one of the world's leading infusion therapy companies.

Sr. Engineering Technician;
ICU Medical, Inc., Pfizer
June 2016 – May 2017

Member of the Consumables R&D organization holding positions of increasing responsibility in the design and development activities for infusion set technologies.

Product Development Test Engineer; Pfizer, Hospira
Aug 2014 – June 2016

- Authored TMV protocols & reports based on design inputs and ISO design specifications for consumable and combination medical devices using Attribute Agreement Analysis and Gage R&R techniques in Minitab.
- Designed fixtures and failure modes for TMV.
- Developed Verification test plans and timelines for ISO 80369-3 and ISO 80369-6 connectors. Established business case for the project, interfaced with vendors, and performed initial feasibility of new connectors.
- Performed laboratory testing on consumable and combination medical devices to support regulatory submissions and new product development verification.
- Sterilization coordinator: Facilitated product sterilization by determining an efficient process to document and execute sterilization for R&D purposes.
- Utilized manually operated and computer controlled mechanized equipment (e.g. Instron) to perform tests per device design specifications.

EDUCATION

Northwestern University & Trilogy Education
January 2022 – July 2022

Full Stack Web Development Boot Camp

Online boot camp to learn the fundamentals of both Frontend and Backend web development. Portfolio at: <https://mae2136.github.io/Miguel-Escobar/>

Minitab

Statistical Tools for Medical Devices

February 2019	In person training course of statistical techniques used in Medical Device manufacturing.
<i>Technology Education</i> April – August 2018	Packaging Science Fundamentals Certificate Online course in the fundamentals of packaging across all industries, including food, medical, and industrial packaging.
<i>Oakton Community College</i> January – May 2017	Certified Solidworks Associate [CSWA] License #: C-222RYPGXAR 14 week course in the methodology associated with designing products ranging from household objects to sheet metal in Solidworks.
<i>Columbia University</i> September 2009 – May 2013	B.S. in Biomedical Engineering Focus Area: Biomechanics Minor: Mechanical Engineering