

John Doe

 Quality Engineer

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 john.doe@example.com

 johndoe

Professional Profile

I am a Chemical Engineer with a passion for problem solving and quality. With my experience with leading medical device manufacturing companies, I have developed skills and knowledge about the regulations of this highly regulated industry with high quality standards.

Work Experience

ABCD Medical

Apr 2022 - Actual: *Quality Engineer*

Implementing regulations, GMP, Lean methodologies, and 6S. Conducting risk management and analysis through FMEAs. Developing and executing protocols, procedures, and validation reports (TMVs). Actively contributing to the creation of a Validation Master Plan for various new production lines. Defining Critical to Quality (CTQs), establishing quality controls, and developing validation strategies for IQs, OQs, PQs, PPQs as required. Drafting Component Specifications (CSs) and overseeing raw material inspection processes (FAIs). Collaborating closely with customers and working alongside operators, technicians, buyers, and sterilization teams to ensure quality and timely deliveries.

Agroindustrial RIMAC

Jan 2022 - Apr 2022: *Regulatory Assistant*

To provide regulatory documentation support for various Active Ingredients

Education

Universidad de Costa Rica

In progress: *Lic. Chemical Engineer*

Thesis topic "Implementation of the Failure Modes and Effects Analysis (FMEA) methodology for risk detection in the electro-surgical pencil device with smoke evacuation to enhance product quality."

Technical Skills

- ✓ Process Validation
- ✓ Quality Regulations and Standards
- ✓ Risk Analysis
- ✓ Problem Solving

Certifications

- ✿ Prints Reading
- ✿ Applied Statistics in Medical Devices Manufacturing
- ✿ Design of Experiments (DOE)
- ✿ Root Cause Analysis

Languages

- 🌐 Spanish - Native
- 🌐 English - Business Competence

References

For reference contact Jane Smith

 **LinkedIn:** jane-smith