

Thanh

Truong

Sr. Quality Engineer

Personal Info

Address

Byron Center, Michigan

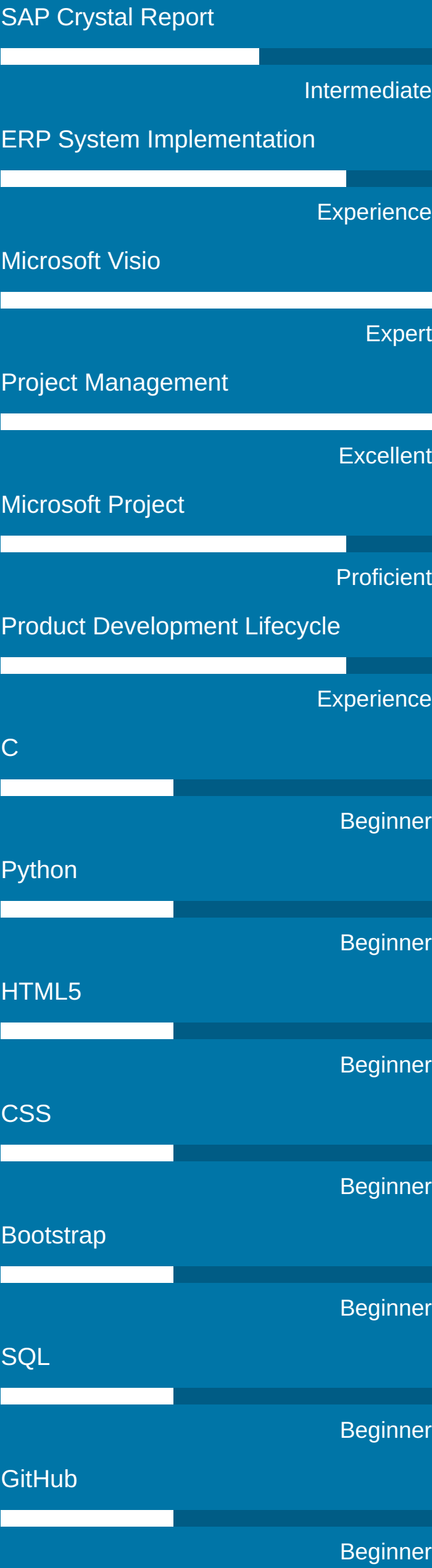
Phone

616-808-9969

E-mail

thanhgvsu@gmail.com

Skills



Sr. Quality Engineer with 8 years experience in medical device industry and strong experience in successful ERP implementation projects including software configuration, implementation, validation, and user-training resulting in significant cost-saving and increase in efficiency.

Skilled with developing reports in SAP Crystal Report from Oracle database. Knowledge in product development lifecycle and excellent communication skills.

2018 Annual Impact Award Nominee from current employer.

Experience

2013-12 - present	<div>Sr. Quality Engineer</div> <div>Medbio LLC</div> <div>Responsibilities:</div> <ul style="list-style-type: none">Manage customer complaints, drive root cause analysis and corrective actions, and communicate complaint resolution with the customer until satisfactionLead and drive to completion several ERP implementation projects to automate processes supporting the quality management system (QMS)<ul style="list-style-type: none">define current vs. future state and system requirementsdesign and propose solutionsorganize and lead design review meetings with stakeholderdevelop and manage project timeline and deliverableconfigure the system per approved design and generate required reportsdevelop test protocols, perform validation, and generate reports documenting test resultscreate procedures, work instructions and train users <div>Technical support for newly-developed ERP systems and management of user account and system security configuration</div> <div>Achievements:</div> <ul style="list-style-type: none">Develop procedures for software validation contributing to the company's success in passing the certification for the new ISO 13485:2016 standard in 2017Develop procedures and worksheets for the company's QMS to guide software development in compliance with FDA regulation for electronic records and electronic signaturesDeveloped and implemented successfully several ERP modules to automate processes used in the QMS leading to significant cost-saving and increase in efficiency. Utilizing an automatic broadcast workflow, checklist, and auto-generated daily/weekly reports, timeliness in review/approval, consistency in following procedures, and automatic tracking of due dates in the new systems have been improved significantly resulting in cost-saving, increase in efficiency, on-time delivery, and reduction in GDP errors.2018 Annual Impact Award Nominee
2010-09 - 2013-12	<div>Project Engineer</div> <div>Transcorp Spine</div> <div>Responsibilities:</div> <ul style="list-style-type: none">Responsible for design and development, project managementOrganize and lead design review, document each phase of the design development cycle in compliance with FDA regulationRegulatory submission for FDA approval of new product <div>Achievements:</div> <div>Successfully submitted and obtained FDA approval for new design of cervical implant product line.</div>

Education

2018-12 - present	<div>Western Governor University</div> <ul style="list-style-type: none">BS in Computer ScienceExpected Graduation: 12/2019
2008-01 - 2010-08	<div>Grand Valley University</div> <ul style="list-style-type: none">BS in Mechanical Engineering
2005-01 - 2008-01	<div>Grand Rapids Community College</div>