PAYMAN SAFFARI

12 Misty Shadow
Irvine, CA 92603
psaffari@gmail.com
510.452.7490

SUMMARY OF QUALIFICATIONS

- Extensive knowledge and experience is design and development of self-expanding Nitinol medical devices including concept development, evaluation, prototyping, modeling and analysis, bench evaluation and fatigue testing, regulatory submission, IDE and PMA submission support, and follow up interactions with the FDA
- Comprehensive experience and exposure to design, development and evaluation of wide variety of medical implants (balloon- and self-expanding) including aortic and mitral transapical and transfemoral heart valves, AAA, TAA, peripheral stents, stent-grafts including shunts and fistulas, venous stents, IVC filters, neurovascular stents and stent-grafts, coronary stent, orthopedic and spine implants, etc.
- Analysis expertise in implementing Finite Element Analysis (FEA) theory to practical applications, skilled in problem solving and excellent conceptual knowledge. Extensive knowledge of Abaqus with experiences ranging from model development, adoption of advanced solution techniques and employment of smart evaluation methods
- Strong knowledge and practical experience in Fatigue of Nitinol with focus on fatigue durability of Nitinol medical devices under in-vivo and in-vitro loading conditions
- Solid management/mentoring skills, demonstrated proficiency in leading and mentoring individuals to maximize levels of productivity, while participating in teamwork environment
- Excellent presentation and communication skills

PROFESSIONAL AND TECHNICAL EXPERIENCE

President – ENGAGE MEDICAL DEVICE SERVICES 2017-Present

- Provide consulting services for design and development, computational analysis (FEA), test design and development, development of the anatomical and physiological boundary conditions, , fatigue evaluation and testing, and IDE/PMA submission support of self-expanding and balloon expanding medical devices.

Senior Principal R&D Engineer – ENDOLOGIX 2015-2017

- Designed a developed next generation concepts for aortic abdominal aneurysm indication. Activities included concept development, preparing invention disclosure for patent submission, developing the anatomical and physiological boundary conditions, concept evaluation using FEA and testing, development and optimization of the manufacturing processes, fatigue evaluation and testing.
- Supported the PMA submission of the Nellix product through performing gap analysis, providing technical evaluations to the regulatory team, communication and conversations with the FDA reviewers, developing technical documents, leading testing and FEA activities to address FDA's requests.
- Lead the Fatigue Team activities and developed fatigue test methods and protocols at Endologix to support PMA, pre-IDE, and design and development activities of the next generation products including radial pulsatile, cyclic bend, cyclic crush, full system fatigue, interaction and fretting fatigue, etc.
- Lead and supported boundary condition determination and development, simulation, and fatigue testing activities for the CHEVAS program at Endologix for CE Mark submission process.

Principal Engineer – NDC 2013-2015

Staff Engineer – NDC 2011-2013

Senior Engineer – NDC 2010-2011

- Designed a developed venous stent for illio-femoral indication. Activities included concept development, evaluation using FEA and testing, working closely with the manufacturing team to optimize the processes, project management, fatigue evaluation and testing, developing Nitinol Fatigue life diagram,

and IDE submission support. Attended cadaver and non-GLP animal studies to determine the in-vivo physiological loading conditions plus evaluation feedback into the design process.

- Designed and developed spiral wireform Nitinol stents (ePTFE encapsulated) used for TAA indication. Worked closely with the prototyping team during the fabrication process while acquired feedback from the clinical tests to advance the design iteration process.
- Extensively involved in development and optimization of a Nitinol transfemoral aortic heart valve over a period of three years. Activities in this project included:
    - Optimized of the main design against fatigue using a combination of FEA and experimental test.
    - Developed two new codes/sizes by adapting and optimizing the main design to new sizes using an iterative process.
    - Managed and executed fatigue experimental tests including acting as the technical lead and managing the technicians, resources, project budget, and timeline.
    - Designed and developed fatigue test to determine the fatigue life limit of this medical implant. Activities in this project ranged from designing, fabricating, and evaluating test surrogates to choosing test conditions and execution of the program.
    - Worked very closely with the customer and attended several design reviews and supported them through their CE regulatory submission process in addition to post clinical support.
- Participated and lead variety of activities during Design, development, evaluation and regulatory support (pre-IDE, IDE, and PMA) of several different medical devices such as AAA, TAA, peripheral stents, stent-grafts including shunts and fistulas, Venous stents, IVC filters, neurovascular stents and stent-grafts, aortic and mitral transapical and transfemoral heart valves, coronary stent, orthopedic and spine implants, etc.
- Participated and lead several internal R&D project to further understand the fatigue of Nitinol. Actively presented the results of these studies in the Nitinol community such as SMST.
- Active participant and of the ASME V&V40 "Verification and Validation in Computational Modeling of Medical Devices " committee. I am currently leading the endovascular sub-committee.

Advanced Application Engineer – DASSAULT SYSTÈMES SIMULIA CORP. 2007-2009

Application Engineer – DASSAULT SYSTÈMES SIMULIA CORP. 2005-2007

- Teamed up and collaborated with the engineering group in design, analysis and evaluation of several FEA models from different industries
- Instructed introductory and advanced courses including Mechanical Modeling of Medical Implants
- Mentored and trained new engineers at SIMULIA Western Region office during their initial training period. Supervised interns throughout their term in the office.
- Supervised and directed the flow of support services at SIMULIA Western Region Office.

COMPUTER EXPERTISE

- **Engineering Applications:** Proficient in Abaqus, SolidWorks, and iSight
- **3D Modeling Tools:** Practical experience with CATIA, ANSYS, AutoCAD, and MSC Patran
- **Operating Systems:** MS Windows, Unix, and Linux

EDUCATION

- **M.S.**, Mechanical Engineering, Temple University 2003-2005
- **B.S.**, Aerospace Engineering, Sharif University of Technology 1998-2002