# BRINGING SFDI TO CLINICAL PRACTICE AT MODULIM

Amaan Mazhar, Modulim, USA
Primary contact: amazhar@modulim.com

Key Words: Spatial Frequency Domain Imaging (SFDI), Circulatory compromise, optical imaging

Modulim (previously Modulated Imaging) is dedicated to bringing optical technologies to the clinical for the non-invasive and rapid assessment of tissue health. We have received 510(k) clearance for two medical devices, with an indication to determine oxygenation levels in superficial tissues for patients with potential circulatory compromise. Our devices are currently the only FDA-cleared systems that uses spatial frequency domain imaging (SFDI) as the underlying measurement method. SFDI uses structured illumination to quantify tissue optical properties over large fields of view. SFDI was developed by researchers at the Beckman Laser Institute and Medical Clinic, and a number of labs have continued to publish on the promise of this technology for assessment of tissue health. In this talk, we will share our experiences in translating technology from an academic lab, building the infrastructure to gain regulatory clearance, and the hurdles we face for going to market. Our translation challenges included finding time and money for technology validation, market evaluation, and risk mitigation. Challenges in building infrastructure included implementation of an appropriate quality system, execution of a regulatory strategy, and incorporation of scalable procedures. Of note, our regulatory work included careful choices for component-wise benchtop verification testing along with pre-clinical and clinical validation to establish substantial equivalence of our device to a predicate device. Lastly, we will cover the challenges faced for our go to market device, the Clarifi Imaging System. These challenges include product/workflow fit, reimbursement, and customer support. A common theme that has been true in all of these phases of growth: investment in individuals to enhance and compliment our team strengths.