

VielightNEWS

Volume 3 Issue 9

September 2019

“Where there is purpose, there is hope.” George Washington Carver

Medical Device Quality Management System

Edited by Gennady Lemud gennady@vielight.com

Vielight Awarded Certification of Quality Management Systems for Medical Device

Vielight Explores Further into Post-concussion Syndrome

Dr. Lew Lim’s Workshop at ISNR 2019 promises to be Special

Vielight Awarded Certification of Quality Management Systems for Medical Device

Vielight is proud to announce that its Quality Management System (QMS) has been assessed and certified as meeting the requirements of ISO 13485:2016. This certification is awarded for compliance in the design and manufacturing of medical devices.

The certification recognizes the company’s readiness to manufacture and supply medical devices at the highest level. It speaks of the company’s intent and effort to be a leader in its space. Furthermore, the aspiration of leadership now extends from technology to the quality of the Vielight products.

At present Vielight devices are classified as low risk general wellness devices in North America. However, various early research and clinical studies suggest the potential of the Neuro RX Gamma qualifying as a medical device. The company is now sponsoring a pivotal clinical trial to demonstrate the required clinical evidence. Alongside these studies, the ISO 13485 certification provides the assurance that

the requisite quality management system is in place. This system is a major step forward to supplying qualified medical devices when regulatory clearances from major jurisdictions are obtained.

According to Vielight’s Quality and Regulatory Affairs Manager, Liyao Ji, “This is a great achievement for Vielight as an innovative and fast-growing company. It is a laudable feat when there are so many other activities in the company. A lot is already happening in the areas of innovation and research. As it happens with all growing companies, Vielight experiences occasional challenges in top quality supplies. Regardless, the company is able to release new quality products that help to improve quality of lives at affordable prices. The ISO 13485 certification provides the globally recognized framework to produce medical devices that are safe and effective. Besides this certification, we are also looking into obtaining regulatory clearance from jurisdictions world-wide.”

Vielight Explores Further into Post-concussion Syndrome

The field of photobiomodulation has been rich in research in traumatic brain injury (TBI). That includes studies in the post-concussion syndrome. However,



many of these studies had largely used laboratory animals. As an exception, Dr. Margaret Naeser has published several studies related to stroke and TBI. Some of them are of retired professional football players.

Dr. Naeser and Dr. Paula Martin of Boston University are now conducting a randomized controlled study to investigate the

For regular updates and to subscribe to our newsletter send us an email to news@vielight.com or visit www.vielight.com



use of the Neuro Alpha on US veterans with the symptoms.

This study is focused on treatment of the symptoms using clinical assessment tools and brain imaging. Dr. Naeser's video interview about her work in this area can be viewed at this [link](#).

Vielight Will Attend the Annual Hyperbaric Medicine Symposium

From September 27 to 29, Vielight will be participating in the 13th Annual Hyperbaric Medicine Symposium in Charleston, South Carolina. The symposium showcases the latest evidence in hyperbaric oxygen therapy for TBI. Vielight will be actively caucusing with researchers and practitioners in the field of HBOT to treat TBI. This will be an exciting symposium with some high-profile retired athletes who are familiar with TBI conditions. More information about this symposium is accessible through this [link](#).

Dr. Lew Lim's Workshop at ISNR 2019 promises to be Special

ISNR is the main annual gathering of neurofeedback practitioners which takes place from 18 to 20 of September 2019 in Denver, Colorado. Five Vielight 810 Infrared PBM devices will be raffled during the 3-hour workshop by Dr. Lew Lim on Sep-

tember 19. Considering the content, this factor should not be the main reason for attending to workshop. There is a growing community of people following the work of Dr. Lim, many of them are neurofeedback practitioners.

Dr. Lim offers a glimpse into his workshop: "I have given many presentations, but never had the opportunity to share deeper insights due to time limitation. The three-hour allotted for this workshop will be fast-moving and packed with valuable take-home information. I will be sharing clear principles behind the successful outcomes, as well as our research directions. More importantly, there will be information on previously unrevealed tips to improve the quality of user benefits with Vielight. These will include thoughts and ideas on how we can significantly improve mental performance."

Photobiomodulation could replace opioids as a new remedy for cancer treatment side effect

A worldwide coalition of researchers and clinicians has agreed that photobiomodulation (PBM) is among the most effective interventions for the prevention of oral

mucositis. This condition involves painful ulcers in the mouth, commonly resulting from cancer therapy.

This claim is supported by the Multinational Association of Supportive Care in Cancer (MASCC) and International Society of Oral Oncology (ISOO). They published the guidelines on July 8, 2019, in the journal *Supportive Care in Cancer*. It presents a significant upgrade in care guidelines for adult cancer patients worldwide.

The guidelines recommend photobiomodulation therapy, a form of low-dose light therapy, for the prevention of oral mucositis. The condition is often caused by radiation therapy for head and neck cancer, or stem cell transplantation.

"Many cancer patients can now benefit from this treatment", said Praveen Arany, DDS, PhD, co-corresponding author on the paper and assistant professor of oral biology at the University at Buffalo School of Dental Medicine.

SEPTEMBER 19

Attend Presentation
by Dr. Lew Lim

Plenary 3 8:00-9:00 AM

Attend Workshop
by Dr. Lew Lim

WS1 3:30-6:30 PM

WIN Raffle!
Five 810 NIR \$499 each



VISIT
VIELIGHT BOOTH

Experience the Vielight
PBM devices

ISNR 2019


"This is a major milestone for the field, and we are confident it will set a clear path for several exciting clinical applications for photobiomodulation therapy from concussions and wound healing to exciting new work with regenerative medicine and stem cells," noted Dr. Arany. Dr. Arany is also the president of the World Association for photobiomodulation Therapy (WALT).

(Source: University at Buffalo, July 9, 2019.)