

Full 'concept through to manufacture' development of acne treatment lamp

Norwegian based pharmaceutical company Photocure identified the need for a new, large area photodynamic treatment (PDT) lamp that could be used in combination with its proprietary pharmaceutical Visonac™ for the treatment of moderate to severe acne.

With time to market and cost of development as key issues, the company recognised that a highly focused development programme would be required. Photocure chose Sagentia as its development partner due to our track record in the medical device sector, our ability to offer a rapid concept to manufacture development programme and the assurance we could offer through our accreditation to the medical device quality management standard ISO 13485.

Based on Photocure's IP and product requirements, Sagentia undertook the complete product development programme, comprising: analytical modelling to identify the best technical concept; all mechanical, electronics, software and optical development work; validation and optimisation of advanced design concepts with clinical stakeholders; the establishment of an extended production supply chain; approvals testing for EU and US regulatory requirements; and transfer to production using Photocure's existing European sub-contract manufacturer.

Photocure's brief called for a large area PDT lamp that could provide uniform illumination of the whole face.

To meet this need, we developed a 3D optical model to simulate illumination across the entire face and investigate the performance of different product concepts. Our 3D model was able to determine that full face illumination could be achieved using just two angled lamp panels rather than the three to five previously considered necessary.

The fully developed lamp – known as Aktilite CL512 – comprises two light panels with 512 light emitting diodes that deliver a controlled dose of red light. The panels can be adjusted to treat either the face or flat areas such as the chest or back. A mobile trolley stand and articulating support arm are used to position the lamp over the treatment area. Clinical trials are due to commence in 2009.



New in-home device aids rehabilitation of stroke survivors

An innovative home device that will help stroke survivors recover the use of an arm was unveiled at the February meeting of the American Physical Therapy Association (APTA) in Las Vegas.

The device, and associated therapy, were co-invented by the University of Maryland (UMB) School of Medicine's Jill Whitall and Sandra McCombe-Waller.

Through a licensing partnership with UMB, US firm Encore Path Inc refined the invention into a compact, retractable and portable device called Tailwind.

Kris Appel, Founder and President of Encore Path, learned of the UMB technology in 2006 when she was a student in the ACTiVATE programme at UMB.

After licensing the device in 2007, Appel engaged Sagentia to help redesign the invention into the current Tailwind model and take it to marketable product.

Sagentia's design work included extensive voice of the customer research, working with stroke patients during the prototype validation, and ultimately designing

a user-friendly device that can dramatically change the lives of stroke victims.

The device works by bilateral training, as the seated patient uses both arms to push and pull handles on separate, or unyoked, tracks with minimal resistance.

Whitall and McCombe-Waller came up with the idea for the arm therapy based on motor control and motor learning principles, as well as clinical experience with patients.

They had previously studied gait therapy but thought there was a greater need for a new kind of therapy of the affected arm, particularly for those who were more severely affected by the stroke. Their invention can mimic natural human physical functions of the upper extremities in a variety of positions.

Following Tailwind's initial showing in Las Vegas, the unit will be launched to business and media at the University of Maryland later this year.