Updated in early 2017 to cover the update to the publication of the FDA (CDRH) document “Applying Human Factors and Usability Engineering to Medical Devices”, this year’s course will include the updates to the MHRA and FDA (CDER) draft publications and the latest ISO publications regarding Human Factors.

This 3-day event will inform you of the Regulatory requirements of FDA, more specifically the interpretation from the Centre for Devices and Radiological Health (CDRH) Human Factors Pre-Market Review Team, as they relate to human factors and the process of applying human factors in design controls and the FDA approval process during the design of a medical device.

We’ll discuss the basic foundation for applying human factors, including:

- The application of user models
- Task analysis
- Analysis of use errors
- How task analysis forms the basis for planning human factors efforts and risk assessment

10 reasons to attend

- How the publication “Applying Human Factors & Usability Engineering to Medical Devices” from FDA/CDRH applies to you
- Hear about the new clauses in the draft publication “Human Factors Studies & Relayed Clinical Study Considerations in Combination Product Design and Development” from FDA/CDER
- Be first with the knowledge on the updates for ISO62366 & HE75
- See how Task Analysis Risk is applied through ISO1497
- Have YOUR questions answered directly by the FDA
- Preliminary Analyses for Pre-Market approval
- Formative Evaluation and Design Modification
- Human Factors Validation Testing
- HF/Usability Report
- Validation Design Exercise
Along with a review of human factors activities: -
- Contextual inquiry
- Heuristic evaluations
- Formative studies
- And Summative studies

We’ll cover relevant Human Factors standards, as well as Human Factors in the post-market arena. And there’ll be hands-on exercises as well as real-life case studies, illustrating the application of Human Factors to medical devices.

In addition, there will be two specific faculty Q&A breakfasts where you can have your specific questions answered.

Workshop Faculty

This world class and unique faculty comes together to bring a wealth of knowledge and direct, first-hand FDA experience.

Dr Robert North

Bob North is Chief Scientist for Human Centered Strategies and an expert on human performance modelling and prediction. Bob is an expert in use error analysis and prediction/prevention for home and hospital medical devices.

Prior to his consulting career, Bob managed the human factors departments at Medtronic and Honeywell International. Not only is Bob co-author on FDA human factors standard: ANSI/AAMI HE-75 Human Factors Design Guidelines for Medical Devices, but he’s also a recognised expert on IEC-60601-1-6 Collateral Standard, Electronic Medical Devices and ANSI/AAMI He-48, Human Factors Design of Medical Devices. He has served as an adjunct faculty member for short courses (representing the FDA’s position) on Design Controls for manufacturers and written over a dozen scholarly articles on Human Factors.
Ronald D Kaye

Until recently, Ron was the Human Factors Pre-Market Evaluation Team Leader for the U.S. Food and Drug Administration (FDA), located in the CDRH Office of Device Evaluation (ODE) and within the Division of Anaesthesia General Hospital and Infection Control Devices (DAGID).

Ron not only has a BS degree in Psychology and Biology, but he also has an MA in Applied Psychology. He’s worked in Human Factors for 30+ years, 15 of which have been with the FDA’s Centre for Devices and Radiological Health (CDRH).

Prior to joining the FDA, Ron worked with Human Factors and human performance testing, training analysis, and research on safety-critical systems, such as nuclear power plant control rooms, military weapons and communications systems, aircraft cockpit systems, air traffic control systems, and medical devices.

Direct Involvement from the FDA

During the course, we hope there will be an opportunity to speak to Shannon Hoste and Irene Chan who are both from the FDA.*

This will involve a 1 hour Q&A session for all delegates where Shannon and Irene will answer questions in all matters relating to the approval of pre-market submissions for Human Factors at the FDA.

*to be confirmed

Event Host

About The Moon on a Stick ltd

We are a company based in the UK, and have been born out of the rebranding of Pure Insight. Our main focus is on working with global organisations to help them embed a sustainable Front End Innovation process into their organisation, allowing them to identify the trends that will affect their businesses in the future and working out scenarios that may occur from those trends and create advantageous opportunity spaces for them to exploit. To date we have taught over 60 companies and in excess of 600 practitioners our easy to follow processes.

As a business we have in excess of 50 years experience in the innovation spaces with companies such as Marks and Spencer, Unilever, Mars, Ford, CPL and Boots Healthcare International.

For more information on what we do, and how we could help you, have a conversation with us by calling +44 (0)7535 669017 or writing to sean@the-moon-on-a-stick.com.
The Venue

Hilton Hotel, Cambridge, UK
Located in the heart of the city, within walking distance to attractions and nightlife, Hilton Cambridge City Centre is the perfect base for exploring the university town. We’re easily accessible by road and rail, and just 45 minutes from London Kings Cross. As the largest central hotel in Cambridge, you’ll find all you need for an unforgettable stay including a fitness room and a relaxed restaurant and lounge.

We do not reserve rooms at venue hotels for delegates as we find that using one of the web based hotel pricing sites offers better prices than we can negotiate.

Making a Reservation

Course Fee
The cost of this 3 day course is £2,150, which will include attendance at all plenary sessions and all course materials. It does not include the cost of travel or accommodation.

How to make a booking
On line at: https://goo.gl/KHYxAP
By telephoning Sean Warren on +44 (0)7535 669017
By e-mail to: sean@the-moon-on-a-stick.com
Terms and Conditions

Payment
Payments must be made before the event takes place. The Moon on a Stick (MOAS) reserves the right to deny access without payment.

Cancellation Policy
Subject to the conditions below, delegates are entitled to a full refund (less administration fee of £75) up to 28 days from the original date of registration. No refunds can be made for cancellations received after this date or for delegates who fail to attend the event. Substitutions are however welcome. In the case of substitutions not being possible, MOAS will offer a credit note, which can be redeemed against future MOAS events for a period of 12 months from the date of cancellation. Where bookings are made less than 28 days prior to the class, only credit notes will be offered should delegates wish to cancel, or not be able to attend.

Cancellation of the Event
In the unlikely scenario of the event being cancelled, either through force majeure or for any other reason, the liability of MOAS will be limited to the full return of the registration fee. No other claims against MOAS will be considered.

VAT
Under EU Council Directive 2006/112/EC MOAS will only charge VAT on events held within the UK.