10 reasons to attend

1. Intensive discussion of FDA perspective, precedents & assumptions to ensure successful HF submissions.

2. What the FDA Guidance, "Applying Human Factors...etc" says about the HF review process priorities and how this applies to YOU.

3. How to understand and respond to FDA feedback and deficiency notices.

4. HF Testing, test theory and perspective on simulated use-based testing, and data, including considerations bias.

5. Considerations of "traditional" Risk analysis of use-related use error scenarios, application of IEC-14971 and FDA review expectations.

6. "How-to" develop your own Use Related Risk Analysis (URRA) for your product and identify critical user tasks.

7. Special discussion of CDER draft guidance for industry: "Human Factors Studies & Related Clinical Study ... etc" AND "Comparative Analyses and Related Comparative Use Human Factors Studies for a Drug-Device Combination Product Submitted in an ANDA".

8. Group Human Factors/Usability validation (Summative) testing. Step by step, with discussion and instruction on each essential phase.

9. Group exercise on formative testing with a sample device.

10. How to write your HF Summary report for to promote efficient review at FDA including the most common stumbling blocks.

This unique course offers you the chance to hear directly from the designer of the initial and on-going Human Factors review process at the FDA, and one of the World's leading consultants in HF in Medical Devices.

With the experience of over 1000 new device reviews at the FDA and 1000's of industry applications under their belts, you will learn what do to, what not to do and how to vastly improve your chances of a right first time submission.

Further developed for 2018 to include a full summative group exercise, HF report writing and development of full validation protocols, this 3-day event will inform you of the Regulatory requirements of FDA, more specifically the interpretation from the Center 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:
**Day One**

- Acronyms, The FDA and Regulatory Law for HF, Recalls and Examples of UI Flaws in Medical Devices, How Use Error/Design Flaws are Detected, “ODP,” Example Flawed Devices, General HF Data Requirements for FDA Review

- “Qualitative vs. Quantitative” Approaches to HF Testing and Evaluation, FDA Reviewer Perspective

- “Traditional” Risk Analysis, Role of HF/Usability Work for High-risk Technology

- Human Factors Guidance and Standards Overview

- Analysing Users and Use Environments, and Defining Device User Interface

- Preliminary Analyses and Evaluations

- Review of analytic and empirical formative evaluation methods to identify use safety related device issues and identify device Critical Tasks. (GROUP EXERCISE using user-device interaction model to identify potential use errors for a medical device.)

**Day Two**

**GROUP EXERCISE:** Applying formative methods to identify use related problems in the design of a medical device

Validation and Documentation

**GROUP EXERCISE:** Development of HF report to directly evaluate a UI design problem

**GROUP EXERCISE:** Applying summative methods to identify use related problems and errors in the design of a medical device.

**Day Three**

Faculty Breakfast Q&A

**GROUP EXERCISE:** Design and present a Summative Validation Test Plan

*a more detailed agenda is available on request

**Day One**

- Critical task identification and development (in class) of a use-related risk analysis (URRA) consistent with FDA expectations for human factors submissions.

- Consideration of use error scenarios within the overall context critical tasks, risk, and HF/U (Summative) testing.

- Considerations for compliance with IEC-62366 and meeting FDA review priorities.

- Discussion of specific HF techniques such as Contextual Inquiry, Heuristic evaluations, Expert Review and Formative testing.

- Class exercise developing a Human Factors/Usability (Summative) test and Test Report consistent with FDA review expectations and priorities will be integrated into the three days of the class including discussion, questions, and critique for each step.

We’ll cover relevant Human Factors standards, as well as Human Factors in the post-market arena. There will be group exercises integrated into explanation and discussion for each step of the process, illustrating the application of Human Factors to medical devices, using methods and language acceptable to FDA HF review teams.

In addition, there will be a specific faculty Q&A breakfast 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.
Essential Human Factors

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-75, 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

Ron Kaye recently retired from the FDA's Center for Devices and Radiological Health where he led the development of its Human Factors initiative during his 19 year tenure at the agency. Ron was the lead author of the original FDA human factors guidance released in 2000, and the current HF guidance released in February 2016, which represents the perspective of the FDA on pre-market submission human factors requirements. During his time at CDRH, Ron participated in over 1000 new device reviews involving human factors work submitted to almost all CDRH divisions, has trained FDA CDRH and CDER HF reviewers and (some) field inspectors, and has participated in Agency post-market responses and recalls associated with use error issues.

Ron has been integrally involved in the education of the FDA and device manufacturers regarding the human factors process in device design and testing. Ron’s participation as a faculty member of the AAMI HFE course has brought the FDA human factors message to over 1200 industry practitioners over the past seven years, resulting in a significant improvement in human factors work for new device submissions. He has also been a co-author of the AAMI/ANSI (HE-75) Standard, Human Factors in the Design of Medical Devices and has participated in the international working group that produced IEC 62366, Application of Usability Engineering to Medical Devices.

Event Host

About The Moon on a Stick ltd

We are a company based in the UK. 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

DoubleTree by Hilton Minneapolis - University Area

DoubleTree by Hilton Minneapolis-University Area is situated east of downtown Minneapolis on the University of Minnesota campus, two blocks from Stadium Village light rail station. Across the street from the University of Minnesota Clinics and Surgery Center, this upscale hotel will excite with contemporary décor and DoubleTree chocolate chip cookie, baked fresh and awaiting your arrival.

The hotel is across the street from the TCF Bank Stadium, home of the Golden Gophers and minutes from the US Bank Stadium, home of the Minnesota Vikings. Watch a game at Target Field, home of the Minnesota Twins or at Target Center, home of the Minnesota Timberwolves. You’ll also be close to Fairview Hospital and the Minneapolis Convention Center.

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 $2,200, which will include attendance at all plenary sessions and all course materials. It does not include the cost of travel or accommodation. For the first 10 delegates booking, we are pleased to offer an early bird discount of $150 from the published price. Discounts are also available for group bookings. Contact us for more information.

How to make a booking

On line at: https://conta.cc/2vz32RF

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