HUMAN FACTORS & THE USABILITY OF MEDICAL DEVICES

THE MOST CURRENT, NO-NONSENSE INSTRUCTION FOR NECESSARY TECHNIQUES, ADVANCED CONCEPTS, FDA REVIEW PRIORITIES, COMMON COSTLY MISUNDERSTANDINGS, AND FUTURE DIRECTIONS.

INSTRUCTORS - RONALD D KAYE & DR ROBERT A NORTH

5th to 7th March 2019 |Radisson Blu Hotel, London Stansted Airport

TEN reasons to attend

1. Intensive and comprehensive discussion of FDA pre-market perspective, precedents & priorities for every topic presented in the course.
2. How the FDA Guidance, **"Applying Human Factors..etc"** applies to your submission to the FDA.
3. How to interpret and understand, and respond to FDA feedback on pre-submissions including "Type C" meetings, and pre-submission review deficiencies.
4. HF Testing, test theory and test data, test processes, protocol development and sources of test bias.
5. Analysis of use-related risks, considerations of IEC-14971, implied or missing methods/priorities.
6. "How-to" identify critical user tasks, and develop a Use-related Risk Analysis (URRA) from scratch that will be acceptable upon review and prevent unpleasant surprises when your HF submission is reviewed.
7. Special considerations discussion, and review expectations of CDER draft guidance for industry - **"Human Factors Studies & Related Clinical Study ...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. In-class Formative testing, theory and practice using a sample medical device with IFU.
9. Group projects beginning with overall HF evaluation plan, identification of users, user groups, use environments, user tasks, task criticality, URRA, formative testing, simulated use-based HF/U (Summative) validation testing, data collection, analysis and evaluation of test data, and HF test report.
10. How to avoid vagueness and incompleteness in your submission.

This unique course is aimed at people who have experience with Human Factors application in Medical Devices, or have been on an introductory course in past (with us or AAMI) and wish to develop their skills to improve their chances of a right-first-time submission to the FDA.

The 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 the assessor is looking for and how to construct your approach and submission strategy to ensure success.

This course has been revolutionised to include **overall unified theory of use-related risk analysis of device usability, evaluation of user interface design, evaluation and testing including HF/Validation (Summative), and FDA review priorities, and occasional apparent inconsistencies.**

Day One

- Theory of testing safety-critical technology using a simulator or simulated use.
- Definition of device medical device user interface (UI) and implications for HF evaluation and test protocol design period.
- Identifying and defining device users, user groups, expected use environments, and validation test environment.
- How to incorporate training in your HF/U validation testing; how to avoid "non-representative" training that could invalidate your testing.
- Pre-submission and "Type C" protocol review experiences, and how to understand and respond to FDA negative feedback; how to evaluate "lack of" specific feedback.
- Use error, use-safety, effectiveness of use, and "residual risk," and their implication for formative testing, HF/U text protocol development, and Reporting
- HF and use safety considerations for software-based medical devices/medical and mobile medical applications.

Day Two

- UI design flaws and design inadequacies.
- **Group Exercise:** Develop a task analysis, identify an define critical user tasks, develop Use-related Risk Analysis (URRA)
- **Group Exercise:** Learn how to use formative test results to identify and fix UI design problems and fix them prior to HF/U validation testing.
- Three essential kinds of HF/U validation test data and why it is sought during HF review. What data is unnecessary for inclusion in your submission.
- Learn the potential applicability and drawbacks of quantitative approaches in HF testing. Rationale or the appropriateness of, and when to use/not use quantitative analyses. How to incorporate quantitative test results, rationale or using/not using quantitative analyses into your HF report.
- **Group Exercise**: Development of a HF/U validation test protocol for pre-submission review or to use directly in HF/U validation testing.

Day Three

- **Group Exercise:** Complete and present and critique a summary of HF/U validation Test Report and HF/U Validation Report.
- What makes a FDA review difficult, and what makes it go smoothly for the reviewer.
- Why can HF reviewers be nitpicky? Why do they sometimes appear to be inconsistent?
- New developments for HF/U testing, the future of HF for medical devices and the FDA.
- Three most important top ask a potential HF test provider
- Finding little or nothing wrong in HF testing; Is this OK? What does it mean?

You will participate in a HF/U (Summative) test exercise that will feature advanced perspective, understanding in advance key concepts and review priorities; that your test protocol is sound, avoids confusing statements, conclusions, incompleteness and other big "no-nos". You will learn how to ensure a valid and comprehensive evaluation of the test data are included in the report you will submit to the FDA.

This 3-day event will inform you of the Regulatory review expectations of FDA, commonly encountered issues and mistakes. You will see how reviews are viewed through the eyes of Human Factors Pre-Market Reviewers at FDA.

We'll discuss the basic foundations for applying human factors, design, evaluation and testing, including:

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

•Construction of user groups and test scenarios.

•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.

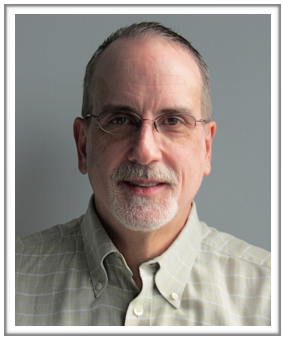
•Class exercise developing a Human Factors/Usability (Summative) test and Test Report consistent with FDA review expectations and priorities will be integrated into the three days of the class including discussion, questions, and critique for each step.

We'll cover relevant Human Factors standards and their appropriate application to FDA submission materials. There will be group exercises, illustrating the application of Human Factors to medical devices, using methods and language acceptable to FDA HF review teams.

Workshop Instructors

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

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.

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 FDA/CDRH guidance Applying Human Factors and Usability Engineering to 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.

Event Host

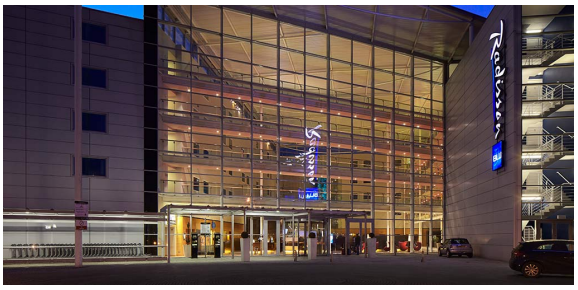
About The Moon on a Stick ltd

We are a company based in the UK, and have been born out of the re-branding of Pure Insight.

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

Radisson Blu Hotel, London Stansted Airport



The Radisson Blu is only 500 metres from Stansted Airport's main terminal, and within easy walking distance of the bus and train station. The airport train station runs direct rains to and from London, Birmingham or Cambridge, and the airport offers flights to a wide variety of international cities.

As with all our events, we do not negotiate rooms rates with the hotel, as we find delegates get better deals with the many internet booking sites. If you do not wish to stay at this hotel there are many other chain (Hilton, Holiday Inn Express and Premier Inn) within a few minutes of the Radisson Blu

Course Fee

The cost of this 3 day course is £1,750, 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://tinyurl.com/yctwzuzc

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

The Moon on a Stick Ltd, Business Central, 2 Union Square, Darlington, DL1 1GL
The Moon on a Stick Ltd is company registered in England and Wales