

Day One Outline

Module	Contents & Topics
Module 1 Introduction & Overview	<ul style="list-style-type: none"> • Identify the scope of Human Factors Engineering and its role in medical device development • Relate Human Factors activities to the medical device Design Controls Process of the Quality System Regulation • Preview the course modules related to key objectives in applying Human Factors in medical device development
Module 2 FDA/CDRH Pre-market Review Perspective	<ul style="list-style-type: none"> • Relate the FDA perspective on safety and use error avoidance to user interface design of medical devices • Identify essential elements of successful FDA submissions regarding human factors and use error analysis • Identify current industry Human Factor trends seen by the FDA in new device submissions regarding
Module 3 Preliminary Analyses for Pre-Market Approval	<ul style="list-style-type: none"> • Identify the key analysis methods and documents for conducting Human Factors Preliminary Analyses requirements of a medical device in the early stages of device development • Identify the relationship of these methods to overall device Risk Management and FDA expectations for pre-market approval • Learn to analyze the user as a system component
Module 4 Formative Evaluation and Design Modification	<ul style="list-style-type: none"> • Identify Formative Evaluation methods that are appropriate for iterative modification of device user interfaces early in Design Concept and Design Input stages • Relate these methods to overall use-related risk identification and management

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Module 5 Human Factors Validation Testing	<ul style="list-style-type: none">• Expectations for comprehensive and adequate HF/Usability validation test• Steps in planning and executing HF/Usability validation studies
Module 6 HF/Usability Report	<ul style="list-style-type: none">• ODE reviewer expectations for pre-market review of HF/Usability in new device submissions• Supports your development of the HF/Usability section of your new device submission
Module 7 Case Study I: Planning and Conducting Human Factors for an Auto-Injector Drug Delivery Device	<ul style="list-style-type: none">• Identify characteristics of a good HF plan• Discuss the creation of a HF plan• Given a scenario, evaluate and make suggestions for improvements

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Module 8 Overview of Human Factors Medical Device Standards	<ul style="list-style-type: none">• Identify the current standards that apply to both the human factors process and device user interface design• Relate the standards to their specific regulatory relationships to FDA and international regulatory bodies' processes
Module 9 Application of Human Factors in Medical Device Design	<ul style="list-style-type: none">• Incorporated Human Factors from design inception• Followed the FDA's Human Factors guidances and ISO IEC standards
Module 10 Validation Exercise	<ul style="list-style-type: none">• Identify characteristics of a good Test Plan and Analysis Elements