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PHARMACEUTICAL REGULATORY AFFAIRS AND IPR

September 25-26, 2017 Chicago, USA

International standards for applying human factors engineering to medical product design

Edmond Israelski AbbVie, USA

Expectations have increased dramatically from international regulators for more comprehensive and rigorous application of human factors/usability engineering in the design and evaluation of medical products. This is true for devices, combination products and traditional pharmaceutical offerings. In this presentation you will learn more about human factors standards and regulations, including: New ISO/IEC usability engineering/human factors standards for medical devices: IEC 62366 Parts 1 and 2; New MHRA human factors standards for the UK; New AAMI standards for HFE and; New FDA guidance for HFE for medical devices and combination products

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