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LEAN ENTRIES LTD

REGULATORY ESSENTIALS IN HEALTH TECH – TRAINING PROGRAM

PART II

Sessions 1 to 4 (Part I) of the training program were held in June 2020. Recordings are available to attendees.

The Part II in September 2020 starts with session 5 that provides regulatory essentials for medical device software (stand-alone and embedded). Sessions 6, 7 and 8 are relevant to all medical device manufacturers.

SESSION 5

MEDICAL DEVICE SOFTWARE

- Software Qualification and Classification
  - The EU perspective – the MDCG 2019-11 guidance document
  - Why do all software land in class IIa or higher in EU, requiring a Notified Body?
  - The US FDA perspective
  - Unregulated software in hospitals – What to take into account?
- Software Life Cycle requirements – Stand-alone and embedded SW
  - The IEC 62304 standard
  - Software classification in IEC 62304
  - From SW architecture to development, testing and validation (incl. IEC 82304)
  - Agile methodologies and review practices
  - SW maintenance

SESSION 6

USABILITY AND LABELLING

- Usability
  - The IEC 62366 standard on Usability
  - The human factors and user experience (UX) to ensure safety and business
  - Relation to Clinical Evaluation and Risk Management
- Labelling
  - Instructions for Use
  - Intended use, contraindications, warnings, off-label use
  - Marketing claims – What can you claim?
  - Use of symbols
  - Unique Device Identifier (UDI)
  - Translations

SESSION 7

CLINICAL EVALUATION IN PRACTICE

- Purpose of Clinical Evaluation
- MDR requirements and guidelines
- Structure of Clinical Evaluation Plan and Report
- Claims and clinical benefits of your device
- Establishing "state of the art"
- Gathering and assessing clinical data
- Conducting and documenting literature and database searches

SESSION 8

RISK MANAGEMENT IN PRACTICE

- Purpose of Risk Management
- MDR requirements and ISO 14971 standard
- Fundamental concepts
- Stages of Risk Management process
- Risk analysis, evaluation and control in practice
- Residual risks and Risk Management Report
- Risk Management throughout the product life cycle