# REGULATORY ESSENTIALS IN HEALTH TECH – TRAINING PROGRAM

## Tampere Health Technology and Life Sciences Ecosystem

Each session covers 2 hours of training, leaving ½ an hour for discussion.

Sessions 1 to 4 form the core of the training. Session 5 is also essential to all medical device manufacturers. Session 6 provides essentials for medical device software (stand-alone or embedded) and Session 7 for hardware.

A certificate of attendance is sent for each trainee based on the sessions they attended.

The ENTRIES digital platform will be utilized and case examples will run throughout the training.

## SESSION 1 – Monday, 1 June 2020 at 13:30 – 16:00

### INTRODUCTION TO REGULATORY ESSENTIALS

- Global medical device regulations as your competitive advantage
  - Safety and clinical efficiency are not negotiable
- Early focus of the health tech developer
  - Intended Purpose as the heart of your product
  - Is my product a medical device and what risk class? Software, hardware and borderlines
  - What does the risk class tell me? Your options for certifications and market approvals
  - How to save resources and time? Avoid re-inventing regulatory compliance
  - Your Regulatory Strategy and roadmap to market entry
- Align compliance with business, marketing and sales needs
  - Know the General Safety and Performance Requirements
  - Early increments: Literature Review, Risk Analysis, Feasibility Studies, Supplier Control
  - Regulatory compliance in your Business Model and Value Proposition
  - The level of regulatory know-how in your business
  - Responsibilities and authorities within the business
  - Regulatory due diligence in investments, mergers & acquisitions - lessons learned

## SESSION 2 – Thursday, 4 June 2020 at 8:30 – 11:00

### EARLY DEVELOPMENT AND MANAGEMENT

- Early development stages
    - Timelines and the Medical Device Life Cycle
    - Capturing the Value Proposition
    - Early validation through Feasibility Studies
    - Preparing for Design Control and Post-Market activities
    - Assigning roles and responsibilities in-house and externally
    - Document and records management, logs and traceability
- Building your Quality Management System (QMS)
    - ISO 13485 and other international QMS related standards
    - Management responsibility
    - From planning to operations - Ensuring consistently safe and efficient devices
    - Supplier Control - From supplier evaluation to contracts and partnership
    - Importer and Distributor relations

## SESSION 3 – Monday, 8 June 2020 at 13:30 – 16:00

### THE CORE OF REGULATORY REQUIREMENTS

- General Safety and Performance Requirements for Medical Devices
    - The heart of the regulation
- Introduction to Clinical Evaluation
    - Related guidelines and standards, MEDDEV 2.7/1 and ISO 14155
    - Literature Reviews
    - Clinical Investigations
    - Post-Market Clinical Follow-up
    - Balancing between the necessary and the business advantage
- Introduction to Risk Management
    - The ISO 14971 standard for Risk Management
    - The sequence of events and Risk Analysis
    - FMEA as the model for Risk Management
    - Risk mitigation
    - Benefit-Risk conclusions - balance with Clinical Evaluation

## SESSION 4 – Thursday, 11 June 2020 at 8:30 – 11:00

### DESIGN CONTROL AND THE REGULATORY ENVIRONMENT

- Introduction to Design Control
  - From Feasibility Studies to Post-Market Surveillance
  - Design Verification and Validation
  - Transfer to production
- Authorities, Notified Bodies and test labs
  - Towards certification – CE-mark, FDA approval and global market access
  - The perspective of authorities globally
  - Auditing and certification practices
  - Communicating with the authorities
- Considerations on the Changing Global Regulations
  - Navigating the transitional periods
  - From the current EU directives to new regulations - IVDD to IVDR, MDD & AIMDD to MDR
  - Strategies for dealing with a variety of requirements and timelines

## SESSION 5 – Fall 2020 (to be announced)

### 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 6 – Fall 2020 (to be announced)

### 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 7 – Fall 2020 (to be announced)

### BIOLOGICAL AND ELECTRICAL SAFETY

- Biological Safety
  - The ISO 10993 series of standards
  - From material characterization and Risk Management to biocompatibility testing
  - External service providers for testing
- Electrical Safety
  - The IEC 60601 series of standards
  - Basic Safety and Essential Performance - Risk Management considerations
  - Collateral and Particular standards for different types of electromedicals
  - Electromagnetic compatibility (EMC) testing
  - External service providers for testing