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Learning Modules

Module 1
- EU MDR and ISO 19011 Overview
  - Key Changes from the MDDs
  - Relationship to ISO 13485:2016
  - ISO 19011:2018 Overview

Module 2
- EU Market Pathway Compliance
  - Device Classification
  - Conformity Assessment
  - Economic Operators
  - Person Responsible for Regulatory Compliance
  - Quality Management System

Module 3
- General Safety & Performance Requirements (GSPR)
  - General Requirements
  - Requirements Regarding Design and Manufacture
  - Requirements Regarding Information Supplied with the Device

Module 4
- Technical Documentation, Identification, & Traceability
  - Technical Documentation Requirements
  - Unique Device Identifier (UDI)
  - Registration Databases

Module 5
- Clinical, Post-Market, & Investigation
  - Clinical Evaluation
  - Clinical Investigations
  - Post-Market Surveillance & Vigilance
  - Post Market Clinical Follow-Up

Course Exam

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Why Do You Need This Training?

- The requirements have changed in both subtle and significant ways
- Knowing the requirements doesn't necessarily imply knowing how to confirm compliance to them
- Compliance isn't just about meeting the requirements, but about achieving their intended outcomes

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Learning Objectives

- Know how to navigate the regulation articles and annexes to find applicable requirements and expectations
  - The MDR is 175 pages! You aren't going to be able to memorize all the details.
- Know the types of questions to start with
  - These will be starting points; Auditors will need to ask further questions relative to initial responses and the detailed requirements being covered
- Know what evidence to request
  - Again, this will be a starting point; additional evidence will need to be requested based on what's observed and how the auditee has chosen to establish documented information
- Understand some of the nuances and interrelationships within the MDR
  - While much more prescriptive than the MDDs, the MDR still has some implied intent and requirements that don't stand on their own

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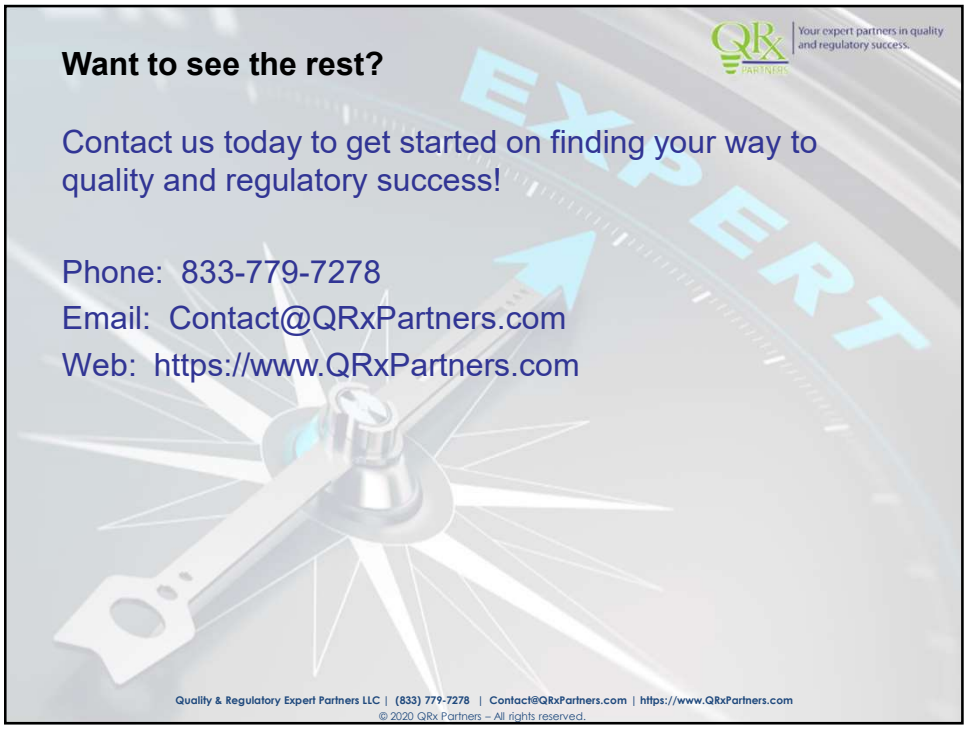
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