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# EU MDR & IVDR REPLAY PACKAGE

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EUROPE'S FIRST DEVICE REGULATIONS: A LOOK INTO MANUFACTURERS' RESPONSE TO THE DELAY, TRANSITION, & IMPLEMENTATION PROCESS





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#### HOW TO MAINTAIN A QMS COMPLIANT TO MDR & IVDR

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MDR WITH BREXIT: HOW THE COMBINATION IS IMPACTING THE EUROPEAN MEDICAL DEVICE INDUSTRY



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# PREPARE NOW FOR THE EUDAMED UDI/REGISTRATION MODULE

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# ECONOMIC OPERATORS: IMPLEMENTATION CHALLENGES AND OPPORTUNITIES

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# ESSENTIALS FOR CLINICAL EVALUATION OF MEDICAL DEVICES

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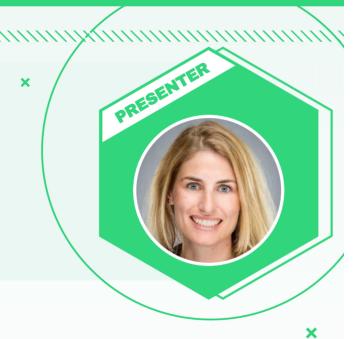
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CE MARK TECHNICAL DOCUMENTATION: CHANGES, APPLICATION, AND NOTIFIED BODY EXPECTATIONS UNDER MDR



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#### EFFECTIVE POST-MARKET SURVEILLANCE IN THE EU UNDER MDR

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### HOW TO CREATE MEDICAL DEVICE LABELS PER EU MDR

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# RISK MANAGEMENT ACCORDING TO EU MDR OR ISO 14971?

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#### SUPPLY CHAIN MANAGEMENT UNDER THE MDR, BREXIT AND SWIXIT











# HOW TO PREPARE FOR COMMON MDR AUDIT PITFALLS

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# IMPLEMENTING AND MAINTAINING CHANGES TO SAMD UNDER MDR

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# THE WHO, WHAT, AND WHEN OF IVDR ENFORCEMENT

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#### HOW TO MEET CYBERSECURITY REQUIREMENTS OF EU MDR & IVDR











THE ROAD TO 2024: REGULATORY
RISKS RELATED TO CHANGED
POST-MARKET SURVEILLANCE
REQUIREMENTS AND NOTIFIED BODY
CERTIFICATION



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# ADDRESSING THE NOTIFIED BODY BOTTLENECK

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# FROM SELF-DECLARATION TO CERTIFICATION: PROVING PERFORMANCE UNDER IVDR

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# THE NEW MDR: IS IT REALLY NEW AND DO WE REALLY NEED IT?

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RESULTS FROM A SURVEY OF OVER 230 MEDICAL DEVICE PRODUCT DEVELOPMENT AND QUALITY PROFESSIONALS.



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