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| I. | **THE NEW EU MEDICAL DEVICE REGULATION (MDR)** |
| | **REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.**<br>**The new regulation has been published on Official Journal of the European Union (L 117/1) on May 5, 2017.**<br>**The new rules apply three years after publication date for medical devices and five years after publication for IVDs.**<br>**The new regulations – which cover not only the design and manufacture of devices, but also clinical testing, authorization and post-market surveillance – have an impact on just about every device manufacturer that sells products in the EU.** |
| | **The purpose of this training course is to enable you to understand the main points under the new Medical Device Regulation (MDR):**<br>**1. Scrutiny procedure for highest risk Medical devices**<br>**2. Public transparency on vigilance and clinical investigations**<br>**3. CMR substances**<br>**4. Medical Device Classification rules**<br>**5. UDI**<br>**6. Technical documentation**<br>**7. QMS**<br>**8. Person responsible for regulatory compliance**<br>**9. Clinical evaluation**<br>**10. Risk management**<br>**11. Registration of devices and economic operators**<br>**12. Economic operators**<br>**13. Conformity assessment procedures**<br>**14. Liability insurance**<br>**15. Post Market Surveillance**<br>**16. The various Committees**<br>**17. Delegated and Implementing acts** |
| | **Our services include:**<br>**Upon completion of this course trainees will:**<br>**A. be able to understand the basics points of the new EU MDR;**<br>**B. be able to understand the actual changes of the new EU MDR;**<br>**C. get familiar with the principles of new EU MDR requirements.**<br>**D. EU MDR Implementation Consulting and maintenance**<br>**Gap analysis, design solution (custom made system), standard operating procedures, implementation, training, verification of effectiveness, and follow up, support certification** |
| | **References**<br>**Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC** |