COUNTDOWN TO EUROPEAN MEDICAL DEVICE REGULATION

by Oliver P. Christ

The implementation of the new European Medical Devices Regulation (MDR) and In Vitro Diagnostic Medical Devices Regulation (IVDR) has reached a critical momentum.

With only 20 months left in the transition period for MDR, medical device manufacturers that want to place medical devices on the EU market after May 26, 2020 are working diligently to implement the new regulatory requirements.

When it comes to budgeting and planning for additional regulatory resources, many manufacturers are still in gap analysis mode. The five hottest topics to meet compliance with MDR are:

- Clinical investigation and evaluation
- New roles and responsibilities for "economic operators"
- Postmarket surveillance and vigilance, and market surveillance
- Risk management and usability engineering/ design input
- Overhaul of labeling and technical documentation

The first notified bodies under MDR notification are expected to operate by the second quarter of 2019, one year prior to the end of the transition period. Compliance audits for MDR need to be prepared using ISO 13485:2016 as a basis for a compliant quality management system by adding in-depth processes required by MDR (e.g. for clinical investigation, postmarket surveillance, etc.). The new MDR Annexes II and III contain more detailed requirements for technical documentation for all classes of medical devices.

Now is the time to update "old" medical devices directive technical files to the new MDR requirements in Annex I (General Safety and Performance Requirements). The graphic above shows the estimated costs of implementing the new regulation. When companies do not have enough resources available in-house to do this job, external resources such as technical file development may be employed to manage the regulatory road map for success. Waiting is no longer an option. If you need assistance with this work, please contact **ochrist@prosystem-nsf.com**.

Cost Drivers for MDR 2017/745-Compliant Technical Files

	Cost Driver Related to new requirements on	**Effect on**	**# of MDR Articles** Due to new requirements	**Days of Work** Estimated
1	Clinical	CER Update (~MedDev 2.7.1 Rev 4)	Evaluation § 61 Investigation §62-82	15-20 days
2	Risk Management	FMEA > Hazard/risk-based [Probability of occurrence of harm]	Annex I GSPR 1-9	5-10 days
3	Usability	No USE ERROR true commitment! [~ IEC 62366-1 + FDA guidance]	Annex I GSPR 5	5-10 days
4	Labeling	Consistency and validity of all labeling information (+ UDI)	Annex I GSPR 23	10-25 days
5	PMS	Living all feedback loops [Annual PMS and clinical follow-ups]	PMS §83 – 100	5-15+ days
6	Editorial Updates	Review of intended purpose Rewrite technical file contents	Annexes II + III	4-8+ days
On average ~2.5 month = ~50 days | Premarket: 39-73+ days | Postmarket: 5-15+ days				

ABOUT THE AUTHOR

Oliver Christ has been active in international standardization efforts for more than 25 years and co-founded PROSYSTEM with the late Dr. Jürgen Stettin in 1999. The company was acquired by NSF International in 2017. In Germany, Mr. Christ has served as chair or co-chair of national committees including Human Factors/Usability for Medical Devices, Risk-Management for Medical Electrical Equipment, and Software for Medical Devices and Networked Medical Systems. Mr. Christ represents Germany on international standard committees for programmable electrical medical systems, human factors, risk management, software life cycle processes, and risk management for IT-networks incorporating medical devices (published as IEC 80001-1:2010). In 2013 Mr. Christ became an international delegate for Germany for the AAMI/UL initiative UL 2800 on Interoperability for Medical Devices. He received the DKE Needle award in 2014.

For more information, contact **medicaldevices@nsf.org** or visit **www.nsfmedicaldevices.org**

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