

Medical Device Safety: Investigating contributions of Human Factors*Kathrin Lange**Medical Devices Division, Federal Institute for Drugs and Medical Devices*

The core tasks of the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte [BfArM]) with respect to medical device safety include evaluating risks arising from the use or application of medical devices (based on incident reports), assessing and coordinating the counter-measures to be taken (i.e. corrective actions), and authorizing clinical trials of medical devices and evaluating the corresponding serious adverse events. Additionally, the BfArM also conducts research on medical device safety, specifically on the possibilities and challenges of data-driven approaches to detect and evaluate risk and on the contribution of human factors to device safety – i.e. factors that may have an impact on how users interact with a device. The present talk focuses on this latter issue. The significance of addressing human factors relating to the use of medical devices results from the contribution of human error to adverse events. For instance, an involvement of human error could be identified in a good 10% of the reports of suspected device-related incidents evaluated by the BfArM between 2005 and 2014. For several reasons, it may be assumed that the true value of device-related incidents involving human error is even larger and that the potential for human error is likely to increase in the future. To effectively reduce the risk for human error – or block its negative outcome - it is imperative to not only identify human error as a significant cause of adverse events, but rather understand the causation of *the error*, including the conditions under which errors are likely to occur. This requires the analysis of the perceptual, cognitive (e.g. attention, working memory, long term memory), motor or motivational processes involved and the identification of relevant factors at the various levels of the socio-technical system. In our research, we currently pursue two selected human factors issues, selected based on the incident-data collected at the BfArM and on the current literature: Insufficient *device knowledge* and the multi-faceted issue of *device alarms*, the latter including both the users' interactions with alarming devices and their perceptual, cognitive, or motor responses to the devices' alarms.