Wound Care Product Training Statement

The delivery of training from wound technology companies is an important resource for NHS staff. However, there is a lack of clarity between the delivery of product training and clinical training. This occurs for two reasons:

1. Training covering both product and clinical training is often combined without clear distinction of which elements are brand related and which are generic clinical components.
2. The same personnel are often used for delivery of both types of training with sales and medical education roles being combined.

Care Quality Commission Fundamental Standards, section C of Regulation 12, states that: "*persons providing care or treatment to service users should have the qualifications, competence, skills and experience to do so safely*". Professionals in health and social care are personally accountable when they use HealthTech products and therefore must ensure that they have appropriate training.

The Medical Device Regulation (MDR), and the UK Conformity Assessed marking (UKCA) legislation, require manufacturers to ensure that the device can be used safely and accurately by the intended user and provide information for safety and, where appropriate, training to users.

Combined, these regulatory frameworks define the need for end users of medical devices to be properly instructed in the use of, and risks associated, with any device, and for the manufacturer to provide training if necessary.

Product training is therefore the provision of the necessary information to ensure that the product can be used safely and effectively in line with the instructions for use. There is no specific format on how such training needs to be delivered.

There is no specific requirement for manufacturers to provide clinical training in the areas of speciality. However, there is a general requirement for company personnel to have the necessary education, background, training and experience to ensure that they can correctly carry out their role.

The criteria for these requirements is embodied in the Life Science Industry (LSI) National Credentialing Register run by the Academy For Healthcare Science (AHCS) which periodically validates against, minimum acceptable standards for training provision and maintains the required standards of conduct, education, training and health & safety criteria. The register is accredited by the Professional Standards Authority.

Version 1. August 2022.
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