

Comparative Study of Smart Operating Theater Guidelines from a Regulatory Perspective and Suggestion of Additional Considerations

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Summary

Purpose: Smart operating theater (SOT) systems called Smart Cyber Operating Theater (SCOT)¹⁾ and OR.NET²⁾ have been developed in Japan and Germany, respectively. Guidelines for product lifecycle processes have also been issued in conjunction with those SOT systems. However, the guideline developed in Japan does not necessarily include medical device regulation in its scope. The purpose of this study was to identify what additional considerations might be necessary when medical device manufacturers develop interoperable products for incorporation into SOT systems according to the Japanese guideline.

Materials and Methods: We looked for sections or requirements related to “risk management” and “verification and validation” as comparable subjects in the guidelines “Development Guideline for System Configuration and Operation of Smart Operating Theatres 2019”³⁾ (Development Guideline for SOT 2019) and “SDC (Service-oriented Device Connectivity) Conformance Principles”⁴⁾. Then, “risk management” was further subdivided into “responsible party” and “safety risks to be addressed”, and “verification and validation” was further subdivided into “verification and validation requirement”, “responsible party” and “lifecycle phases subject to verification and validation”.

Results: Our study indicates that the Development Guideline for SOT 2019 provides a reasonable reference for non-medical devices, but additional considerations are needed for medical devices. These additional considerations include postmarketing surveillance and assessment of risk concerns related to essential performance of SOT elements for risk management and a structural approach and periodical testing for verification and validation. We also suggest that further consideration of suitable risk analysis methodology for SOT systems is needed for both guidelines.

Key words

Smart Operating Theater, Interoperability, Guideline, Japan, Germany