

Reference project

Gap analysis for existing product files



During a TÜV audit it was found that the documentation of the existing product lines requires checking and adaptation to the current regulatory standards, so that the products can continue to be offered on the market.

Activities

EXCO reviews the complete documentation of the product lines currently on the market and highlights the discrepancies as compared to the current regulatory standards:

- Classification of the documentation according to the requirements of the regulatory Standards
 - Creation of an actual analysis which highlights the gaps that require resolving
 - Creation of a list of measures to be taken for the closing of the gaps
 - Updating the risk analysis
 - Creation of a requirements list for technical documentation, specially including the current regulatory Standards
 - Collaborating on closing the gaps
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Realization

EXCO creates a dossier with lists of performance characteristics for the diagnostic medical device. To prove the performance, EXCO researches study documents in the relevant product technical documentation and client archives. EXCO also compares the study reports and results with the current regulatory requirements (e.g.) DIN EN ISO 18113, CLSI) and the current client standard. EXCO then assesses whether the completed studies satisfy the current regulatory standards, identifies the discrepancies, and ensures the closing of the gaps.

Our employees demonstrate a high level of personal responsibility, independence and motivation. By engaging external resources, our customers' workload is reduced.

Jörg Petrullat, Project Manager Conformity und Documentation, EXCO GmbH

Client benefits

- The client gains an overview of the gaps in the product technical documentation.
- A plan can be implemented in order to close these gaps so that the product satisfies the current requirements as specified by the authorities once again.
- The subsequent TÜV audit was passed.

Client

Medical equipment manufacturer, Germany

Expert contact



Thomas Wagner

T+49 3641 30949-110

[Email contact](#)