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# Approach to biomaterials selection using a risk-based approach

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## **Approach to biomaterial selection using a risk based approach**

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Global source of materials for Healthcare applications continues to attract industry attention and regulators' scrutiny, mainly due to the nature of the supply chain and its complexity, calling for more traceability, security, and reliability. Therefore, it becomes critical, when choosing a biomaterial, to use a risk based approach when assessing its function and intended use prior to its qualification. Key risk elements are to be identified, assessed and documented to obtain a reliable product performance and safety profile. A rigorous material qualification plan, based on science, a controlled quality system as well as a change control mechanism are to be in place. Once on the market, vigilance including continuous monitoring of complaints, claims around the material application are important. To be successful, such a risk management process will highly depend on a good communication mechanism between the key players (raw material suppliers, converters, integrators and end-users); it has to be science based, involve relevant stakeholders and *not be over engineered as it may not address the pertinent risks!*