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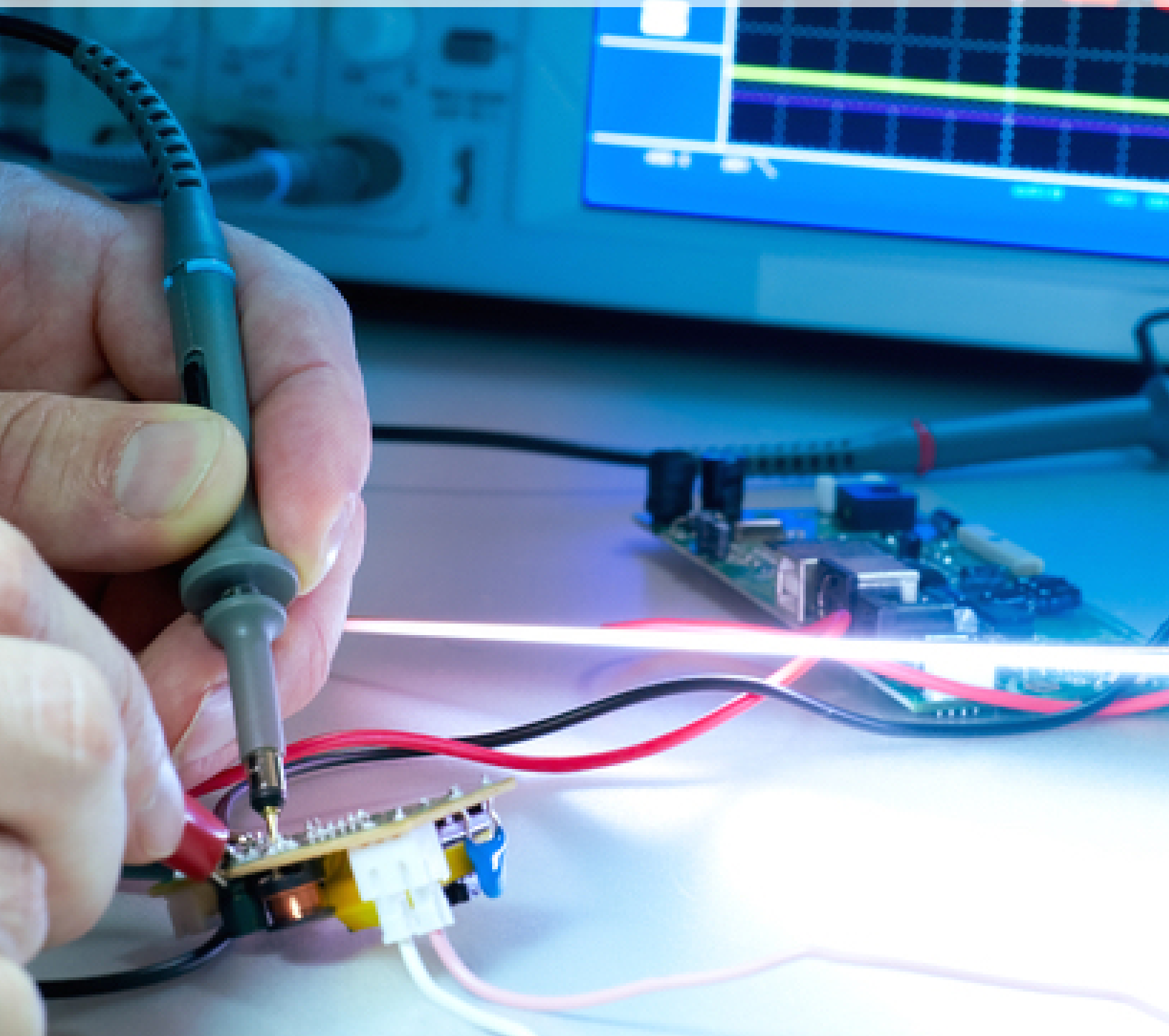
De-Risking in the MedTech Industry



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Risk Management Plans & ISO 14971

Risk analysis is an essential component of your quality management system.

A mandatory task for every new medical device about to hit the market is creating an appropriate Risk Management Plan as required by ISO 14971, the international standard for applying risk management to the design and manufacture of medical devices.

ISO 14971 defines risk management as: "The systematic application of management policies, procedures and practices to the tasks of analyzing, evaluating and controlling risk." To that end, a Risk Management Plan is established at a project outset to document how risks are identified, evaluated and traced. This plan should define the entire scope of the risk management process, including the purpose of the device, its life cycle, responsible parties and authorities, and data collection and analysis all the way through post production.

1 Risk Identification

One of the first steps in creating a Risk Management Plan is Risk Identification. The concept of risk is a combination of the likelihood of harm occurring, and the severity of that harm. Risks are identified by evaluating the product architecture, its intended use (and possible misuse), and the environments in which the product is to be used. Hazards are identified and their risks estimated.

2 Risk Evaluation

The second step to creating a Risk Management Plan is Risk Evaluation. An example of effective Risk Evaluation is establishing criteria and an associated scoring system to evaluate each hazard identified in the Risk Identification step. Risks can be scored on a scale of one to five. Those scoring three and below are acceptable, and those scoring four and five require mitigation.

3 Risk Trace

For those risks that require mitigation, the risk must be traced to determine that effective changes were implemented in the design phase. If applicable, design verification testing may also be required to prove that the changes to design details were implemented correctly in the product prototype or final product.

The Importance of De-Risking During Developmental Stages

A de-risking approach to medical device development focuses first and foremost on the critical challenges that need to be addressed, rather than avoiding them until late in the project when changes are costly.

For example: If you are assessing a new in-vitro diagnostic technology for use in a clinical lab, it is important for overall program success to first de-risk the fundamental diagnostic technology - whether that is related to automatic sample preparation or to detection - rather than working on a feature like power management. Both are critical to product success, but ensuring that the fundamental technology is sound first will save cost and heartache later. Focus on retiring the most challenging risks first and the rest of the development should follow.

Reducing Risk in New Product Development

Businesses with a constant, full, new product development (NPD) pipeline are traditionally the ones that enjoy long term success and growth.

The risk assessment phase of NPD is absolutely critical to maintaining the health of the new product pipeline and preventing unpleasant surprises late in the game when a product is almost ready for release. Focusing on risk elimination early can filter multiple concepts, preparing them for the more costly process of advancing them down the pipeline.

Technical Risk

Assessed with basic proof of concept prototypes and technology research that address specific aspects of the product that are considered high risk.

Supply Chain Risk

Assessed through detailed conversations with manufacturing vendors and suppliers. Risk may be significantly minimized by reducing single-point failures. Trusted vendors often prove to be invaluable resources later in the NPD process and should be involved as early as possible.

Regulatory Risk

Minimized through careful planning of the submittal process and preliminary discussions with regulatory personnel. For products that will be launched into regulated environments, regulatory acceptance of the product is critical to product success.

Market Risk

Assessed with targeted market studies, limited voice of the customer (VOC) interviews, and other information. For medical products, preliminary research to understand the reimbursement environment for the product may be of particular importance.

The 3 Key Strategies to Evading Risk

1 De-Risk Early

Adopt a de-risking philosophy early, even in the planning stage of projects. Write them out and develop a plan for retiring them. Include as many stakeholders as possible to identify risks to the project, which can range from market and product risks to technical, schedule and regulatory risks. Report on risk status regularly so that the team is informed and executive management can make decisions accordingly on how to proceed.

2 Weigh up the Risks

Take on risk only where it makes sense in a program - where it is worth the reward. For example, instead of designing custom sensors, use off the shelf components to avoid reinventing the wheel and causing headaches late in the development stage due to avoidable custom sensor failures.

3 Test Early and Often

Test early and often with prototypes or test bench setups that are representative of the finished product. Testing for one risk source at a time helps to separate effects and helps to understand the potential individual failure sources prior to integrated performance testing.

8-Point Assessment Checklist

To staying focused on de-risking early and throughout product development.

PERFORMANCE Does it work?

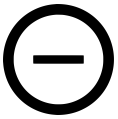
PERFORMANCE AT THE LIMITS Does it work outside the best case scenario?

SENSITIVITY How sensitive is it to changing conditions?

REPEATABILITY Does it work the same way every time?

RELIABILITY Will it last?

SCALABILITY Will it work in a final product?



PRACTICALITY Can it work with fewer features?

INTERFERING CLAPTRAP Can it work with added features?

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Since 1998, Key Tech has been transforming complex technologies into intuitive products. We design and develop medical, industrial and consumer products using novel sensors, wireless, ultrasound, microfluidics, optics and robotics, just to name a few. Our uniquely personal approach attracts industry leading global companies, as well as innovative startups to our Baltimore Headquarters. The Key Tech team of interdisciplinary scientists, engineers and designers take technologies into new applications, keeping your development pipeline fresh.