

RIM Readiness Checklist

When deciding to implement a RIM system, medical device companies need to consider many factors to ensure that they have the needed systems, processes, and personnel in place.

Technology requirements		
<input type="checkbox"/>	Digitized documentation:	Are your regulatory documents, such as technical files and design history files, in a digital format?
<input type="checkbox"/>	Application infrastructure:	Does your organization already have a system infrastructure in place, such as eQMS, PLM, or ERP system?
<input type="checkbox"/>	No competing major IT initiatives:	Will a RIM implementation be given dedicated resources and the attention of the management team?

Corporate priorities		
<input type="checkbox"/>	Digital transformation strategy:	Does your organization have a digital transformation strategy?
<input type="checkbox"/>	Recognized need:	Is your management team prioritizing a RIM project?

Timing a RIM implementation		
<input type="checkbox"/>	Expanding geographic reach:	Are you expanding from one country or region into multiple markets?
<input type="checkbox"/>	Growing product portfolio:	Does your organization have plans to launch new products?
<input type="checkbox"/>	Greater product complexity or risk:	Is your RA team managing devices in higher risk classes? (Ex: Class II and III in the U.S.)
<input type="checkbox"/>	Significant upcoming product or entity changes:	Is your company planning a possible acquisition, major design updates, or any other change that would trigger re-registration activities?

Teams and Personnel		
<input type="checkbox"/>	Dedicated regulatory personnel:	Does your organization have one or more regulatory professionals responsible for obtaining and maintaining market clearance for your products, and interacting with government health authorities?
<input type="checkbox"/>	Committed Management Team:	Is your management and executive team committed to providing the resources that a RIM implementation will require?

About Rimsys

Rimsys is bringing regulatory order to the medtech industry. The Rimsys Regulatory Information Management (RIM) platform digitizes and automates regulatory activities, freeing teams from inefficient administrative work, and helping them confidently establish and secure global regulatory compliance. Unlike complex spreadsheets or expensive consultants, Rimsys centralizes all regulatory information, automates submission processes, and monitors relevant expirations, standards, and global regulations. Overburdened regulatory affairs teams struggle to keep pace with the increasingly complex global landscape. Rimsys streamlines all regulatory activities in an integrated platform, helping MedTech companies get to market more quickly and reduce risk of non-compliance, product recalls, and unexpected expirations.

For more information about Rimsys or to get a free demo of our platform, please visit rimsys.io

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