

Workflows

OnRule is bringing automation & intelligence to **Global Market Access**, enabling a rapid launch of a **Product Regulatory Plan** & collaborative execution, leading to testing & acquisition of product regulatory certifications for different markets.

Background: The New Product Introduction (NPI) process includes, among other things, testing and validating a product for the regulatory compliance of different markets and disciplines. Our customers are launching multiple new products every year. Additionally, existing products have to undergo retesting for multiple reasons, including but not limited to, expiration of an existing certificate, major change in design, change of a critical component used in the product, change of a manufacturing location, or change of a standard originally used in testing the product.

Problem Statement: The activity of testing a product requires interactions and close collaboration among multiple stakeholders within the company's ecosystem partners. Additionally, understanding the testing deliverables for a product-market mix is a big challenge, consuming significant time to plan a project before initiating it.

Providing details about the product, establishing the testing deliverables, conducting the tests and finalizing the results leading up to self-declaration or receiving the approval certificates from the regulatory authorities – these complex set of activities call for a sound compliance project management with the special knowledge of technical & regulatory requirements.

Our Solution: *Rapid discovery & launch of a Product Regulatory Plan; collaborative & multi-party execution of the plan:*

- Create & leverage readymade templates by products or countries; instantly initiate a compliance project
- Identify & assign tasks, schedules, check lists, and deliverables to different individuals within the ecosystem
- Secure the supporting documents from R&D, required by test labs for testing
- Collaborate with test labs to review drafts and provide input; and when satisfied, approve the finalized version of the test reports
- Instantly find the status of a compliance project or a deliverable
- Maintain the history & access the repository of all deliverables in one place

