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ISO 9001:2015 Product Development Flowchart

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FORWARD

ISO 9001 is an internationally recognized standard that establishes standards for quality management systems. These requirements apply to all aspects of an organization's operations, including product development. The product development process described in ISO 9001 is intended to reinforce a development system that is customer focused and quality based -and can be utilized by companies of all sizes.

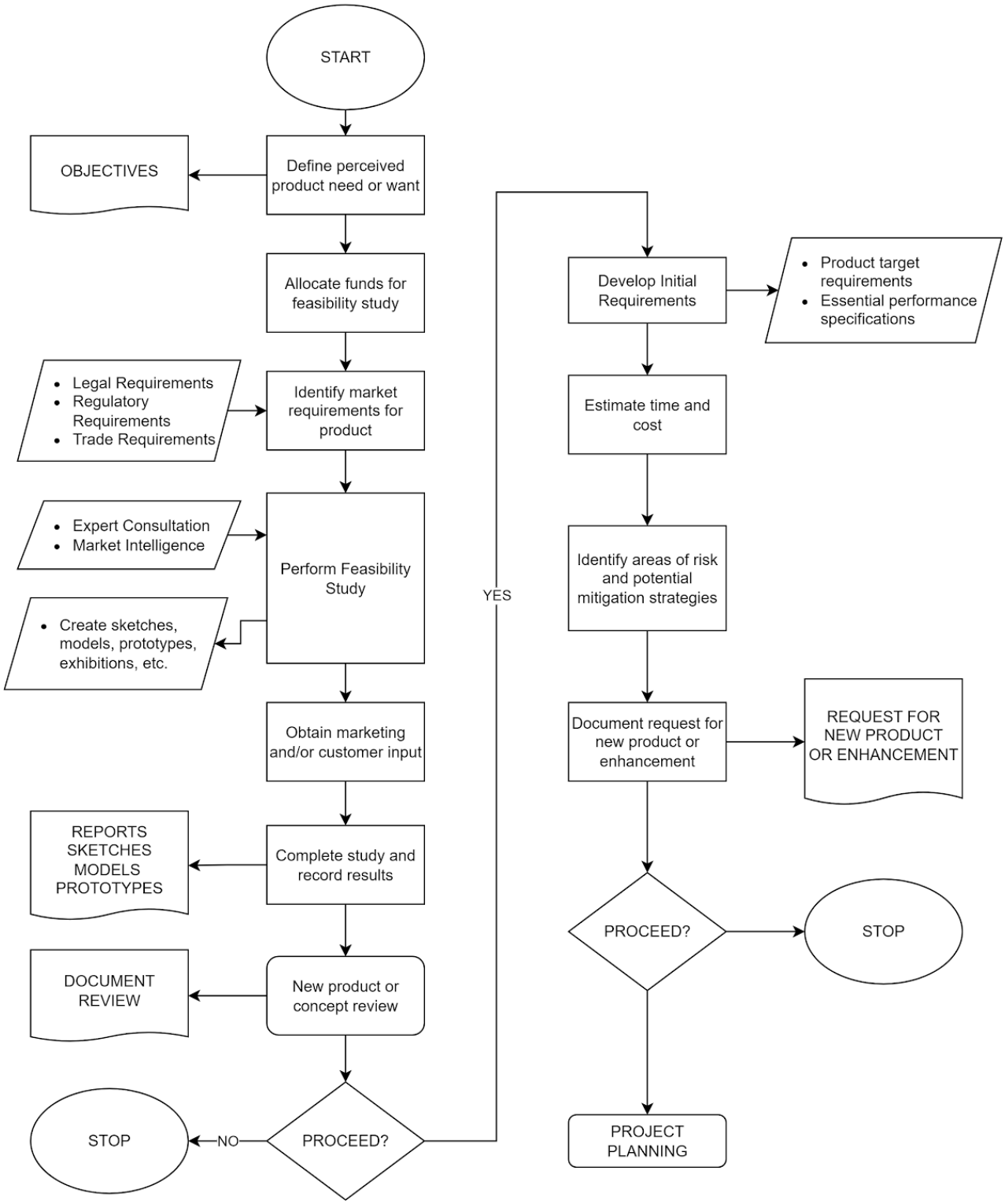
After years of product development, from consumer products to industrial machines, I realize there is no ‘one size fits all’ development method. Every company has a different culture and will need to develop a process that works best in their environment. There are, however, a basic set of checks and balances to ensure that products are developed consistently and with a quality outcome. I have summarized these steps in a set of flowcharts that can be used as the basis for a 9001:2015 product development process.

The process is divided into 7 phases:

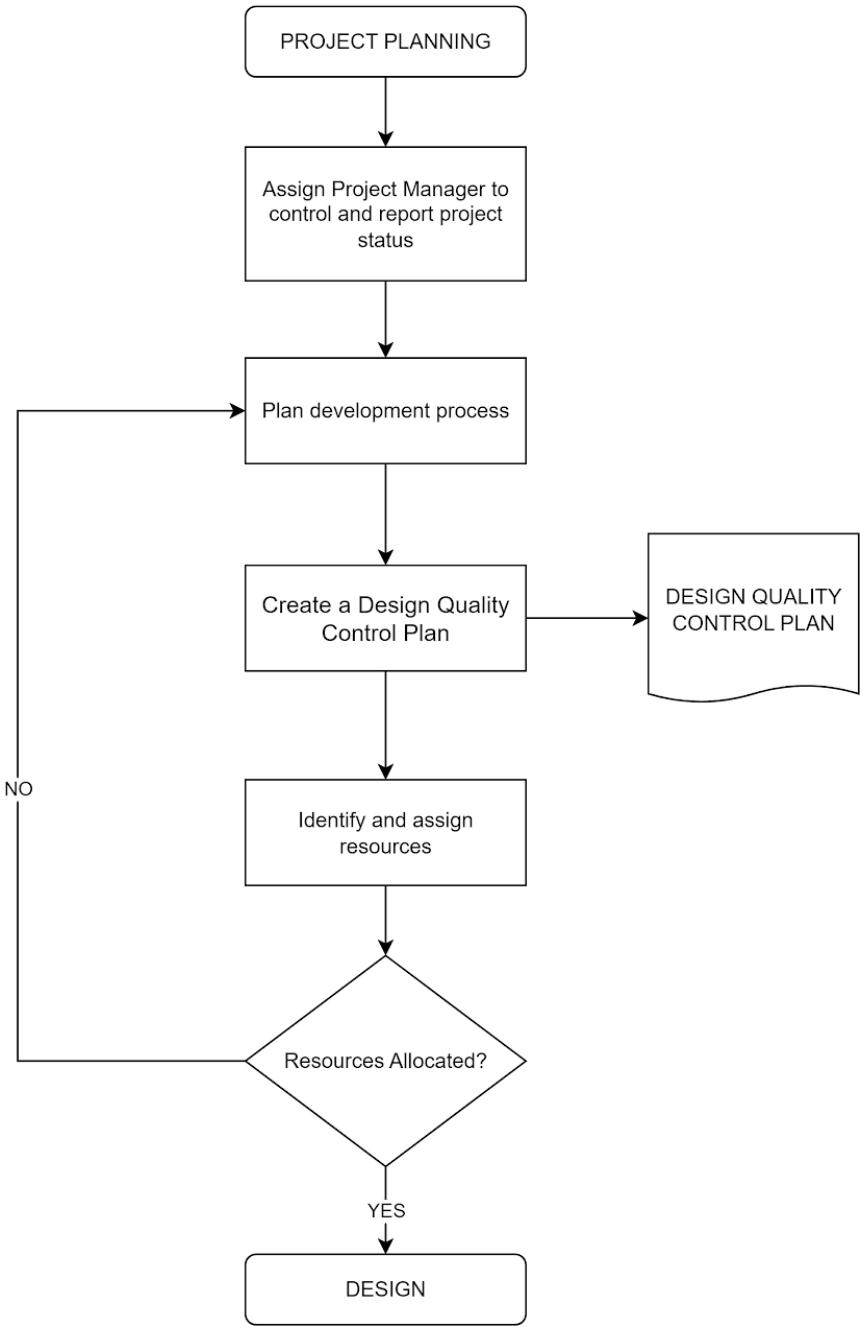
1. Feasibility
2. Project Planning
3. Stage 1 Design
4. Stage 2 Design
5. Stage 3 Design
6. Verification and Validation
7. Product Release

Again, every company has different development requirements and may distribute the steps into different stages or not need as many design stages, but understanding the steps and implementing a process is the first step to ensuring consistent product development and quality.

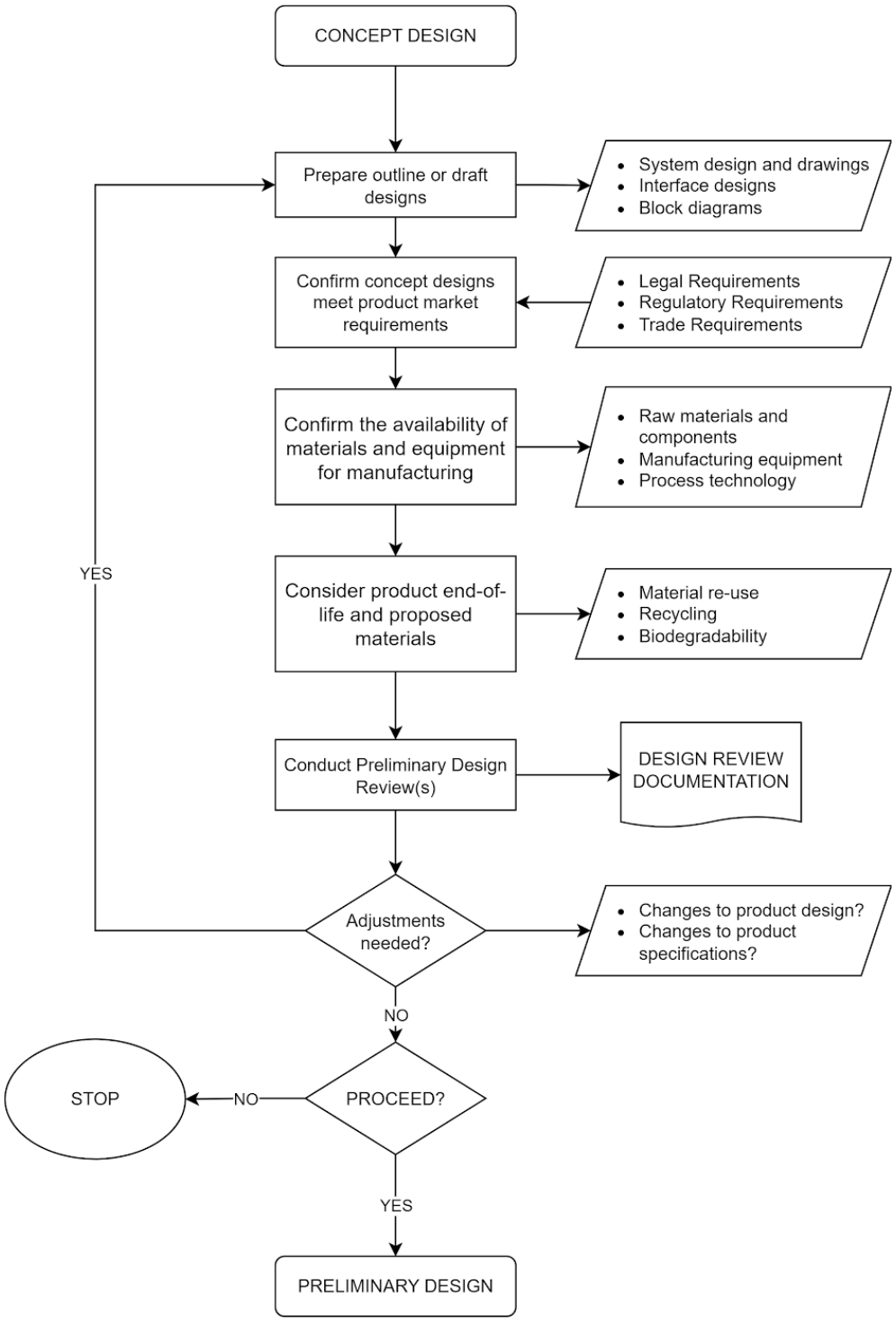
FEASIBILITY



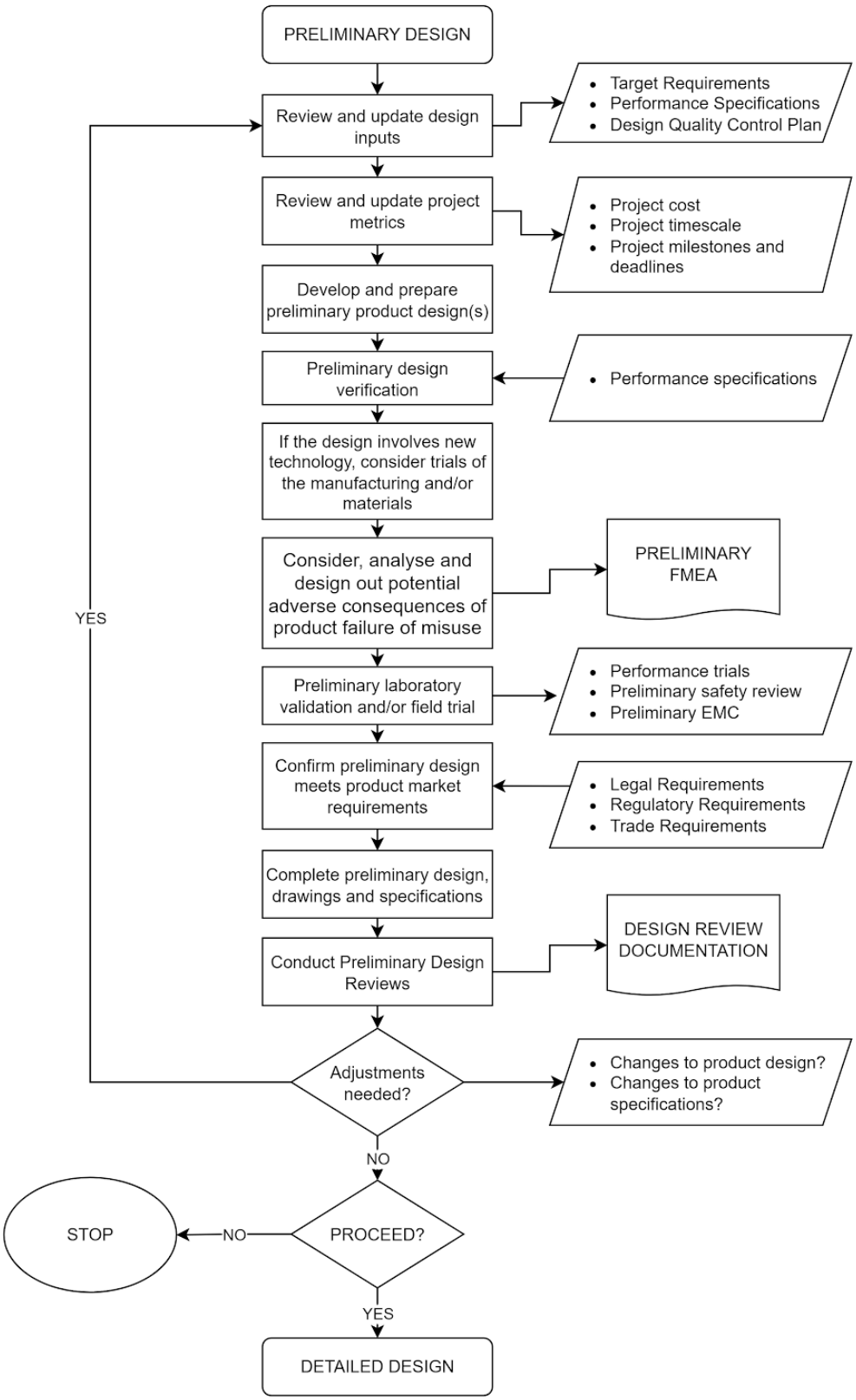
PROJECT PLANNING



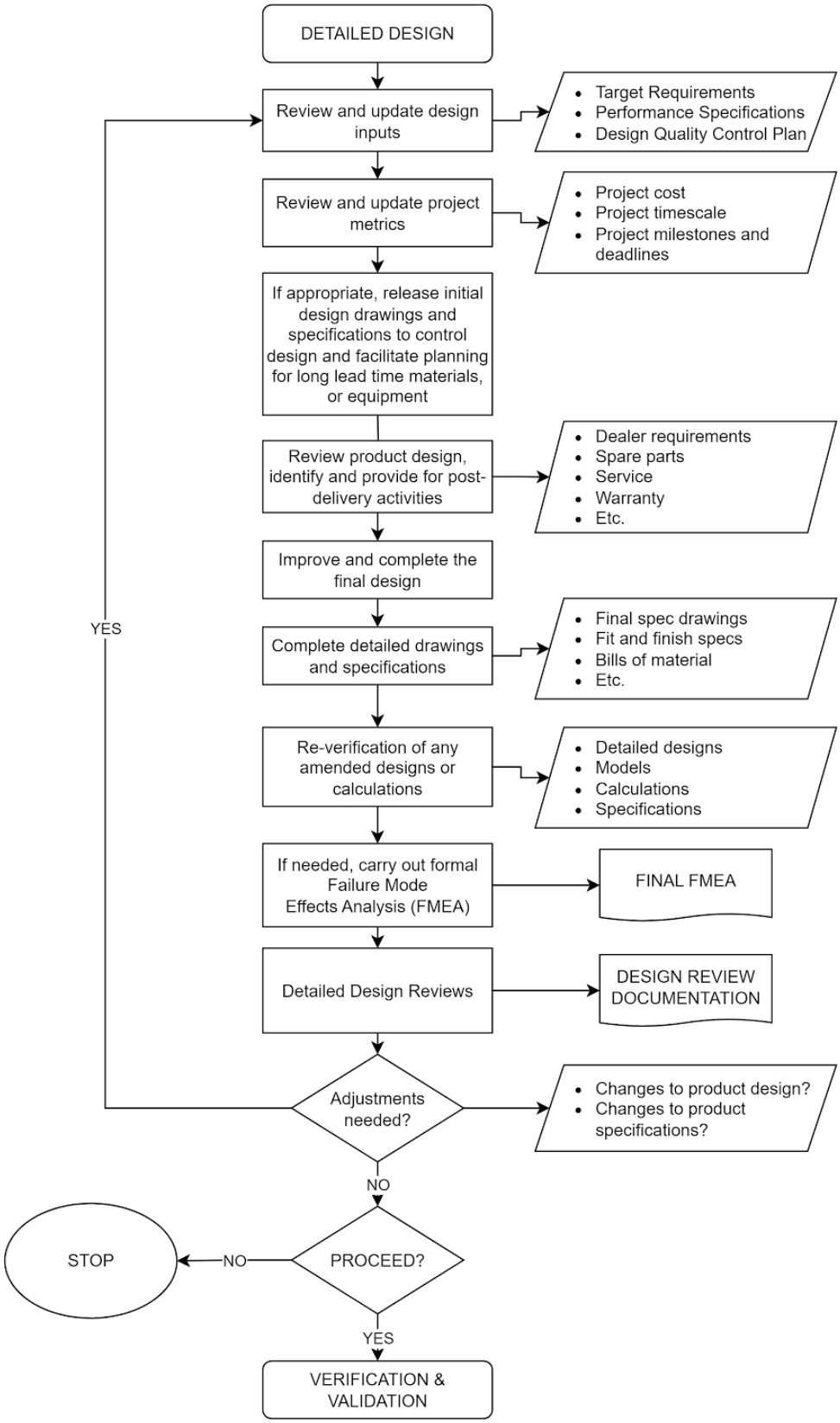
STAGE 1 DESIGN



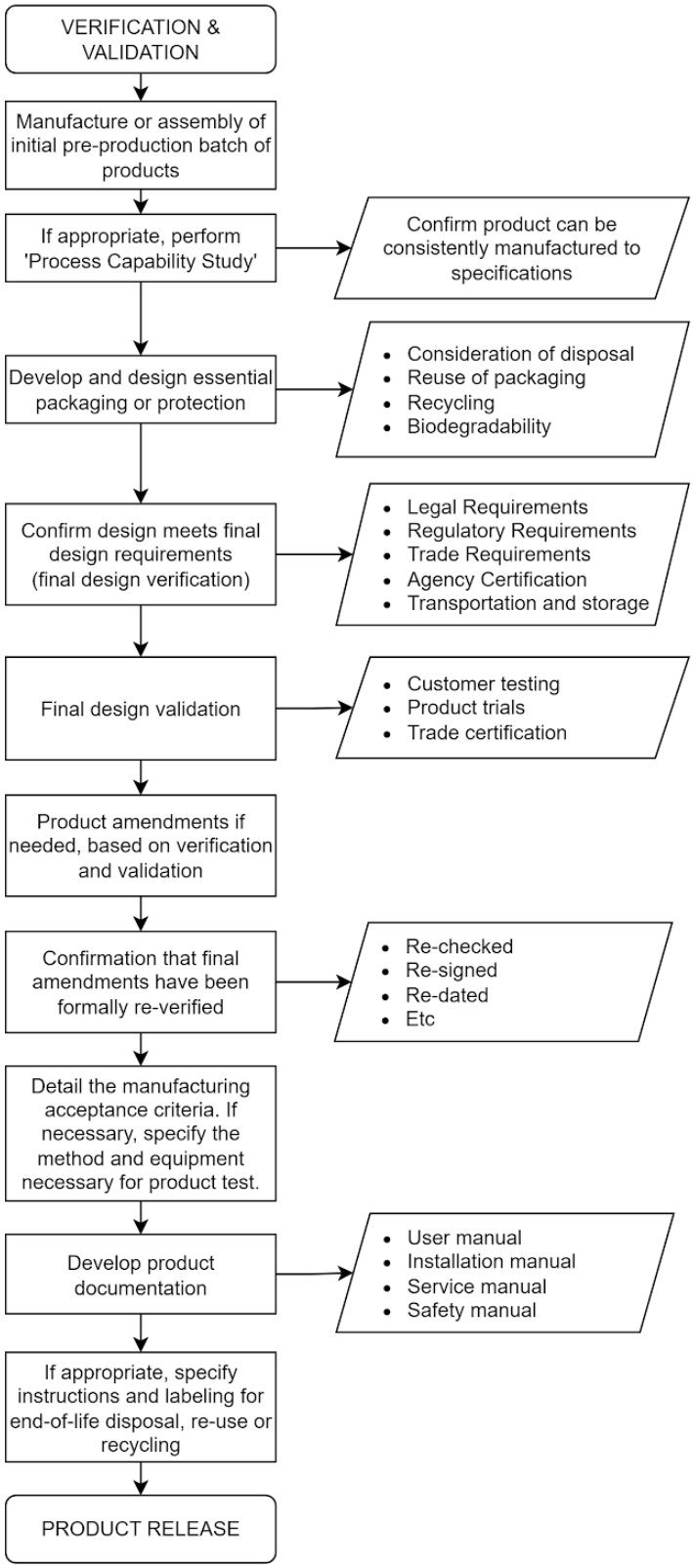
PRELIMINARY DESIGN



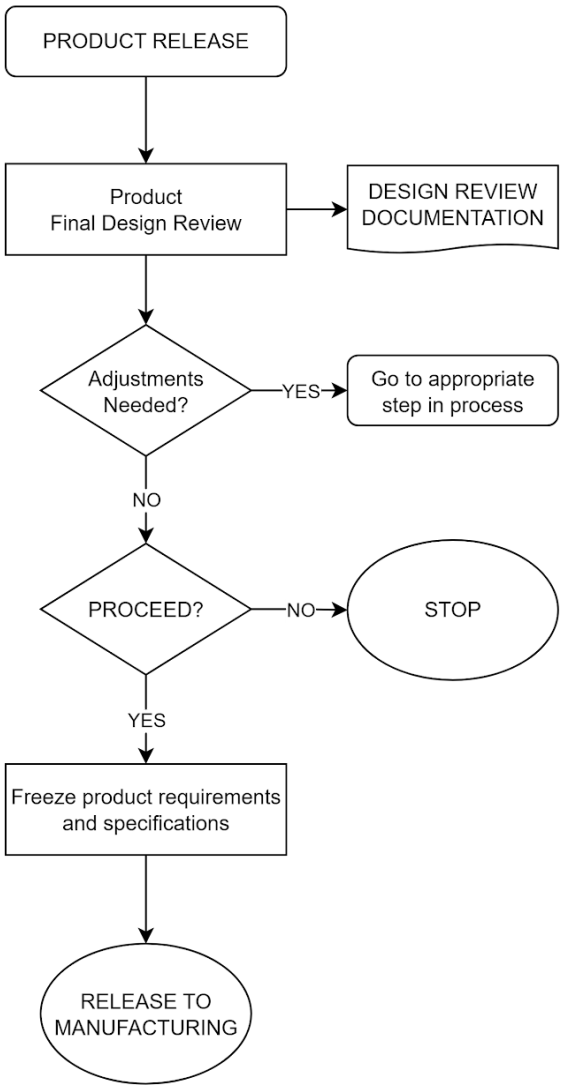
DETAILED DESIGN



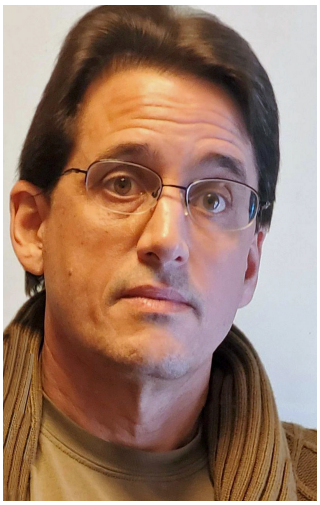
VERIFICATION & VALIDATION



RELEASE TO MANUFACTURING



ABOUT THE AUTHOR



David Connor is President of Striper Solutions LLC, providing consulting services for product development and global regulatory compliance. He is a registered IEEE consultant with over 25 years of experience in technology development, product design, regulatory compliance, and equipment manufacturing for global markets.

As Vice President of Engineering for ECRM Imaging systems, he developed award winning laser-based scanning products for the global printing industry for over 16 years, including OEM products sold by Mitsubishi, Agfa, Kodak and others. David started Striper Solutions LLC in 2013, providing product consulting services for a variety of industries.