CONTRACT RESEARCH FOR THE MEDICAL DEVICE INDUSTRY: CREATIVELY SOLVING COMPLEX CHALLENGES WITHIN DESIGN CONTROL

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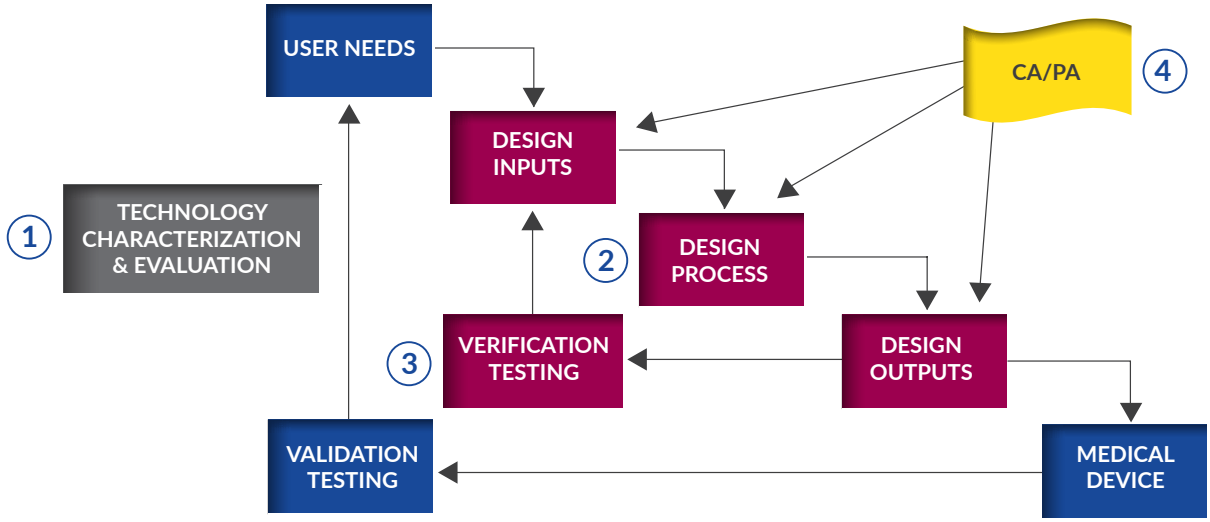
MEDICAL DEVICES AND DESIGN CONTROL

The FDA has prescribed, in the code of federal regulations and a number of guidance documents, a process—Design Control—for companies to follow when developing a new device. The agency expects filings to reflect that process; iFyber's preclinical contract research and development activities are a natural fit for organizations navigating the product development cycle under design control.

iFyber has a team of applied scientists, skilled in chemistry, biology, chemical engineering, and materials science that have worked on client sponsored projects at every point in a regulated design process. Consider iFyber as consultants with laboratories that can back up ideas with data, and as an extension of your development team with complimentary skill sets that can tailor studies to the needs of your technology, without sacrificing budget and timeline.



1. TECHNOLOGY CHARACTERIZATION AND EVALUATION:

Before a product even enters development, technology must be evaluated to see if it is a good candidate for a product slated for commercialization. iFyber is skilled at performing the bench testing necessary to screen and de-risk a technology—helping to make the decision of suspending efforts before spending additional resources, or to take the next step and enter development. Whether you're a startup company evaluating a technology for a new application, or a global leader evaluating a set of technologies to license or buy, iFyber has an experienced scientific team to help determine the best path forward. Representative projects include development and testing of numerous wound care formulations, evaluation of academic and other early-stage hemostat technologies and advancement of in vitro diagnostic technologies.

2. DESIGN PROCESS:

Once a technology has entered development, of utmost importance is designing a product that meets the design inputs. Design inputs are the requirements that a product must meet to address user needs. iFyber can assist with design inputs by providing feedback on project plans, product requirement documents and risk assessments. Within the design process, iFyber has experience in working on the design outputs, or specific design of the product. iFyber has helped numerous groups develop specifications around chemistry/materials, formulation, and process flow, which must be defined with sufficient detail to manufacture the product. It's important to periodically check that the proposed design meet the inputs—nobody wants to be surprised in verification. iFyber excels in matching materials specifications with performance requirements, and developing relevant methods for testing those requirements. iFyber has experience working through the design process with our clients on a variety of implantable and topical medical devices having complex chemical constituents. Our expertise in synthetic and polymer chemistry, analytical chemistry and biomaterials, coupled with our ability to test for these materials provides our clients with an extended R&D team with complementary skill sets to advance through the design process under shorter timeframes.

3. VERIFICATION:

Verification is a formalized process for objectively demonstrating that the design meets the requirements specified in the design inputs. A protocol will be written and approved by the team, and then executed according to the plan. Prior to moving into formal verification activities, typically done under good laboratory practices (GLP) with extensive quality oversight, preliminary studies that de-risk aspects of the design are done so verification does not need to be repeated if a design change is necessary. iFyber excels at these earlier stage de-risking studies by creatively using science with statistically defensible results to guide verification.

4. CA/PA:

What happens when things don't go according to plan? Corrective actions (CA) or preventative actions (PA) are documented processes that detail unforeseen deviations that occur during the iterative design process. It could be a change in a supplied material, a process, or new information coming to light on how the product is used in the market. In any case, an investigation takes place to get to the root cause of the issue. iFyber's team of scientists can help the client's team find this root cause and work through the remediation, all of which falls under design control.

For more information on iFyber's services
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