



OBJECTIVES

- Develop the research questions that must be answered for regulatory guidelines and marketing needs
- Develop questions to ask test participants in order to answer research questions



RELEVANT RESOURCES



Concept Evaluation Module



Regulatory Strategy Supplemental Reading



OUTCOMES

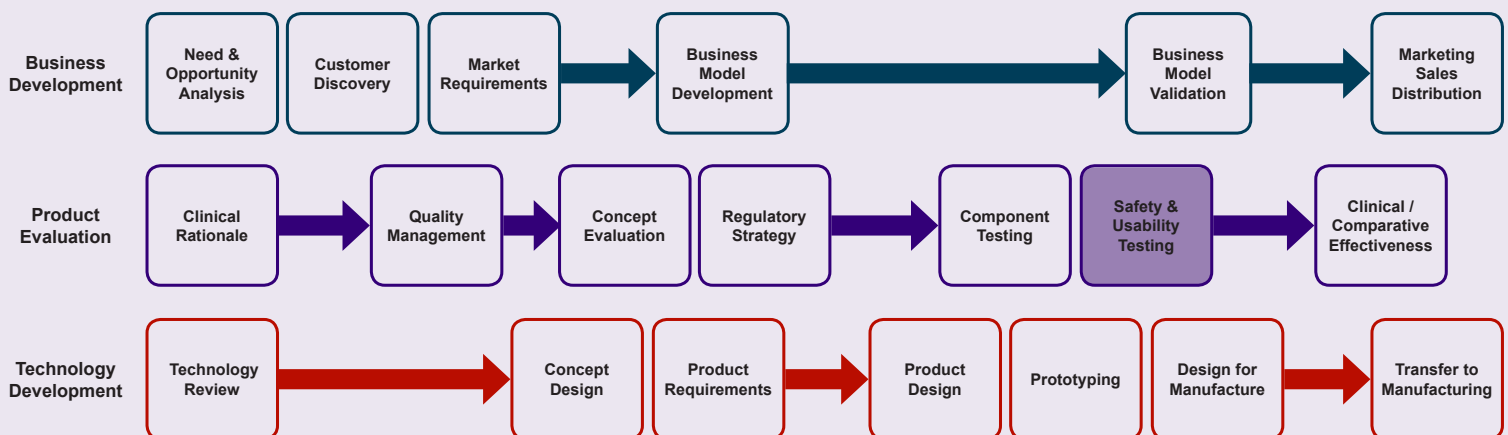
- Ensure the design follows customer’s wants and needs for use
- Inform any necessary changes to prototype before finalizing



NEXT STEPS

- Seek out appropriate participants to test prototype
- Schedule and carry out usability tests
- Finalize the product design in line with feedback and design for manufacture (DFM)
- Align preliminary DFM with Business plan

COMMERCIALIZATION METHODOLOGY





APPROACH

- Observing participants using the prototype
- Asking them questions about using the device or answering questions based on observation
- For dimensions for which naïve use or feedback would be helpful (e.g. (clarity of instructions etc. or intuitive use), minimal presentation may be desired.

POTENTIAL QUESTIONS FOR TESTING PARTICIPANTS

Clarity of instructions

- Can the target users understand the instructions, use the device with ease?
- Can people of different backgrounds or age understand the instructions and use the device with ease?

Safety

- What are potential risks in using the device?
- How have these been mitigated (e.g. design, training, instructions)?
- Have these approaches worked? E.g. Can the target users use the device safely?

Basic Operation

- Can you easily grasp the device and use it to....
- Is the device comfortable to hold/wear/use?
- Are there any sharp edges or features that are bothersome?

Performance

- Can you easily and quickly complete XXX task with the device?
- Can you easily see the sign that the medication is ready/mixed?
- Can you hear the signal that indicates....?
- Can you feel the indicator that indicates....?

Cleaning/Maintenance

- Will the device be convenient to clean?
- How would you clean it? (How do you clean your current case?)