

Standard Assay Development Steps

From concept to commerce

RAPiVD's standard stages for taking medical and non-medical assays from concept to commercialisation - or any development step(s) along the way.

Medical Devices		Non-medical Devices
Brief	Objective development	Brief
Step 1	Prove concept (wet) & optimise	Step 1
Step 2	Test assay (dry) & optimise	Step 2
Step 3	Test with real samples & optimise	Step 3
Step 4	Document assay standards	Step 4
Step 5	Prototype production	Step 5
Step 6	Customer/lab' testing & refinements	Step 6

Step 7	Design & Development planning	Tech' transfer	Step 7
Step 8	Tech' transfer	Test batch production	Step 8
Step 9	Test batch production	Testing, validation and documentation	Step 9
Step 10	Testing, validation and documentation	Volume production	Step 10
Step 11	Trial production	Packaging, promotion, logistics, sales	Step 11
Step 12	Product/Clinical trials		
Step 13	Regulatory approval		
Step 14	Volume production		
Step 15	Packaging, promotion, logistics, sales		



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