Life Sciences Technology Readiness Level

TRL 1	Basic principles observed. Scientific technical watch maintained. Potential scientific application to defined problems is articulated.
TRL 2	Technology concept and/or application formulated. Research ideas, hypothesis and protocols are developed, peer reviewed and approved.
TRL 3	Basic research, data collection and analysis. First hypothesis testing, alternative concepts explored and initial proof of concept (PoC) is demonstrated in a limited number of in vitro & in vivo models.
TRL 4	PoC and safety of candidate formulation/device or system is demonstrated in a defined laboratory or animal model (non GxP). Identification of relevant parametric data required for technological assessment.
TRL 5	Technology validated in relevant environment. Pre-clinical studies, including GLP animal safety & toxicity, for data collection sufficient to support further trials.
TRL 6	Technology demonstrated in relevant environment. For pharma, phase 1 clinical trials support proceeding to phase 2 clinical trials. For medical devices safety is demonstrated and in line with predictions.
TRL 7	System prototype demonstration in operational environment. For pharma, phase 2 clinical trial is completed. Phase 3 clinical trial plan is approved. For medical devices the final product design is validated and final prototypes are produced and tested
TRL 8	System complete and qualified. For pharma, phase 3 clinical trial is complete and licencing/authorisation given. For medical devices, market approval given.
TRL 9	Actual system proven in operational environment (competitive manufacturing in the case of key enabling technologies). Post marketing studies and surveillance.