# Startup Regulatory Strategy Checklist – Medical Device & IVD Edition

## Startup Readiness Planning

- Product classification determined and mapped for FDA and EU MDR requirements
- Intended use and indications documented
- Regulatory risk assessment conducted to identify potential compliance gaps.

## Submission Pathway & Timeline

- Regulatory pathway selected (e.g., 510(k), De Novo, CE Mark, etc.)
- Pre-sub/Q-sub strategy defined (if applicable)
- Design verification & validation milestones aligned with regulatory expectations
- Notified body or FDA engagement planned as part of submission strategy

## QMS & Documentation Readiness

- Scalable QMS approach aligned with ISO 13485
- Early DHF/technical documentation structure planned
- Risk management aligned with ISO 14971 and EN ISO 13485:2016/QMSR
- Clinical or performance evaluation strategy defined for regulatory submission

## Strategic Positioning

- Regulatory strategy aligns with business milestones and product launch plans
- Investor deck includes regulatory roadmap and key milestones
- Consideration of expansion to other markets (e.g., UKCA, ANVISA, TGA)