MEDICAL DEVICE DEVELOPMENT PATH

PRE-DEVELOPMENT **DEVELOPMENT** **MANUFACTURING**

GOALS

Optikos-Customer Alignment; Identify Risks; Scope Proof of Concept (POC)	Early Discovery; Reduce Technical Risk; User Feedback	Resource Plan & Budget; Implement Design Controls	Alpha Design & Build; Preliminary Verification	Manfacturing Ready Design; Engineering Verification	Transfer Production Process; Manufacturing Readiness	Production Process Validation; Deliver First Production Run; First Article Inspections	Recurring Production; Post-Release Support; Continuous Improvements

PHASE

P0 FEASIBILITY	P1 RISK REDUCTION	D0 PLANNING & SCOPE	D1 ALPHA DEVELOPMENT	D2 BETA DEVELOPMENT	M0 MANUFACTURING PROCESS	M1 PILOT BUILD	M2 PRODUCTION

OUTPUT

POC Development Plan & Scope; Requirements (Draft); Risk Matrix (Draft)	POC Demo; Requirements (Revision); Risk Matrix (Revision)	Project Plan; Requirements (Release); Design Inputs	Alpha Design Reviews; Alpha Prototypes & Test Reports	Beta Design Reviews; Beta Prototypes & Test Reports; Design Output (Release)	Production Work Instructions; Quality Control Plan; Manufacturing Readiness Review	Production Verification & Validation Report; Pilot Production Units; First Article Inspection Report	Production Units; Cost Reduction & Process Improvements; Continuous Quality Monitoring

MILESTONES

Proof-of-Concept Demo

Design Freeze

Engineering & Design Verification

Production Verification

Recurring Production

QUALITY

PROJECT CONTROLS | QUALITY & DESIGN CONTROLS | MANUFACTURING CONTROLS

TYPICAL DURATION

3-6 MONTHS | 12-24 MONTHS | 6-8 MONTHS

Optikos is ISO 9001 & ISO 13485 Registered