

# VALIDATION

What's Your Level?

## Medbio's Standard Validation Levels

### Level 1

- RMT - Our standard scientific injection molding workbook
- Full Layout - One piece per cavity
- Capability Study - 30 shots (nominal process)

### Level 2

- RMT - Our standard scientific injection molding workbook
- Full Layout - Three pieces per cavity
- OQ Runs - One 1-hour each, at high and low process (15-shot capability study)
- PQ Run - One 1-hour run at nominal process (30-shot capability study)
- Injection Molding - Process cycle card created
- APQP document package (control plan)

### Level 3

- RMT - Our standard scientific injection molding workbook
- Full Layout - Three pieces per cavity
- OQ Runs - One 1-hour each, at high and low process (15-shot capability study)
- PQ Run - Three 4-hour runs at nominal process (30-shot capability studies)
- 3-Way DOE (3 factor, 2 repeats, 5 shot subgroup, 25 runs = 125 shots)
- Injection Molding - Process cycle card created
- APQP document package (process flow diagram, PFMEA, control plan)

## Validation shouldn't slow you down

We provide three levels of validation. These segments allow you to quickly reference the degree of validation that you need, and implement it as needed. This gives your team valuable time to focus on product design and commercialization.



Over 30 years  
of medical  
experience



Our quality lab  
uses the latest  
technology,  
including the  
OGP SmartScope



ISO 13485-2016  
Certified