

Customized qPCR Solutions for Assay Development and Commercial Scale-Up



Why customization matters



Manufacturing Scale-Up



Custom Fills



Improved Efficiency



Workflow Complexity



Custom Formulations



Simplified Workflows



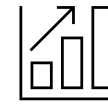
Cold Chain & Stability Challenges



Lyophilized Solutions



Room Temperature Stability



Commercialization Needs



Private Label Solutions



Focus on commercialization



QC & Documentation Requirements



Custom QC Options



Greater Operational Confidence

Customization helps align reagent **supply, workflow requirements** and **commercialization goals**.

Why collaborate with Thermo Fisher for customization



Scientific experience

Support from R&D and manufacturing experienced professionals



Commercial scalability

Solutions supporting transition from development to commercialization



Supply continuity

Forecast-based planning and change management support



Workflow flexibility

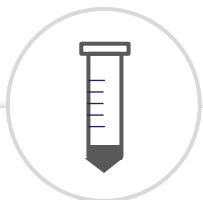
Customization aligned to customer-specific manufacturing and assay needs.



End-to-end support

Project management, technical support, documentation, and supply coordination

Flexible Solutions Across The qPCR Workflow To Support Your Needs



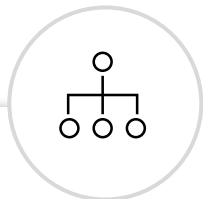
Custom Formulations

Tailored reagent compositions to meet performance goals



Custom Fills

Right volumes for your workflow and scale



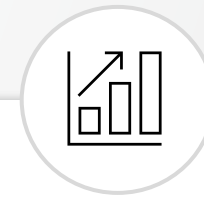
Custom Packaging

Custom packaging designed for your workflow



Lyophilized solutions

Enhanced stability and simplified logistics



Private Label Solutions

Branded solutions for your commercial assay



Custom QC Testing

Additional testing and documentation for confidence



Our customization capabilities are designed to help you optimize workflows, accelerate development, and scale with confidence

Packaging Configurations Aligned to Manufacturing Workflows



Customer needs	Customization parameter	Potential benefits
Scale-up manufacturing	• Fill size	• Reduced reagent handling
Automation workflows	• Bottle or vial type • Labeling	• Improved manufacturing efficiency • Simplified inventory management
Reduced handling	• Packaging configuration	• Better fit for automated workflows



Workflow-Specific Reagent Optimization



Customization Parameter

Customer Benefits

Amounts of existing components adjusted

Special components added
(passive reference, tracking dyes, enzymes etc.)

- Workflow-specific optimization
- Simplified workflows
- Reduced internal reformulation effort



Customized TaqPath™ ProAmp™ Master Mix:

- Tracking Dye added;
- ROX concentration increased;
- 250 mL in amber bottles

Accelerate Development Of Lyophilized qPCR Assays

Lyo-ready mixes designed for performance, stability, and workflow efficiency



New to lyophilization

**2.5X Lyo-Ready Master Mixes
with excipient**

Optimized formulations with built-in stabilization and lyophilization guidelines simplify assay development



Advanced lyophilization Users

**5X Lyo-Ready Master Mixes
without excipient**

Formulation flexibility for
experienced developers



Customer benefits



Simplified assay
development



Optimized
post-lyophilization
performance



Support for
room-temperature
workflows

Optimized lyo-ready master mixes designed for performance, stability, and formulation flexibility

From Cold-chain Dependence To Room-temperature Freedom



Lyophilized solutions enable room-temperature stable molecular workflows

Customer needs	Solution	Potential benefits
Decentralized testing	Lyophilized qPCR Master Mix or assay, composed of Thermo Fisher reagents	• Reduced cold-chain dependency • Simplified global logistics • Improved assay stability • Support for decentralized testing environments
Global distribution		
Reduced cold-chain dependency		



Lyophilized solutions help simplify distribution, expand testing access, and reduce dependence on cold-chain infrastructure

OEM and Private-Label Manufacturing Support



Customer needs	Benefits
Commercial assay deployment	• Reduced operational burden • Integrated manufacturing support
Outsourced manufacturing	
Branded solutions	



Maintain brand ownership and focus on commercialization while Thermo Fisher supports manufacturing and supply.

Quality Testing Tailored to Customer Requirements



Customer needs	Benefits
Specialized release testing	• Support for incoming material qualification • Alignment with internal QC workflows • Reduced qualification burden
Additional quality requirements	
Internal qualification support	



Assay-specific QC supports efficient qualification and quality workflows

Customization Supports Long-term Operational And Commercial Success

Workflow optimization

- Product configuration aligned to assay needs
- Reduced operational complexity
- Improved ease of use

Technical collaboration

- Access to scientific and manufacturing experience
- Troubleshooting support
- Assay optimization collaboration

Supply support

- Forecast-driven planning
- Change control notifications
- Dedicated SKU management

Commercial scalability

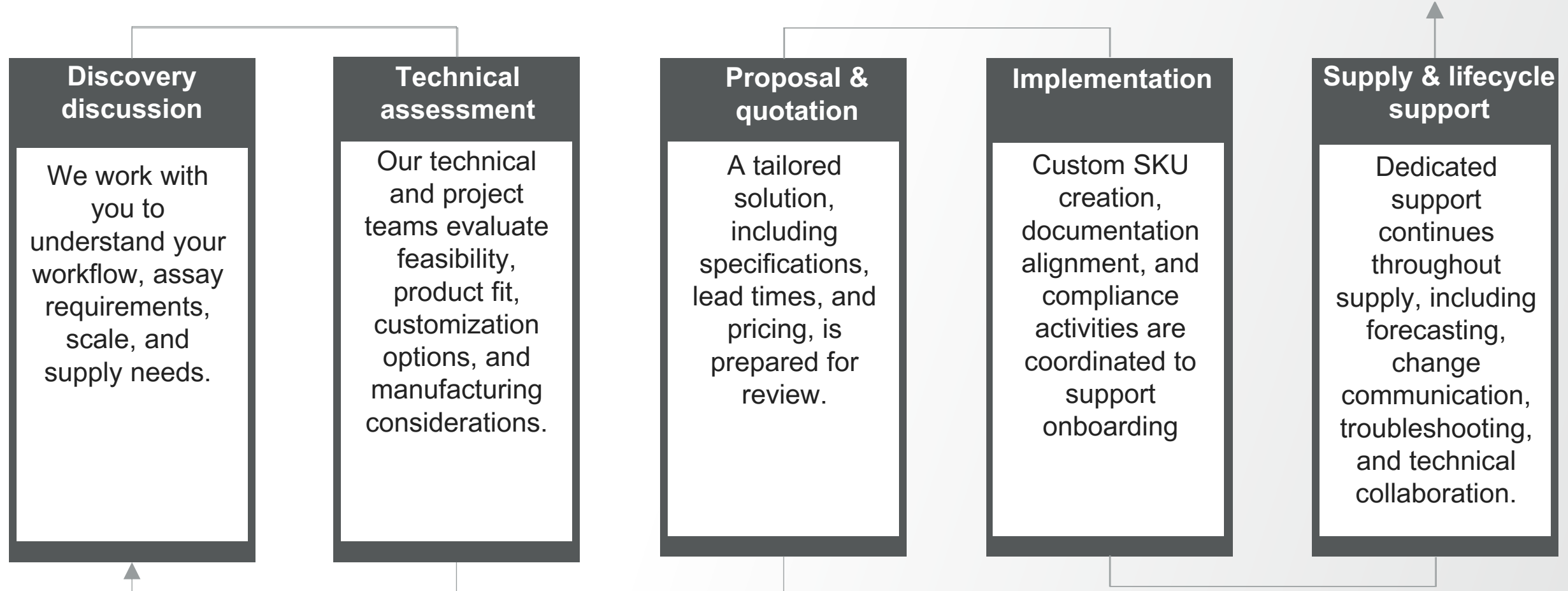
- OEM readiness
- Manufacturing support
- Documentation flexibility



Dedicated Support Throughout Implementation



A Collaborative Process Designed To Support Implementation And Long-term Supply

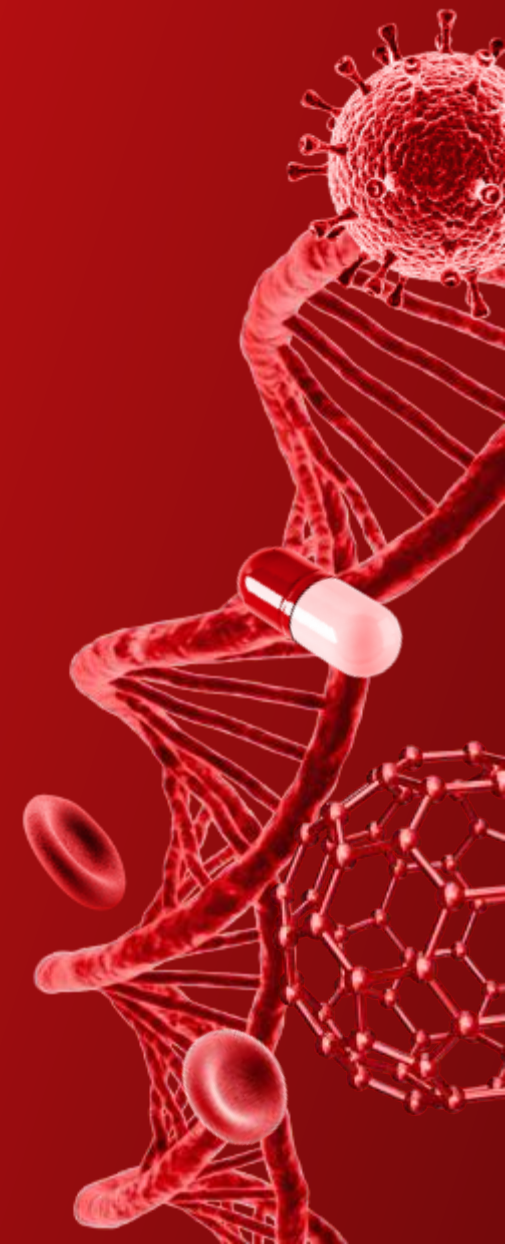


Let's discuss your workflow and customization needs!

Thank you

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Customization Solutions Overview



Workflow need	Customization solution	Desired Outcome
Scale-up manufacturing	Custom fills	Improved Efficiency
Assay optimization	Custom formulations	Simplified Workflows
Faster lyophilization development	Lyo-ready mixes	Accelerated Development
Room temperature stability	Lyophilized solutions	Room-Temperature Stability
OEM/commercialization	Private label kits	Focus on Commercialization
Enhanced quality requirements	Custom QC	Greater Operational Confidence

Customization solutions designed to support research, assay scalability, workflow simplification, and supply continuity