qPCR and dPCR for biopharma

QualTrak real-time PCR and digital PCR ecosystem for streamlined biologics development

Biologics—including vaccines, cell and gene therapies, monoclonal antibodies (mAbs), and their biosimilars—have great potential for the treatment and prophylaxis of a broad range of diseases. As of 2018, eight of the top ten best-selling drugs in the US were mAbs [1]. mAb biosimilars are expected to follow a comparable path, with the biosimilars market set to double by 2025 [2]. Cell and gene therapies are also predicted to increase, with a projected compound annual growth rate (CAGR) of almost 25% in the near future [3]. This growth offers tremendous opportunities, especially for manufacturers who can develop new and effective therapies quickly.

Rapid and efficient development of new and effective biologics is no easy feat. Researching, developing, and manufacturing new biologic therapies is an arduous and expensive process fraught with regulatory and supply chain challenges. It takes an average of 10 years and $2.6 billion to develop a new treatment, and only 12% of candidates make it to market [4], while others end up in "the valley of death"—the transition from laboratory to trial where candidates often fail.

With such drastic implications for time and resources, it is imperative that biologic manufacturers choose the right commercial collaborators from the start—agile partners who can improve predictivity, speed, and consistency to bridge basic and clinical research.

Work with a partner who offers reliable, high-quality PCR products for every step of the development process

The role of Thermo Fisher Scientific in PCR-based detection of coronavirus

"PCR" became a household term because of its common use in SARS-CoV-2 detection and surveillance; however, its applications in the coronavirus crisis do not end there. In particular, qPCR continues to play an important role in the development of SARS-CoV-2 treatments and vaccines. qPCR assays, reagents, and instruments developed by Thermo Fisher were not only cited in detection, but also in the development research for several SARS-CoV-2 vaccines, contributing on many levels to pandemic mitigation efforts.

Leverage high-throughput, high-quality products throughout the entire workflow

Table 1. Suggested applications for qPCR and dPCR in biopharma discovery, development, and manufacturing.

Phase	Goal	mAbs applications	Vaccine applications	Cell and gene therapy applications
Discovery				
Process development				
Preclinical and clinical research				
Manufacturing				

qPCR and dPCR offer more consistent results due to innovative instrumentation, optimized master mixes, and predesigned and custom assays

Instrumentation

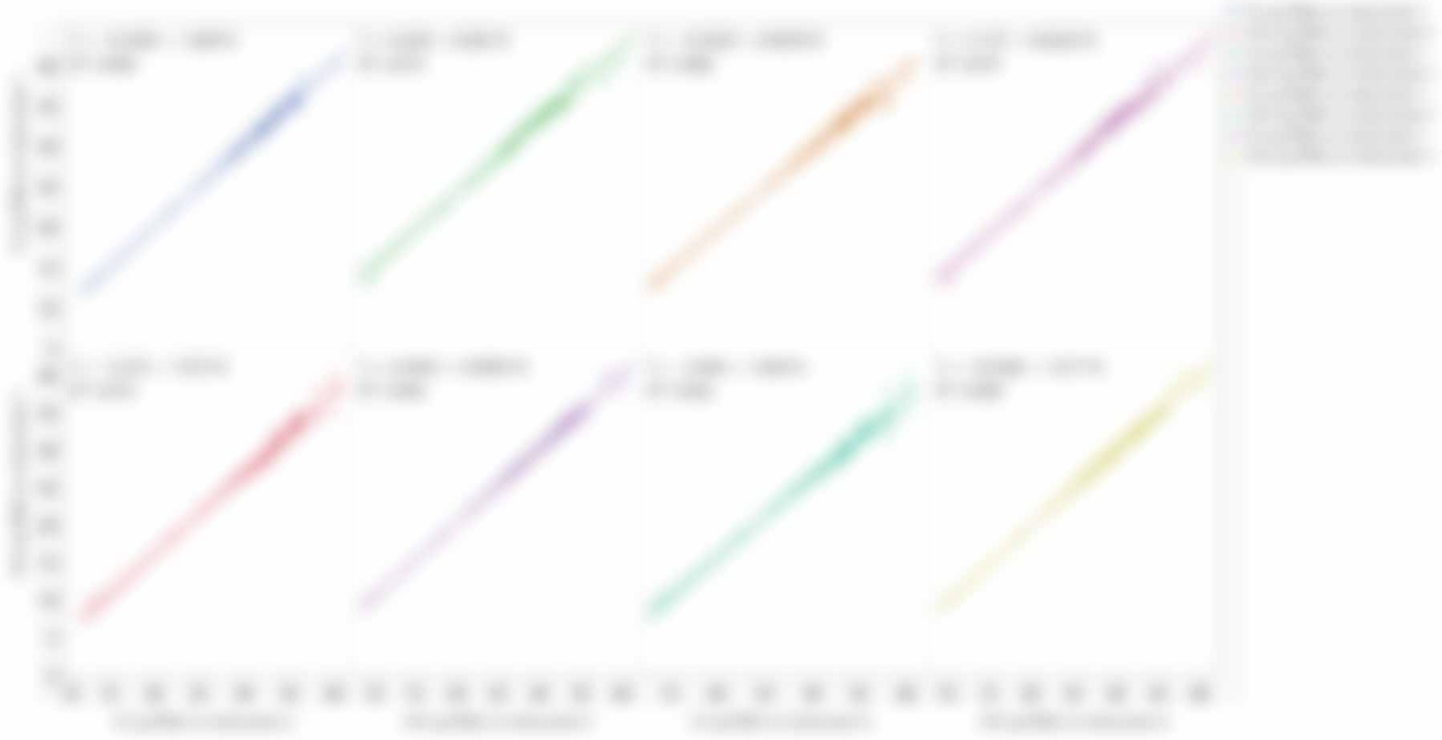

Figure 1. Reproducibility of gene expression measurements using Applied Biosystems™ MicroAmp™ Fast Optical 96-Well Reaction Plates on different instruments. Pairwise comparisons of cDNA data from 10 ng or 100 ng universal human reference (UHR) RNA on 3 different instruments show high correlations from instrument to instrument.

Master mixes

Figure 2. Genotyping results from TaqPath ProAmp Multiplex Master Mix and master mixes from other suppliers. In three TaqMan™ genotyping assays performed under standard conditions, TaqPath ProAmp master mix consistently produced accurate genotype calls and excellent cluster resolution across multiple assays, demonstrating higher data precision compared to other suppliers' mixes.

Predesigned and custom assay formats

Ensure quality assurance (QA), control, and compliance with advanced technology and compliant software, documentation, and facilities

Leverage a robust supply chain to ensure uninterrupted PCR operations

Conclusions

Choosing to adopt better PCR technology and the right partner offers tremendous benefits for discovery, development, and manufacturing of biologics, including vaccines, cell and gene therapies, mAbs, and their biosimilars. To unlock the most effective instruments, master mixes, assays, and compliant software for your biologics program, find a vendor with a complete and thriving qPCR ecosystem.

Thermo Fisher is a long-established, trusted leader that can provide the leading cGMP-compliant QualTrak Real-Time PCR technologies and support to guide you through every PCR step of biologics development. Thermo Fisher guarantees continuous automation, accuracy, consistency, and compliance to its partners—setting them up for success from the first phase of discovery through widespread distribution of their biologic.

Visit **thermofisher.com/qpcr/biopharma** to get started with Thermo Fisher Scientific as your full-service biopharmaceutical PCR products provider. Our Applied Biosystems QualTrak biopharma-specific qPCR and dPCR products and workflows are designed to fast-track your biologics development pipeline, allowing you to develop the highest quality mAbs, biosimilars, vaccines, and other therapeutics in the shortest amount of time.

References

1. Lu RM, Hwang YC, Liu IJ, et. al. (2020). Development of therapeutic antibodies for the treatment of diseases. *Journal of Biomedical Science* 27(1).
2. Chen Y, Monnard A, Santos da Silva J (7 June 2021). "An inflection point for biosimilars." *McKinsey & Company.*
3. Global Cell and Gene Therapy Market Report 2020: Market to recover and grow at a CAGR of 24.1% in 2023. (7 January 2020) *Business Wire.*
4. Campbell H (26 August 2015). "Video & infographic: Developing a new drug is actually harder than rocket science," *PhRMA.*

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