

Selecting the Right OEM for Scalable Molecular Diagnostics

Accelerate Progress With an OEM Partner You Can Trust



Visit bio-rad.com/CFXOpusDx for more information.

More Than a Vendor: Choosing the Right OEM Partner

Selecting your OEM partner is not a simple purchasing choice but a long-term strategic business decision that directly impacts time to market, regulatory success, scalability, and sustainable growth across the molecular diagnostics lifecycle.

An ideal OEM partner functions as an extension of your organization, aligning with your goals, protecting your reputation, and reducing risk. The OEM partner supports long-term success through trust, transparency, communication, and shared objectives rather than just delivering a technology.

Aside from quality equipment, Bio-Rad brings hands-on experience, regulatory readiness, and technical expertise to support molecular diagnostic development, validation, and commercialization. Partnering with Bio-Rad means gaining more than an instrument. It means access to a dedicated team that works alongside you to help accelerate innovation while reducing complexity.

Characteristics of a Strong OEM Partner



Strategic Partnership Built on Communication

Transparent communication is fundamental to a successful OEM partnership. It fosters alignment, builds trust, and supports operational continuity by ensuring all parties understand expectations, timelines, and responsibilities. This alignment reduces the risk of errors that could impact product quality, regulatory compliance, or market delivery.

Bio-Rad is a collaborative partner that functions as an extension of your team, offering transparency and responsiveness. Dedicated points of contact and regular updates keep validation, product implementation, and ongoing support on track. Our dedicated account management structure allows teams to respond quickly to changing needs and maintain uninterrupted operations, which is essential for laboratories and diagnostic companies that rely on consistent performance and uptime. With shared goals and clear communication, you gain a partnership where Bio-Rad works alongside you to deliver long-term value for your organization and your customers.



Technical Expertise That Accelerates Innovation

A strong OEM partner provides access to advanced technologies and engineering expertise, along with guidance that extends beyond basic instrumentation. This combined capability enables support across the entire product lifecycle, from development and validation to deployment and long-term support.

Bio-Rad brings more than 70 years of experience developing and manufacturing innovative technologies for life science research and clinical diagnostics markets, including over 35 years of leadership in PCR innovation.

We offer comprehensive technical services, including troubleshooting, maintenance, and customization, to help maintain consistent performance and long-term reliability. We are also a trusted supplier of qPCR reagents and plastics, customized to fit specific workflow needs through flexible volumes, barcoding, and packaging options.



Regulatory Rigor That Reduces Risk

An OEM relationship is a long-term commitment, so partners should be equipped to support regulated operations over time. The ideal OEM partner operates under a robust quality management system, maintains appropriate industry certifications, and has a demonstrated history of successful audits and regulatory inspections. These elements help support consistent, high-quality production backed by thorough documentation and traceability. A partner that falls short in these areas can jeopardize regulatory submissions, global distribution, and overall regulatory compliance.

Bio-Rad has extensive experience in the clinical diagnostic market. Our established quality systems, reliable service and support, and strong compliance culture minimize regulatory and operational risk for our partners. We adhere to global and regional regulatory standards, including those required for FDA and CE marking. Our manufacturing sites are ISO 13485 certified and have a long track record of successful audits and inspections. Our long history of executing OEM supply and quality agreements reflects the industry's trust in Bio-Rad's ability to support regulated manufacturing and commercialization over the long term.



Operational Excellence That Helps You Scale

Long-term success depends on an OEM partner with the capacity and systems to maintain continuity as needs evolve. The right OEM partner can help secure uninterrupted supply through global reach, manufacturing redundancies, and multiple distribution centers supported by reliable logistics, robust inventory management, and demonstrated delivery performance. The ability to scale production in line with demand is essential for maintaining predictable timelines and resilient supply chains.

Bio-Rad operates with a global workforce of over 7,500 employees and supports over 85,000 research, clinical, and industry customers worldwide through an extensive international operations network. Our strategically located manufacturing sites and distribution centers, combined with established supply agreement frameworks, enable resilient supply chain management and scalable manufacturing capacity. Transparent logistics and inventory practices, supported by proven risk-mitigation strategies, ensure consistent, dependable delivery for our partners.



Financial Stability for Long-Term Confidence

Financial stability of an OEM partner is a critical factor in reducing risk and supporting long-term success. A financially stable partner is better positioned to sustain operations, invest in quality systems and R&D, and honor long-term supply, service, and support commitments. This stability is especially important in regulated diagnostic markets where product lifecycles extend for years. Strong financial health also reduces the risk of disruptions caused by restructuring, cost-cutting, or insolvency, all of which undermine supply continuity, regulatory compliance, and customer trust.

Bio-Rad offers competitive, transparent pricing with predictable cost structures and clear terms for long-term agreements. This approach helps protect partners from unexpected expenses and supports a lower total cost of ownership over time. Our financial strength is grounded in decades of market leadership and a reputation for reliability and dependability.

OEM Partnership in Practice: The CFX Opus Dx Real-Time PCR System

Bio-Rad's OEM partnership model is reflected across our molecular diagnostics portfolio, with systems designed to support regulated development, validation, and long-term commercialization. The CFX Opus Dx Real-Time PCR System illustrates how our approach to system design, quality, documentation, and lifecycle support comes together to help OEM partners reduce risk and accelerate progress.

- **Lifecycle partnership and services:** OEM-focused guidance and technical support during development, validation, and scaleup, supported by established quality management systems and ISO certifications
- **Consistent system performance:** proven PCR engineering and run-to-run consistency during analytical and clinical validation
- **Readiness for regulated workflows:** purpose-built for regulated IVD applications, supporting efficient implementation within established validation frameworks
- **Compliance-ready software and data integrity:** CFX Maestro Dx Security Edition software includes controlled user access, time- and date-stamped audit trails, and electronic signatures to support data integrity and compliance requirements, including US FDA 21 CFR Part 11 and IVDR, when implemented within a quality system
- **Regulatory documentation support:** master files for the CFX Opus Dx Real-Time PCR System are on file with the US FDA. Access can be authorized for FDA reviewers to support OEM partner submissions, helping streamline the review process

Move Forward With the Right OEM Partner

Choosing an OEM partner as a diagnostic manufacturer or regulated laboratory is not just about meeting today's technical requirements. It's about securing a partner who can support your product, regulatory strategy, and business as it evolves.

Bio-Rad brings together proven PCR expertise, established quality systems, and a collaborative partnership approach to help you move forward with confidence. By working alongside you from development through regulatory implementation and beyond, we help enable consistent performance, regulatory readiness, and long-term scalability. With Bio-Rad by your side, you gain more than a supplier. You gain a trusted partner committed to helping you develop differentiated, compliant molecular diagnostic solutions and sustain them over time.



CFX Opus Dx Real-Time
PCR System

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