

OEM partner checklist

1. Customization options available

- Simple component alterations
- Custom reagents
- Molecular synthesis (e.g., custom oligos, custom protein, including enzyme, production, etc.)
- Custom plastics
- Custom kitting and packaging

2. Global security of supply

- Manufacturing redundancies
- Multiple distribution centers
- Ability to cover operational logistics, such as:
 - Handling product demand variability
 - Managing manufacturing downtime
 - Scalable production capacity

3. High-quality products and solutions

- Global standards
- Lot-to-lot performance
- Lot size
- Stability/shelf life*

4. Industry expertise and resources

- Broad range of platform technology that can address:
 - A broad set of requirements
 - Clinical applications
 - Diagnostic markets
- Industry leaders and experts who are:
 - Knowledgeable
 - Resourceful
 - Advocates on your behalf
- Training services and support
 - Global on-site field support and training
 - Global remote* support and training

5. Robust quality management system (QMS)

- Quality checks and procedures
- Certified quality documentation, such as:
 - Certificate of Conformance (CoC)
 - Certificate of Analysis (CoA)
- Manufacturing facilities that meet the following certifications:
 - ISO 9001
 - ISO 13485
 - ISO 14001
 - FDA registration
- Processes in place that adhere to regulatory standards
 - Material quality assessment techniques
 - Low batch variability

6. Access to commercial-use rights

- Supports commercial models that enable your business (e.g., reagent rental)
- Grants the ability to sell in a specific country or region

7. Global industry presence

- Global logistics support
- Global manufacturing sites
- Global distribution sites
- Regional and local expertise
- Experience with global commercialization

8. Dedicated team and point of contact

- A dedicated account team to support you throughout your workflow
- Access to supporting experts and resources

9. Understands your needs and prioritizes your goals

- Freeing up your time
- Maximizing your resources
- Enabling more space for innovation

* Dependent upon intended use

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