



Clinical Labeling Vendor Checklist

1. Does the vendor maintain robust quality management systems with continuous improvement? New applications and technologies are emerging all the time, especially with biologic applications. You want to work with a vendor who maintains quality and continuous improvement programs to assure your project will be completed to the most recent and advanced standards. The vendor should regularly review and refine the labeling process, incorporating lessons learned from past errors or near misses.

2. Does the vendor maintain a set of Standard Operating Procedures (SOPs)?

It's important the vendor maintains clear SOPs for label design, production, verification, and application, and all team members are trained on these procedures. Without these SOPs quality can vary, putting your project at risk. Look for a vendor who can demonstrate these documented SOPs and their processes for keeping all team members trained and up to date on them.

3. Does the vendor conduct and maintain records of regular audits?

There's no room for error in clinical labeling so it's critical the vendor supports their quality and continuous improvement processes with regular internal and external audits of the labeling process to identify potential weaknesses or areas for improvement. Ask to see records of these activities.

4. Does the vendor have an in-house label design and project management team?

Working with a vendor who has in-house label design capability and expertise is invaluable. You want to work with a vendor who understands your project requirements and can translate your unique needs into a workable solution. Working with a vendor who's "been there and done that" assures the best, most cost-efficient application is used every time.

5. Does the design and project management team check every detail of the customer design?

For example, if a customer gives a label size does the vendor just use that, or does the vendor perform an additional check of that size against their diagram to assure the design will work. Does the vendor check the country list against the content provided? Does the vendor notice if the phone number is different on different pages? Does the vendor notice if a quantity ratio is provided 1:1 when the label text indicates 1:4? The list of potential seemingly small errors that can derail your entire project is long. You want a vendor who has the knowledge and experience, and who goes the extra mile to assure the project will be a success long before the first label is printed.



6. Does the vendor conduct a multidisciplinary review on each project?

The best vendors involve representatives from various departments, including clinical, regulatory affairs, pharmacy, and quality assurance, in the label review process to ensure comprehensive oversight.

7. Is the vendor cGMP compliant?

This gives you peace of mind that your vendor partner is adhering to the highest industry standards.

8. Does the vendor maintain Quality Control (QC) Checks for each project?

Beyond cGMP compliance robust quality management processes must be supported by multiple QC checkpoints throughout the label production process. For instance, after label printing, a QC specialist can review a sample or all labels before they're applied to the products.

9. Does the vendor train staff on the importance of the labeling process?

The best vendors regularly train staff involved in the labeling process about the importance of labeling, potential errors, and the procedures in place to prevent them.

10. Does the vendor maintain version control of the labeling projects?

Using version control for label designs ensures that only the most recent and approved version is in production.

11. Does the vendor have a dedicated clinical label manufacturing facility?

This means the staff and processes are focused exclusively on unique needs of clinical label printing. This also assures your timelines won't be impacted by long commercial runs.

12. Does the vendor fulfill all their projects in-house?

If your labeling vendor subcontracts work out there is higher risk of quality or timing issues.

13. Does the vendor have redundant presses?

This ensures capacity and throughput won't be impacted if mechanical issues arise, keeping your project timelines on track.

14. Does the vendor have additional approved manufacturing sites if needed to support business continuity?

If there is a disruption to the label production process, you want to work with a vendor who has additional manufacturing sites to assure continuity and timelines of your project.

15. Does the vendor maintain raw stock inventory on site?

This helps avoid stock outs with a core portfolio of material for different types of projects and applications.

16. Does the vendor maintain full traceability of raw components in all batch records?

The supply chain of clinical labeling components is vast and global. You want to work with a vendor who maintains full traceability of the upstream supply chain to assure all inputs are genuine and safe.