



Ensuring Reliability in Clinical Trial Packaging

Creating packaging materials for a clinical trial is a highly specialized job with many nuances involved in the process as well as very particular demands for proper and consistent printing and labeling. Broader experience in healthcare or Pharma packaging alone simply is not enough.

Print production partners on such projects must have a keen sense of the special demands from the clinical leaders overseeing the trial, possess advanced project management to oversee the complexity of components that must come together for successful production, and have made the necessary investments in staff and resources to provide the depth and diversity of expertise needed to ensure the project's needs are successfully met.



The Unique Production Demands Associated with Clinical Trials

Simply put: Clinical trial packaging is not like other print projects. "These kinds of projects necessitate a high degree of repeatability, and there is unusually low margins for variations in color, clarity, label placement, and so forth," says Chuck Campisi, VP Sales and Marketing from CCL Healthcare.

The main impetus for this level of consistency is the need to keep the study blinded. "Patients should not be able to perceive a difference between drug packages, bottles or labels that could influence their opinion of whether they are taking a placebo or trial drug" continues Karl Hoelper, Director of Marketing. "If they can discern a difference, it could negatively influence the trial, making the results unusable and leading to a significant loss of time and financial resources and even perhaps delay research needed to advance clinical care."

Another distinctive element with clinical trial projects are the approach to inspection and quality verification. "Nothing can be left to chance, and even the slightest variations must be detected," says John Dultz, Process Improvement Manager. "If there is an error, there is a highly-specific and time-consuming process that the printer must follow to ensure the replacement label is affixed in precisely the right location and the packaging is the same as the others."

Clinical trial samples and packages require a lack of variation within and across job runs. "Such consistency can be extremely challenging to reliably achieve, particularly if there are three to six months between runs," says Stephen Hawkes, Director of Sales. "Over such spans, colors can degrade and the printer must account for the potential differences when determining the correct color match for later lots."

Finally, printers must have a highly reliable process in place to keep track of which job lots are for clinical trial drugs and which are for placebo medications. "There can't be any mix up between the two, or the results of the survey could be impacted," says Stan Dultz, General Manager Clinical Operations.

Advanced Project Oversight

High-level project management is needed to successfully support production complexity. Most clinical trial customers have little expertise in printing because they are scientists whose focus is chiefly on leading the trials and learning from the research. Therefore, the best way to start the production process begins with ensuring both entities share a common understanding of the project.

“Usually projects kick off with some sort of written communication from the trial leader describing the project and packaging details,” says John Dultz. “Oftentimes, the information in this document will be missing, and we can then start working to identify and capture the relevant data that will be needed for the project’s success.”

Once the printer has sufficient direction, it must prepare a plan for packaging and aid in file preparation. “Substantial work occurs up front to make sure the text, file, drawing, and packaging design are just right before printing,” comments Stan Dultz. “The more exact the file, the more efficiently and effectively the print job can run.”

Once the client signs off on the file, the printer will manage the core steps of print production:

- Production planning
- Prepress and plates
- Baseline booklet printing
- Booklet finishing
- Assembly
- Inspection
- Quality assurance

“Having detailed procedures for each of these steps is crucial to ensure a quality output that meets the specific needs of the study while remaining on budget and on time,” says Stan Dultz.

“Without clear processes, a project of this scope can quickly get off track.”

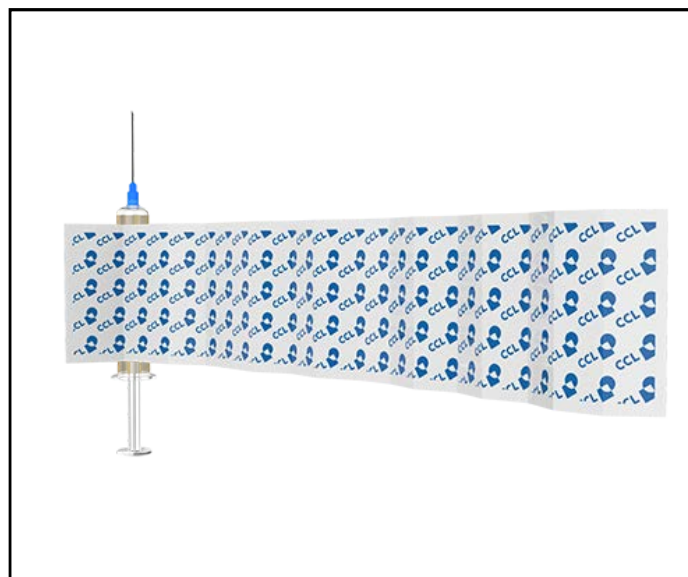


5 Characteristics of The Right Clinical Trial Printing Partner

Selecting the right partner for execution is key. To be successful, clinical leaders typically seek several qualities in a print partner.

- **Experience.** “Since printing for clinical trials is a specialized area, you want to work with a company that has deep experience in this type of project,” says John Dultz. “The company should also have a solid reputation in the marketplace for high-quality, reliable, and repeatable work.”
- **Global reach.** Many clinical trials involve patients from around the world. Consequently, the printer should operate internationally to ensure continuity across countries. “No matter where packages are printed, there should be the same manufacturing controls, market knowledge, and approach to clinical trials,” says Karl Hoelper. “An international company can also print booklets in multiple languages with assured accuracy, which minimizes the variations between packages going to different countries.”

- **A knowledgeable team.** An experienced partner will assign a dedicated team to guide the project from start to finish. “This group will include people who intimately understand the business and its nuances and are acquainted with the challenges of clinical trial packaging,” comments Stan Dultz. “Team leaders will be familiar with the goals of these kinds of projects and fully understand how to overcome any issues that arise.”
- **Well-versed in printing options.** Clinical trial packaging can vary widely depending on the study. As such, printers should be experienced in multiple printing and labeling styles, including booklet, single-ply label, tear-off label, and so forth. As John Dultz notes: “Although many companies use different printers for different label types, it’s particularly valuable working with a company that can produce all forms of clinical trial labeling and packaging because there is less chance for error and more cost efficiencies due to economies of scale.”



The printer also should be comfortable with different printing surfaces, including syringes, vials, boxes, and cartons—all key elements to successful project completion. In addition, the company must be able to reliably meet temperature, humidity, and heat specifications as well. “It can be especially beneficial if the printer can accommodate single-sheet printing,” Stephen Hawkes. “This helps prevent cross-contamination in drug samples and greatly minimizes the risk of missing or incorrect pages.”

Ultimately, clinical trial printing and labeling requires a level of commitment and dedication that not all companies have. A good partner is focused on delivering reliable processes right now and is also committed to applying new technologies, such as e-labels, that stand to enhance the reliability, efficiency, and cost-effectiveness of this important work.



About CCL

CCL Healthcare, a division of CCL Label, is focused on producing secondary packaging within cGMP facilities. We pride ourselves in partnering globally with companies of all sizes and manufacturing our products locally to our partners. That is why we have over 30 cGMP facilities worldwide and are growing. With over 65 years of printing experience, CCL Healthcare knows quality matters.

That is why we have invested heavily into 100% Vision Inspection Systems and deployed the most rigorous Quality Assurance process in the industry. What does this mean for our partners? CCL Healthcare is dedicated to providing our partners with the lowest cost of ownership in the industry. Our products are designed to increase packaging line throughput, minimize the investment in equipment, and deliver the highest quality products on the market.



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