**The Art of Kamishibai in Medical Device Manufacturing**

When an organization refers to their lean manufacturing processes, they typically talk about 5S programs, kanban systems, and kaizen events. Once standardized work has been developed and documented, how does the company ensure that it’s sustained? This is where kamishibai comes in.

**Art**

It’s fitting that kamishibai is a form of Japanese storytelling or paper theater, since the most accurate description of kamishibai as a tool for a Quality Management System (QMS) or lean manufacturing is “the art of checking.” It combines standardized work with accountability and visual control into a golden triangle of sustainability and culture change.

A fundamental part of the Lean approach is the Gemba walk, in which members of management visit the manufacturing floor to observe a process, ask questions, and look for opportunities to reduce waste or improve the process. All of this is carried out while interacting with and coaching operators to solve problems with lean tools.
and methods. Kamishibai supports this practice by making adherence to standardized work visual on the gemba walk.

"Gemba" means “place” in Japanese. In the context of lean manufacturing, gemba refers to the manufacturing floor, where value is created.

Science

Kamishibai uses a status board, observation cards, and a schedule for when staff members must visit production to observe an operation. The kamishibai board is a visual management tool, indicating which processes must be checked each hour. Observation cards are similar to work instructions and list the process or system observations that should be made.

To improve the effectiveness of kamishibai, work center observation cards should also be chosen at random, so that any operation on the kamishibai board could be observed at any hour.

Ideally, any issues that are uncovered are addressed and corrected immediately by the area leader and the operator, through an on the spot kaizen event. If an issue cannot be corrected immediately, a countermeasure is recorded and documented at the work area.
While kamishibai is a process, much like a kaizen event, there is inherent flexibility to its premise, in that observations can be adjusted based on the risk of failure of individual processes or areas. For example, at Phase 2 observations are made in the production area every hour, and supporting processes in the warehouse or office areas are conducted one time per day. There is also a weekly review of all observations, countermeasures and actions taken by top management.

**Culture**

A key outcome of kamishibai is that it establishes the principle that everyone serves the manufacturing floor. This is an important cultural change, and one that is difficult to implement. But kamishibai reinforces this thinking by actively engaging the management team – all the way up to the President or CEO – in supporting the production team.

For example, completion of the Gemba walk using kamishibai is a mandatory task, assigned to employees on a regular schedule, just like a step in a production process. If the assigned person is not available to complete the gemba walk, they must find someone to carry out the task in their place. “Skipping” a gemba walk is considered a disservice to the production team.

Kamishibai supports the QMS by uncovering potential problems and initiating countermeasures before they escalate to Non-Conforming Material Reports (NCMR’s) or Corrective and Preventive Actions (CAPA’s).
At Phase 2 Medical Manufacturing’s locations, both in Rochester, NH & Tijuana, MX, employees are further motivated to support the company's lean journey through an incentive program based on five key metrics. Every employee is eligible for a bonus, based on NCMR’s and complaints, as well as revenue, on-time delivery, and productivity. Every week, the company holds a short, 15-minute, all-employee meeting where these five metrics are reviewed.

**Proof**

The medical device industry is highly regulated, and many suppliers are ISO 13485 compliant or FDA registered, meaning that they not only have to comply with government requirements for product safety and traceability, but also with ISO requirements to demonstrate that their quality system is implemented and maintained. Kamishibai supports the supplier’s efforts to meet these requirements by ensuring that standardized work is followed and by engaging the management team, making it a fundamental tool in the company’s QMS.

From a customer’s perspective, a supplier who has implemented kamishibai will not only be able to talk about their lean manufacturing processes, they will be able to show proof that those processes, and the entire QMS, are sustained.