



CHANGE MANAGEMENT FOR AN EYE SURGERY DEVICE IN DEVELOPMENT

Our customer is one of the world's leading manufacturers of medical technology devices. With their patented technology, they have set a new level of standards for phaco devices worldwide. Processes that are more stable lead to greater safety and efficiency. This provides more time for the operating surgeons to concentrate on the most important task: cataract surgery (removal of cataracts).

From discontinued components through approval-related adjustments

Project coordination encompassed all change tasks: discontinued components (End of Life), supplier changes, production process optimizations, design and electrical changes, as well as some adjustments necessary for approval (e.g., IFUs and labels).

Thanks to its broad range of available services, konplan was able to effectively reduce the burden on the developers, process planners, product managers, and regulatory affairs managers: in addition to project coordination, konplan handled component design and qualification, verifications, the adaptation of Product Labeling Reports, procurement specifications, and the preparation of Regulatory Affairs checklists.

Transparency about the status of each change was provided by the team using the JIRA ticket system in real time (kanban) with a customized JIRA Decision Board. konplan also managed the Complaint Board for customer complaints and prepared the final 8D report.

Change management in series production

With the comprehensive documentation and verification in the electronic DMS, konplan ensured that the implementation of changes to the device continuously complied with regulatory requirements all the way to series production. And, thanks to konplan's moderation and management of the boards, the customer team gained much more time for development work.

Result

- Change Mgmt. for Series Production
- Efficient Change Tracking
- Reduce the burden for Regulatory Affairs Manager

Methodology & Technologies

- SAP
- eDMS
- JIRA
- Kanban

Scope of Services

- Leading / Moderating JIRA-Boards
- Planning, Management, and Change Implementation
- Creating or revising technical documentation and verifications



36 months



2-3 employees – konplan
15 employees – customer



Conception, development, production

