



Document Control Solution Highlights

- Web-based submission of change requests.
- Identification of impacts due to the proposed change.
- Online review of proposals.
- Assignment, tracking and verification of change impact actions based upon the category and type of change.
- Tracking, management and verification of change implementation activities (training, document updates and downloads).
- Closure of changes after all document updates and all training has been completed.
- Integrated deviation with time/lot/serial number/quantity expiration.
- Workflow-driven due dates and reminders based upon the overall schedule.
- Flexible search of requests and documents.
- Integrated storage of requests, documents and markups.
- Up-to-date charts/reports of status and trends.

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Request ID

Originator

Originating Department

Overall Description of Change Request

Documents Included in Change Request

Document ID	From Rev	To Rev	Document Name	Reason	Description of Document-specific Change	Markup
Info 4430023	B	C	Super Mover 2004 Assembly Drawing	Improve Product/Process	Drawing change, larger wheels	design.ppt
Info 4430024	B	C	Super Mover 2004 BOM	Improve Product/Process	BOM change, Larger wheel sizes	Super Mover 2004 BOM.xls

Change Impacts

Applies?	Change Impact Name	Instructions	Description	Evidence
Yes	Design - Design Validation	Revalidate design based upon proposed change. Include supporting evidence.	re-validated the design	performed required design validation
Yes	Regulatory Impact	Determine 1) regulatory impact (yes/no), 2) if yes, describe impact, 3) attach completed reg form	determined regulatory impact	reg analysis/conclusions
Yes	Risk Analyses Affected	Review for Risk Analysis impact. Attached FMEA form when necessary.	impact of proposed change on risk profile	completed risk profile assessment

My Tasks

Document Control
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