

12 Things to Check in Your Complaint Handling & PMS System Before an Audit



- Are complaints consistently captured across all sources?
- Is complaint data categorized for trend analysis?
- Are signal detection thresholds defined?
- Are recurring issues automatically flagged?
- Is complaint data linked to CAPA activities?
- Are trend reports generated regularly?
- Can signal evaluation decisions be demonstrated?
- Are PMS reports aligned with regulatory requirements?
- Is complaint data linked to risk management activities?
- Are serious incidents escalated appropriately?
- Is PMS documentation audit-ready?
- Can actions taken from trends be demonstrated?