APPEAL MANAGEMENT PROCESS

Entered as „Appeal"

(A)

Clarification questions to inquirer if needed

Information to KAM for KA

5.6 Investigation + decision: Appeal valid or not

Valid?

— No → 5.7a Ensure answer is given

— Yes → 5.7b Immediate action to solve the issue

Answer

5.8a Answer accepted by inquirer?

— No → Possibly Involvement of other Institutions (Advisory Board) by inquirer → External Decision: Appeal Valid?

— Yes (from 5.7b) → External Decision: Appeal Valid?

— Yes (5.8a) → Close case

— No (External Decision) → Close case

Close case

5.8b Ensure answer is given

Answer

Level 2 / 3?

— No → Close case

— Yes → 5.9 Root cause analysis, corrective and preventive actions, effectiveness check

CAPA process closed?

— No → 5.9 Root cause analysis, corrective and preventive actions, effectiveness check

— Yes → 5.10 Ensure final answer is given where applicable

Answer

Close follow up action