CORRECTIVE AND PREVENTIVE ACTION (CAPA)

Quality assurance

CAPA no.	Date opened	Source	Source reference
Product	Batch nos.	Department and line	Raised by
Risk class	Change control	Target closure	CAPA owner

Problem statement (what, where, when, how many, how found)

Immediate correction and containment

Impact assessment (other batches, products, lines, markets)

Root cause: 5 whys

Why	Question	Answer and evidence

Root cause

Risk score (severity x occurrence x detection, 1 to 10 each)

Severity	
Occurrence	
Detection	
Risk priority number, before CAPA	
Occurrence after CAPA	
Detection after CAPA	
Risk priority number, after CAPA	

Actions

No.	CA or PA	Action	Owner	Target	Done	Evidence

No.	CA or PA	Action	Owner	Target	Done	Evidence

Effectiveness check (criteria, period, result)

Effective?	Closed on	Reported in product quality review

Raised by	CAPA owner	Head, quality assurance (approval and closure)