

Pharma A/S				Doc No:	PAS-QA-CAPA-008
Corrective and Preventive Action (CAPA) Report "YR" is present year				Resp.:	QA Mgr
				Version:	
To be filled out by QA	CAPA Report No:	23	Received QA date (d/m/y):	21/08/(YR-1)	
	Corrective action needed:	X	Origin external type:	Audit UniPharma	
	Preventive action suggested:		Origin internal type:		
	Initiated by; name, function:	Initials, Quality Mgr			
	Description of issue and potential impact:				
	<p>During UniPharma audit it was claimed that our training of new process operators, maintenance craftsmen, utility operators and logistics operators was deficient in various aspects which led to a Major NC by the UniPharma auditors.</p> <p>Several operators and craftsmen in all mentioned areas did not have training records, many training records were incomplete and the auditors found the operators and craftsmens knowledge and responses in many cases were vague.</p> <p>UniPharma has decided not to do business with us until this issue is resolved. They are waiting for an invitation to come back and audit our training performance and training system again.</p>				
Responsible for resolution (name/function)				Prod Mgr & Maint Mgr	

	Responsible acknowledged	Initials:	Prod Mgr	Date (d/m/y)	25/08/(YR-1)
To be filled out by Responsible	Root Cause analysis: An investigation was performed within Production which revealed: One of our production supervisors did not have the necessary technical and human skills to be an efficient trainer. The follow up on the production operators training program and progress lacked focus and organization. Several production SOPs were of dubious quality. The Logistics Mgr concluded that the Logistics supervisor was unfit for the task to start up and train a new unit. Maintenance manager pending root cause analysis for utility operators.				
	Action plant with Milestones and dead lines: Production supervisor to be replaced asap. Done January (YR) due to difficulties recruiting. Experienced process operators from our sister plant in the US have been asked to do temporary training assistance for a 2-3 month period. None of the US process operators have been interested so far. A new training matrix overview has been introduced for the production operators during 4Q (YR-1). The system is not completely implemented due to lack of resources. A priority list of SOPs to be revised has been made including 7 new documents. We have set up a collaboration with our sister plan in the US for them to help revise and make our SOPs. As of the end of Dec (YR-1), 9 have been revised however none of the new SOPs have been made.				
	Logistics supervisor replaced as of 01/10/(YR-1).				
	Responsible finalized action plan (d/m/y):				

QA Approves implementation	Initials:		Date (d/m/y)	
QA Comments:				
CAPA to be reviewed at Mgt Review?			Yes	