

YR = Present year

Pharma A/S Management Review No 3 – Q1 YR				
To:	General Mgr., Quality Mgr., Production Mgr., Maintenance Mgr., Logistic Mgr			
Cc:	QA Engineer, QC Supervisor, Sales & Marketing Mgr. HR Mgr. Big Pharma Berlin			
Meeting held:	22.01.(YR), 9:00- 11:00			
Present:	General Mgr., Quality Mgr., Production Mgr., QA Engineer, QC Supervisor, Logistics Mgr. (part time)			
Absent:	Maintenance Mgr. Excused			
Topic	Comments	Action	Responsible	Due
Approval of last Mgt Review meeting No 2-Q3 (YR-1)	General Mgr: Mgt Reviews (YR-1) were all overdue or cancelled. We agreed to do a review quarterly	Schedule future Mgt reviews in Outlook	Quality Mgr	Immediately
Customer Satisfaction	Key Performance Indicators Q4-(YR-1): 1. Delivery on time: 98% (> 95%) 2. Packaging integrity: 82% (> 99%) 3. Certificate of analysis: 98% (> 95%)	1+2: Packaging inspection procedure to be revised. Packaging operators to be re-trained.	Logistics Mgr.	01.03.YR
Production	Key Performance indicators Q4-(YR-1): 1. Fermentation: Yield 78 % (> 80%) 2. Centrifugation: Yield 3. Ultrafiltration: Yield 4. Spray Drying: Yield 92 (>95%) 5. Average product yield: 6. Product on spec: 82 % (>90%) 7. Training of process operators:	Action plan to be presented next Mgrs meeting Q2-YR	Prod Mgr	
Maintenance	Key Performance indicators Q4-(YR-1): 1. Preventive maintenance program. 2. Calibration of critical equipment in due time: 87% (100%) 3. Utility down time: (>98%) 4. Training of utility operators:	1. On schedule 2. Revisit critical equipment calibration frequency with Production 3. Follow up on Utility log sheet	1. Maint. Mgr 2. Maint Mgr 3. Maint Eng	2. Update next MR Q2-YR 3. Immediately

Audits & Inspections	1. Training of internal auditors: 3 out of 6 done. 2 in progress. 1 not started (6) 2. Internal audits done: 2 (3) External audits since last Mgt Review: 3. PharmaLion audit: 3 minor NC, 6 Obs 4. DMA follow up audit: 4 minor NC and 4 Obs 5. Major NC in Q320 UniPharma audit	1+2: We have problems making internal auditors available for training  3: In progress 4: In progress 5: General training issue. CAPA report No 23	1+ 2: All  5. Mgt Team	MR Q2-YR  5. MR Q2-YR
Work environment & Safety	1. No accidents with absence: 2 2. Safety Introduction for employees: 65% (100%)	1. Accidents were discussed at last Mgrs meeting Q3-(YR-1) 2. Action plan at next Mgrs meeting Q2-YR	Prod. Mgr & Maint Mgr	
Corrective & Preventive Action	1. CAPA registration: 97% (>95%) 2. CAPA plan completion on time: 36% (>90%)	2. Root cause investigation	2. Quality Mgr	MR Q2-YR
Sales	1. Sales existing products: 102% (105) 2. Sales new products: 65% (> 50) 3. Sales Total:: 98% (100)	1. Revisit sales forecast with Berlin	Gen Mgr & Sales Mgr	MR Q2-YR