

PR#: 14729

Deviation No.:D-2021-0248

Record Status: Closed-Done

基本信息 General Information

厂区 Division: Innovent Biologics (Su Zhou) Co., Ltd

发起人 Originator: 赵永俊(PID-000368)

发起日期 Date Opened: 2021.05.21

简短描述 Short Description:

M1b DS2 人员使用超24小时效期的单页记录签批上岗证 M1b DS2 operator use the records beyond 24 hours validity to sign the work licence

到期日期 Date Due: 2021.05.24

关闭日期 Date Closed: 2021.05.24

偏差信息 Deviation Information

发现人 Discovery By: 章胜红20003905

发现日期 Discovery On: 2021.05.20

汇报人 Report By: 赵永俊20003329

汇报日期 Report On: 2021.05.20

发生部门 Occurred Department: M1b DS2

汇报部门 Report Department: M1b DS2

偏差描述 Deviation Description:

2021.05.20 15:30 纯化生产人员(20003905)在查阅本人上岗证时,发现其中2份上岗证上的文件打印日期分别为2021.03.25和2021.04.05,但实际使用时间对应分别为2021.03.30和2021.04.07(见附件1),与《记录控制规程》(SMP00067)中规定的“单页记录有效期为24小时,24小时内未填写单页记录即失效,应及时销毁,不得使用”不符,故按照《偏差管理流程》(SMP00090)发起偏差。

描述的附件 Description attachment:

附件1上岗证扫描.pdf

是否及时上报? Reporting in Time?: Yes

未及时上报的理由 Reason for not in Time:

NA

已采取的即时措施 Immediately Action Taken:

即时措施附件 Immediately Action Attachment:

厂房设施名称 Facility Name:

M1b

产品所属阶段 Product Phase:

N/A

初步影响/风险评估 Initial Impact/Risk Assessment

产品影响评估 Product Impact Assessment:

生产人员(20003905)已按照《M1b车间吸附深层过滤现场操作考核表》(TP00357)、《M1b车间层析现场操作考核表》(TP00350)、《M1b车间除病毒过滤现场操作考核表》(TP00352)、《M1b车间超滤洗滤现场操作考核表》(TP00351)完成相关文件培训和实操考核,并完成考核方案和上岗证的签批上岗过程未发生异常,符合上岗流程(附件2);且该员工上岗证签批后未发生人为操作导致的偏差。本偏差中生产人员(20003905)使用有效期超24小时的单页记录签批上岗证(SMP00072-R7),但实际已通过上岗考核具备实操的能力,不影响操作的真实性和有效性。综上,本偏差涉及人员操作资质无误,对产品质量无影响。

生产/检测的影响评估 Production/Testing Impact Assessment:

目前已建立偏差行动项(PR#14738)在原上岗证上已完成备注说明,确认该员工(20003905)人员操作资质无误,对后续的生产活动无影响。

其他影响评估描述 Other Impact Assessment Description:

此偏差由于人员疏忽使用超效期的单页记录签批上岗证,是一起偶发性事件。实际该人员具备实操的能力和资质。本偏差发生后已建立偏差行动项(PR#14737)对上岗证签批的相关人员(包括生产人员,签批上岗证的生产管理人员及区域QA)培训本偏差,强调在签批上岗证或其他文件时需注意查看所使用的单页记录在24h内使用。

偏差报告 Deviation Report

PR#: 14729

Deviation No.:D-2021-0248

Record Status: Closed-Done

初步影响评估附件 Initial Impact Assessment Attachment:
附件2 人员考核方案.pdf

偏差分级 Deviation Classification

偏差严重性 Deviation Severity:

对产品SISPQ的影响:

生产人员 (20003905) 已按照《M1b车间吸附深层过滤现场操作考核表》(TP00357)、《M1b车间层析现场操作考核表》(TP00350)、《M1b车间除病毒过滤现场操作考核表》(TP00352)、《M1b车间超滤洗滤现场操作考核表》(TP00351) 完成相关文件培训和实操考核, 并完成考核方案和上岗证的签批上岗过程未发生异常, 符合上岗流程 (附件2); 且该员工上岗证签批后未发生人为操作导致的偏差。本偏差中生产人员 (20003905) 使用有效期超24小时的单页记录签批上岗证 (SMP00072-R7), 但实际已通过上岗考核具备实操的能力, 不影响操作的真实性和有效性。综上, 本偏差涉及人员操作资质无误, 对产品质量无影响。

偏差发生率 Reoccurrence Probability of Deviation:

过去12个月同类型缺陷回顾 (关键词搜索: M1b DS2 人员、使用超24小时效期的单页记录、签批上岗证)
未发现同类型缺陷。

偏差分级 Deviation Classification: Minor

分级的理由 Reason for Classification:

05/24/2021 05:28 PM (GMT+8:00) added by 育芳 刘 (PID-000093):

该偏差原因及影响明确, 无需进一步调查。

综上, 该偏差定义为次要偏差。

是否需要调查? Investigation Required?: No

主调查人 Lead investigator:

不需要调查的理由 Reason for not Investigation:

该偏差原因及影响明确, 无需进一步调查。

调查总结&根本原因分析 Investigation & RCA

调查总结 Investigation Summary:

调查附件 Investigation Attachments:

根本原因分析 Root Cause Analysis:

此偏差由于人员疏忽使用超效期的单页记录签批上岗证, 是一起偶发性事件。

根本原因分析附件 Root Cause Analysis Attachment:

原因描述 Cause Description:

此偏差由于人员疏忽使用超效期的单页记录签批上岗证, 是一起偶发性事件。

原因分类 Cause Category
Others

原因子分类 Cause Sub-Category
Others

原因归属部门 Cause Department
M1b DS2

偏差报告

Deviation Report

PR#: 14729

Deviation No.:D-2021-0248

Record Status: Closed-Done

缺陷描述 Defect Description:

2021.05.20 15:30 纯化生产人员 (20003905) 在查阅本人上岗证时, 发现其中2份上岗证上的文件打印日期分别为2021.03.25和2021.04.05, 但实际使用时间对应分别为2021.03.30和2021.04.07 (见附件1), 与《记录控制规程》(SMP00067)中规定的“单页记录有效期为24小时, 24小时内未填写单页记录即失效, 应及时销毁, 不得使用”不符, 故按照《偏差管理流程》(SMP00090) 发起偏差。

缺陷类型分类 Defect Category

Others

缺陷类型子分类 Defect Sub-Category

Others

是否是重复偏差 Repeat Deviation?: N/A

判定重复偏差的原因 Justification for Repeat Deviation:

无同类型缺陷。

重复偏差的原因描述 Reason of Repeat Deviation Description:

相关的重复偏差 Repeat Deviation Records

PR#

deviation#

简短描述 Short Description

Record Status

最终影响/风险评估 Final Impact/Risk Assessment

对产品质量的影响 Impact on Product Quality:

对其他批次的影响 Impact on Other Batches:

对系统/设备的影响 Impact on System/Equipment:

对验证状态的影响 Impact on Validation State:

对产品注册的影响 Impact on Product Registration:

对法规符合性的影响 Impact on Regulation Compliance:

对稳定性的影响 Impact on Stability:

对其他方面的影响 Impact on Other Aspects:

受影响的部门 Impact Departments:

影响/风险评估附件 Impact/Risk Assessment Attachment:

PR#:14729Deviation No.:D-2021-0248

Record Status: Closed-Done

受影响的产品信息 Impacted Product Information

产品最终处置建议 Product Disposition Proposal:

产品名称 Product Name:

产品代码 Product Code产品批号 Batch No.:数量 Quantity处理决定 Disposition

受影响的物料信息 Impacted Material Information

物料名称 Material Name:

物料代码 Product Code批号 Batch No.:数量 Quantity

受影响的溶液信息 Impacted Media/Buffer Information

溶液名称 Media/Buffer Name:

溶液代码 Media/Buffer Code:批号 Batch No.:数量 Quantity:

受影响的设备信息 Impacted Equipment Information

设备名称 Equipment Name:设备代码 Equipment Code

偏差处理措施 Deviation Action Items

PR#:14737			
责任人 Assigned To: 赵, 永俊(PID-000368)		部门 Department:	M1b DS2
截止日期 Date Due: 2021.05.24		完成日期 Completed Date:	2021.05.24
确认人 Verified By: 邓, 陈琪(PID-000209)		确认日期 Verified On:	2021.05.24
行动项详细描述 Action Description: 对M1b生产人员（包括签批上岗证的管理人员）及区域QA培训此偏差，强调签批上岗证时需注意查看所使用的单页记录在24h内使用。			

PR#:14738			
责任人 Assigned To: 赵, 永俊(PID-000368)		部门 Department:	M1b DS2
截止日期 Date Due: 2021.05.24		完成日期 Completed Date:	2021.05.24
确认人 Verified By: 邓, 陈琪(PID-000209)		确认日期 Verified On:	2021.05.24

PR#:14729Deviation No.:D-2021-0248

Record Status: Closed-Done

行动项详细描述 Action Description:
偏差涉及人员自上岗证签批至今未发生生产操作相关的偏差，且上岗培训过程无异常。需在原上岗证上进行备注说明。

纠正信息 Correction Information

PR#:

责任人 Assigned To: 部门 Department:

截止日期 Date Due: 完成日期 Completed Date:

确认人 Verified By: 确认日期 Verified On:

行动项详细描述 Action Description:

纠正与预防措施 CAPA

PR#:

责任人 Assigned To: 部门 Department:

截止日期 Date Due:

行动项详细描述 Action Description:

附件 File Attachments

关联记录 Reference Records

PR#	Record Type	简短描述 Short Description	Record Status
-----	-------------	------------------------	---------------

相关子记录 Related children

PR#	Record Type	简短描述 Short Description	Record Status
14737	Deviation Action Items	对M1b生产人员（包括管理人员）及区域QA培训此偏差 Training the deviation to M1b operator (including managers) and area QA	Closed-Done
14738	Deviation Action Items	在原上岗证上进行备注说明 Make remarks on the expired records	Closed-Done

偏差报告 Deviation Report

PR#: 14729

Deviation No.:D-2021-0248

Record Status: Closed-Done

Initial Approval

QA Initial Review

Area QA Initial Reviewed By:	邓, 陈琪	Area QA Initial Reviewed On:	2021.05.21 16:47
Classify Completed By:	刘, 育芳	Classify Completed On:	2021.05.24 17:34

Department Initial Review

Department Leader 1 Reviewed By:	邓, 献存	Department Leader 1 Reviewed On:	2021.05.24 18:00
Department Leader 2 Reviewed By:		Department Leader 2 Reviewed On:	
Department Leader 3 Reviewed By:		Department Leader 3 Reviewed On:	
Department Leader 4 Reviewed By:		Department Leader 4 Reviewed On:	
Department Leader 5 Reviewed By:		Department Leader 5 Reviewed On:	
Area QA Leader Reviewed By:	代, 圆圆	Area QA Leader Reviewed On:	2021.05.24 17:37

Quality Initial Approval

Quality Approver 1 Approved By:	管, 国兴	Quality Approver 1 Approved On:	2021.05.24 18:21
Quality Approver 2 Approved By:		Quality Approver 2 Approved On:	
Quality Approver 3 Approved By:		Quality Approver 3 Approved On:	

Final Approval

QA Final Review

QA Final Reviewed By:	QA Final Reviewed On:
-----------------------	-----------------------

Investigator Final Review

QA Representative Reviewed By:	QA Representative Reviewed On:
Investigator 1 Reviewed By:	Investigator 1 Reviewed On:
Investigator 2 Reviewed By:	Investigator 2 Reviewed On:
Investigator 3 Reviewed By:	Investigator 3 Reviewed On:
Investigator 4 Reviewed By:	Investigator 4 Reviewed On:
Investigator 5 Reviewed By:	Investigator 5 Reviewed On:
Investigator 6 Reviewed By:	Investigator 6 Reviewed On:
Investigator 7 Reviewed By:	Investigator 7 Reviewed On:
Investigator 8 Reviewed By:	Investigator 8 Reviewed On:

Department Final Approval

Department Leader 1 Final Approved By:	Department Leader 1 Final Approved On:
Department Leader 2 Final Approved By:	Department Leader 2 Final Approved On:
Department Leader 3 Final Approved By:	Department Leader 3 Final Approved On:
Department Leader 4 Final Approved By:	Department Leader 4 Final Approved On:
Department Leader 5 Final Approved By:	Department Leader 5 Final Approved On:

Quality Final Approval

Quality Approver 1 Final Approved By:	Quality Approver 1 Final Approved On:
Quality Approver 2 Final Approved By:	Quality Approver 2 Final Approved On:

偏差报告
Deviation Report

PR#: 14729

Deviation No.:D-2021-0248

Record Status: Closed-Done

Quality Approver 3 Final Approved By:

Quality Approver 3 Final Approved On:

Product Final Disposition

Disposition Proposed By:

Disposition Proposed On:

Proposal Reviewed By:

Proposal Reviewed On:

Product Disposition Approved By:

Product Disposition Approved On: