偏差报告
Deviation Report

PR#: 13011 Deviation No.:D-2021-0155

Record Status: Closed-Done

基本信息 General Information

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

发起人 Originator: 张, 明帅(PID-000248) 发起日期 Date Opened: 2021.04.06

简短描述 Short Description:
M1b DS2 IBI305 UFDF工序提前点击“NO” M1b DS2 click "NO “ advanced in IBI305 UFDF process.

到期日期 Date Due: 2021.04.07 关闭日期 Date Closed: 2021.04.07

偏差信息 Deviation Information

发现人 Discovery By: 徐小森20001075 发现日期 Discovery On: 2021.04.04

汇报人Report By: 徐小森20001075 汇报日期 Report On: 2021.04.04

发生部门 Occurred Department: M1b DS2 汇报部门 Report Department: M1b DS2

偏差描述 Deviation Description:
2021.04.04 22:54 生产部人员（20001075）在纯化二线25C22房间，进行贝伐珠单抗注射液M1b 3000L DS2102008批次超滤浓缩工序生产操作，在产品回收阶段，超滤系统控制界面出现提示信息“Repeat buffer flush again？”生产操作人员误点击“NO”，与《贝伐珠单抗注射液M1b 3000L原液纯化批生产记录》（BPR100332/11）超滤/洗滤工序，6.3.5超滤浓缩换液第34步操作指令中描述：在超滤系统弹出“Repeat buffer flush again？”时（此时请勿点击“NO”）不符，故产生偏差。

描述的附件 Description attachment:

是否及时上报？ Reporting in Time? : No

未及时上报的理由 Reason for not in Time:
由于偏差在4月4号节假日，于节后第一个工作日4月6日发起。

已采取的即时措施 Immediately Action Taken:
04/06/2021 11:33 AM (GMT+8:00) added by 明帅 张 (PID-000248):
手动开启T0442-UF0402缓冲液流路阀门，并打开超滤浓缩罐进口阀门，待浓缩罐溶液达到需求量时，关闭T0442-UF0402及浓缩罐进口阀门，打开浓缩罐出口管路将浓缩罐中的溶液转入超滤浓缩收集液中进行定容，定容结束后，关闭浓缩罐出口管路，取样送检QC，蛋白浓度合格后，关闭T0442-UF0402缓冲液流路阀门，并将超滤系统阀门恢复至批记录要求的状态，继续进行后续操作。生产部20001075/2021.04.05

即时措施附件 Immediately Action Attachment:

附件1即时措施批记录.pdf

厂房设施名称 Facility Name: 产品所属阶段 Product Phase:

M1b Commercial

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

产品影响评估 Product Impact Assessment:
偏差发生时，产品已回收结束，缓冲液冲洗超滤系统已完成，中间产品浓度定容按照批记录要求执行，浓度定容结束后按批记录要求取样送检QC，最终蛋白浓度结果为32.1g/L（合格范围28.0~45.0g/L），故该偏差对产品无影响。

生产/检测的影响评估 Production/Testing Impact Assessment:
偏差发生后采取了即时措施，对当前生产无影响，即时措施为手动开启和关闭buffer到用点的相关管路的阀门，没有改变程序方法，对设备无影响，对后续生产无影响。

其他影响评估描述 Other Impact Assessment Description:
本偏差发生在超滤Process即将结束阶段，此时操作人员提前点击提示信息“Repeat buffer flush again？” “NO”指令，在产品定容过程只手动开启和关闭buffer到用点的相关管路阀门，其他操作按照批记录执行，未涉及程序方法逻辑的改变，定容结束后，将管路阀门恢复至原先状态，后续程序程序运行正常，对设备和程序方法无影响。
此偏差原因明确，是操作人员拖移提示信息框时触碰到了“NO"指令，是一起人员操作失误的偶发性事件，且《贝伐珠单抗注射液M1b

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3000L原液纯化批生产记录》（BPR100332/11）超滤/洗滤工序的6.3.5超滤浓缩换液第34步对此处已有明确提醒，即‘此时请勿点击NO’的描述（见附件2批记录提醒），能有效指导后续生产。

初步影响评估附件 Initial Impact Assessment Attachment:
附件2批记录提醒.JPG

偏差分级 Deviation Classification

偏差严重性 Deviation Severity:
1.偏差发生时，产品已回收结束，缓冲液冲洗超滤系统已完成，中间产品浓度定容按照批记录要求执行，浓度定容结束后按批记录要求取样送检QC，最终蛋白浓度结果为32.1g/L（合格范围28.0~45.0g/L），故该偏差对产品无影响。2.偏差发生后采取了即时措施，对当前生产无影响，即时措施为手动开启和关闭buffer到用点的相关管路的阀门，没有改变程序方法，对设备无影响，对后续生产无影响。3.本偏差发生在超滤Process即将结束阶段，此时操作人员提前点击提示信息“Repeat buffer flush again？” “NO”指令，在产品定容过程只手动开启和关闭buffer到用点的相关管路阀门，其他操作按照批记录执行，未涉及程序方法逻辑的改变，定容结束后，将管路阀门恢复至原先状态，后续程序程序运行正常，对设备和程序方法无影响。

偏差发生率 Reoccurrence Probability of Deviation:
过去12个月未发生类似缺陷（搜索关键词：超滤浓缩工序，点击，提前）

偏差分级 Deviation Classification: Minor

分级的理由 Reason for Classification:
04/07/2021 10:20 AM (GMT+8:00) added by 怡菁 王 (PID-000230):
该偏差的发生未对产品质量造成影响，且过去12个月未发生类似缺陷，故定为次要偏差。

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:
该偏差原因明确，且未对产品质量造成影响，故不需要调查。

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:

此偏差原因明确，是操作人员拖移提示信息框时触碰到了“NO"指令，是一起人员操作失误的偶发性事件，且《贝伐珠单抗注射液M1b 3000L原液纯化批生产记录》（BPR100332/11）超滤/洗滤工序的6.3.5超滤浓缩换液第34步对此处已有明确提醒，即‘此时请勿点击NO’的描述，能有效指导后续生产。

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

原因描述 Cause Description:
操作人员拖移提示信息框时触碰到了“NO"指令

原因分类 Cause Category	原因子分类 Cause Sub-Category	原因归属部门 Cause Department
Others	Others	Others

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缺陷描述 Defect Description:
生产部人员在进行贝伐珠单抗注射液M1b 3000L DS2102008批次超滤浓缩工序生产操作产品回收阶段，超滤系统控制界面出现提示信息“Repeat buffer flush again ?”生产操作人员误点击“NO”，与《贝伐珠单抗注射液M1b 3000L原液纯化批生产记录》（BPR100332/11）超滤/洗滤工序，6.3.5超滤浓缩换液第34步操作指令中描述：在超滤系统弹出“Repeat buffer flush again ?”时（此时请勿点击“NO”）不符。

缺陷类型分类 Defect Category	缺陷类型子分类 Defect Sub-Category
Production/Process	Operation

缺陷描述 Defect Description:
生产部人员在进行贝伐珠单抗注射液M1b 3000L DS2102008批次超滤浓缩工序生产操作产品回收阶段，超滤系统控制界面出现提示信息“Repeat buffer flush again ?”生产操作人员误点击“NO”，与《贝伐珠单抗注射液M1b 3000L原液纯化批生产记录》（BPR100332/11）超滤/洗滤工序，6.3.5超滤浓缩换液第34步操作指令中描述：在超滤系统弹出“Repeat buffer flush again ?”时（此时请勿点击“NO”）不符。

缺陷类型分类 Defect Category	缺陷类型子分类 Defect Sub-Category
Others	Human execution error

是否是重复偏差 Repeat Deviation? : No

判定重复偏差的原因 Justification for Repeat Deviation:
过去12个月未发生类似缺陷，故不是重复偏差。

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:

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受影响的部门 Impact Departments:

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

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: 贝伐珠单抗注射液M1b 3001L原液(商业化)

产品代码 Product Code	产品批号 Batch No.:	数量 Quantity	处理决定 Disposition
DS30-305	DS2102008	3000L	

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: 超滤系统 设备代码 Equipment Code MFG-M1b3-068

偏差处理措施 Deviation Action Items

PR#: 13015

责任人 Assigned To:	张, 明帅(PID-000248)	部门 Department:	M1b DS2
截止日期 Date Due:	2021.04.07	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:
在IBI305 process/IBI305 503 op/recorvey by buffer.opn中添加浓度合格的提示信息。

纠正信息 Correction Information

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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
13015	Deviation Action Items	IBI305超滤process中添加提示信息。Add message in IBI305 UFDF process.	Closed-Cancelled

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Initial Approval

QA Initial Review

Area QA Initial Reviewed By:	邓, 陈琪	Area QA Initial Reviewed On:	2021.04.06 12:28
Classify Completed By:	王, 怡菁	Classify Completed On:	2021.04.07 10:33

Department Initial Review

Department Leader 1 Reviewed By:	康, 云	Department Leader 1 Reviewed On:	2021.04.07 11:48
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:	吴, 烜	Area QA Leader Reviewed On:	2021.04.07 14:33

Quality Initial Approval

Quality Approver 1 Approved By:	管, 国兴	Quality Approver 1 Approved On:	2021.04.07 18:13
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:

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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: