

PR#: 13904

Deviation No.:D-2021-0210

Record Status: Closed-Done

基本信息 General Information

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

发起人 Originator: 章磊(PID-000273)

发起日期 Date Opened: 2021.05.02

简短描述 Short Description:

M1bDS1DS2103013AEX收集后平衡流量与BPR要求不符DS2103013 The flow of equilibration after AEX collection is not in conformity with BPR

到期日期 Date Due: 2021.05.06

关闭日期 Date Closed: 2021.05.07

偏差信息 Deviation Information

发现人 Discovery By: 章磊20000162

发现日期 Discovery On: 2021.04.30

汇报人 Report By: 章磊20000162

汇报日期 Report On: 2021.04.30

发生部门 Occurred Department: M1b DS1

汇报部门 Report Department: M1b DS1

偏差描述 Deviation Description:

2021.04.30, 纯化人员 (20000942) 在除病毒前纯化间 (26C15) 进行DS2103013AEX, 在运行AEX process DS2103013至22.93CV时, HMI提示 "when collect is end, click next breakpoint", 确认阴离子收集结束后, 在process运行了23.01CV时插入命令 "next breakpoint", 此时阴离子平衡液运行了0.76CV, 纯化人员 (20000162) 发现与批记录 (BPR100468) 要求 (4.3.13(12)上样后层析参数) 的阴离子平衡液至少3CV不符, 故发起偏差。由于偏差发生后是假期, 故在假期后的第一个工作日发起。

描述的附件 Description attachment:

是否及时上报? Reporting in Time?: Yes

未及时上报的理由 Reason for not in Time:

已采取的即时措施 Immediately Action Taken:

05/02/2021 02:10 AM (GMT+8:00) added by 磊章 (PID-000273):

手动处理, 在运行至23.47CV是暂停程序, 此时阴离子再生液已运行0.46CV, 上报MST、QA、生产后, 手动插入 "Inlet A4, flow1413.7L/hour" Hold程序手动插入 "Inlet B close" 在运行至25.56CV时, 手动插入 "InletB1 flow 1570.8L/hour, InletA close" 此时阴离子平衡液运行了3.07CV满足要求, 在运行至27.08CV时, continue程序, 后续程序正常运行。生产部 2021.04.30

即时措施附件 Immediately Action Attachment:

附件1 即时措施.docx

厂房设施名称 Facility Name:

M1b

产品所属阶段 Product Phase:

Clinical

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

产品影响评估 Product Impact Assessment:

本次偏差发生在收集结束的后处理阶段, 产品已经收集结束, 故对产品没有影响。

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

在发现偏差后, 及时处理, 并手动操作, 在偏差发生后平衡液运行了3.09CV, 再生液运行了3.06CV均符合工艺规程, 故对后续生产没有影响。

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

批记录及工艺规程要求上样后平衡至少3CV, 再生至少3CV以保证再生效果, 在process程序中无需执行 "next breakpoint" 指令, 实际执行了 "next breakpoint" 指令, 发现偏差后手动操作, 使平衡液运行了3.09CV, 再生液运行了3.06CV, 对再生效果没有不利影响, 仅有流程不符, 未产生其他影响。

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初步调查：本次偏差发生的直接原因是因为人员在收集结束后的平衡液3CV冲洗完成前执行了“next breakpoint”命令。经过对现场人员的询问及对程序run log（附件2）的检查得知，在阴离子层析收集结束后，弹出了message“when collect is end, click next breakpoint”此时平衡液运行了0.72CV，现场人员（20000942）根据程序的提示信息确认阴离子已收集完成，未注意到批记录中对于上样后平衡体积的要求，故执行了“next breakpoint”命令，使平衡液运行了0.76CV就进入到再生阶段，造成了本次偏差。

1、本次偏差发生原因明确，操作人员具备操作资质（附件3）。未注意到批记录中对于上样后平衡体积的要求，错误执行了“next breakpoint”命令。回顾历史偏差，未发生类似缺陷，判断为偶发的人为忽略问题。

2、批记录指令清晰、文件（SOP200544）规定明确，流程无问题。已制定行动项结合偏差案例给相关人员进行培训（附件4）。故无需制定CAPA，不需进一步调查。

初步影响评估附件 Initial Impact Assessment Attachment:

附件2 AEX process run log.pdf

附件4 相关人员偏差培训记录.pdf

附件3 人员（20000942）上岗证.pdf

偏差分级 Deviation Classification

偏差严重性 Deviation Severity:

- 1、本次偏差发生在收集结束的后处理阶段，产品已经收集结束，故对产品没有影响。
- 2、在发现偏差后，及时处理，并手动操作，在偏差发生后平衡液运行了3.09CV，再生液运行了3.06CV均符合工艺规程，故对后续生产没有影响。

偏差发生率 Reoccurrence Probability of Deviation:

过去12个月未发生类似缺陷（关键词：M1bDS、AEX、平衡流量）。

偏差分级 Deviation Classification: Minor

分级的理由 Reason for Classification:

05/06/2021 07:04 PM (GMT+8:00) added by 四弟 李 (PID-000227):

该偏差对产品无影响，过去12个月未发生类似缺陷，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:

- 1、本次偏差发生原因明确，操作人员具备操作资质（附件3）。未注意到批记录中对于上样后平衡体积的要求，错误执行了“next breakpoint”命令。回顾历史偏差，未发生类似缺陷，判断为偶发的人为忽略问题。
- 2、批记录指令清晰、文件（SOP200544）规定明确，流程无问题。已制定行动项结合偏差案例给相关人员进行培训（附件4）。故无需制定CAPA，不需进一步调查。

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:

偏差发生原因：人员未注意到批记录中对于上样后平衡体积的要求，错误执行了“next breakpoint”命令，判断为偶发的人为忽略问题。

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

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原因描述 Cause Description: 人员未注意到批记录中对于上样后平衡体积的要求，错误执行了“next breakpoint”命令，判断为偶发的人为忽略问题。		
原因分类 Cause Category Others	原因子分类 Cause Sub-Category Others	原因归属部门 Cause Department Others

缺陷描述 Defect Description: 纯化人员（20000942）在除病毒前纯化间（26C15）进行DS2103013AEX，在运行AEX process DS2103013至22.93CV时，HMI提示“when collect is end，click next breakpoint”，确认阴离子收集结束后，在process运行了23.01CV时插入命令“next breakpoint”，此时阴离子平衡液运行了0.76CV，纯化人员（20000162）发现与批记录（BPR100468）要求（4.3.13(12)上样后层析参数）的阴离子平衡液流量不符。	
缺陷类型分类 Defect Category Production/Process	缺陷类型子分类 Defect Sub-Category Operation

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（关键词：M1bDS、AEX、平衡流量）。故非重复偏差。

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
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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:

产品代码 Product Code	产品批号 Batch No.:	数量 Quantity	处理决定 Disposition
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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
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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:
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受影响的设备信息 Impacted Equipment Information

设备名称 Equipment Name:	设备代码 Equipment Code
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偏差处理措施 Deviation Action Items

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:

纠正信息 Correction Information

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PR#:

责任人 Assigned To:

截止日期 Date Due:

确认人 Verified By:

行动项详细描述 Action Description:

部门 Department:

完成日期 Completed Date:

确认日期 Verified On:

纠正与预防措施 CAPA

PR#:

责任人 Assigned To:

截止日期 Date Due:

行动项详细描述 Action Description:

部门 Department:

附件 File Attachments

关联记录 Reference Records

PR#	Record Type	简短描述 Short Description	Record Status
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相关子记录 Related children

PR#	Record Type	简短描述 Short Description	Record Status
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Initial Approval

QA Initial Review

Area QA Initial Reviewed By:	吴, 烜	Area QA Initial Reviewed On:	2021.05.06 09:32
Classify Completed By:	李, 四弟	Classify Completed On:	2021.05.06 19:11

Department Initial Review

Department Leader 1 Reviewed By:	邓, 献存	Department Leader 1 Reviewed On:	2021.05.07 15:43
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:	2021.05.07 10:02

Quality Initial Approval

Quality Approver 1 Approved By:	管, 国兴	Quality Approver 1 Approved On:	2021.05.07 15:45
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:
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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: