偏差报告
Deviation Report

PR#: 13012 Deviation No.:D-2021-0156

Record Status: Closed-Done

基本信息 General Information

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

发起人 Originator: 王, 金祥(PID-000083) 发起日期 Date Opened: 2021.04.06

简短描述 Short Description:
M1b DS1 DCS程序执行错误 M1b DS1 DCS Recipe program execution error

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: 王金祥05040068 发现日期 Discovery On: 2021.04.03

汇报人Report By: 王金祥05040068 汇报日期 Report On: 2021.04.03

发生部门 Occurred Department: M1b DS1 汇报部门 Report Department: M1b DS1

偏差描述 Deviation Description:
2021.04.03 23:47 生产人员（05040068）在执行完IBI308 DS2101013DCS程序（Recipe: PU_CIP_AKTA_L1_OP Formula:CIP_CH0303_POST2）后发现，该程序涉及的管道T0332-03和T0333-03的状态未由Process Out切换为Dirty（附件1）。故在查看批记录和DCS程序后发现操作人员（05030053）误将程序PU_CIP_AKTA_L1_PR执行为PU_CIP_AKTA_L1_OP与《信迪利单抗注射液M1b 3000L原液纯化批生产记录》（BPR100322-14，批号DS101013）“5.3.15层析系统CIP”中“（4）DCS系统运行”要求不一致（附件2），导致管道T0332-03和T0333-03的状态无法由Process Out切换为Dirty，无法执行后续CIP，故发起偏差。

描述的附件 Description attachment:
附件1状态未由Process Out切换为Dirty.docx
附件2执行与批记录不一致.docx

是否及时上报？ Reporting in Time? : Yes

未及时上报的理由 Reason for not in Time:
2021.04.03报告偏差后，2021.04.04-2021.04.05为节假日，故在第一个工作日2021.04.06发起。

已采取的即时措施 Immediately Action Taken:
04/06/2021 11:24 AM (GMT+8:00) added by 金祥 王 (PID-000083):
1、汇报上级。经生产、QA、MST管理人员讨论后，决定手动将管道T0332-03和T0333-03的状态由Process Out修改为Dirty。
MFG/2021.04.04

即时措施附件 Immediately Action Attachment:

附件3 即时措施.docx

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:
该程序发生在阴离子层析（AEX）工艺步骤结束后，仅针对AKTA设备做处理（CIP、Flush、storage），因此不涉及产品的工艺生产，故对产品无影响。

生产/检测的影响评估 Production/Testing Impact Assessment:
程序PU_CIP_AKTA_L1_OP相较于程序PU_CIP_AKTA_L1_PR仅少了两个修改状态的UP（详见附件4），除此之外程序执行的功能效果一致；汇报上级。经生产、QA、MST管理人员讨论后，采取纠正措施 ：T0332-03和T0333-03状态由Process Out手动修改为Dirty（附件3）；手动修改后对当前生产无影响，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:
本次偏差发生在AEX工艺生产结束后，启用了PU_CIP_AKTA_L1_OP，除了管道状态有影响外，未涉及程序逻辑的改变；手动修改状态后，后续程序运行正常。
由于纯化人员未按照批生产记录的要求，核对正确再启用程序，导致了偏差。《信迪利单抗注射液 M1b 3000L原液纯化批生产记

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录》(BPR100322/14)阴离子交换层析工序5.3.15层析系统CIP第4步已经明确说明；“DCS系统运行Recipe：PU_CIP_AKTA_L1_PR”，现有流程无问题，能够有效指导后续生产。因此，由于人员疏忽导致操作错误是本次偏差发生的原因。截至目前已经商业化生产了19批，未发生类似事件，因此为一起人员操作失误的偶发性事件，暂不考虑制定相关CAPA。

初步影响评估附件 Initial Impact Assessment Attachment:
附件4 PR程序状态搭建.docx

偏差分级 Deviation Classification

偏差严重性 Deviation Severity:
1、该程序发生在阴离子层析（AEX）工艺步骤结束后，仅针对AKTA设备做处理（CIP、Flush、storage），因此不涉及产品的工艺生产，故对产品无影响。
2、程序PU_CIP_AKTA_L1_OP相较于程序PU_CIP_AKTA_L1_PR仅少了两个修改状态的UP（详见附件4），除此之外程序执行的功能效果一致；汇报上级。经生产、QA、MST管理人员讨论后，采取纠正措施：T0332-03和T0333-03状态由Process Out手动修改为Dirty（附件3）；手动修改后对当前生产无影响，对设备无影响，对后续生产无影响。

偏差发生率 Reoccurrence Probability of Deviation:
过去12个月类似缺陷回顾（关键词搜索：M1b DS1、程序执行、错误），未发生类似缺陷。

偏差分级 Deviation Classification: Minor

分级的理由 Reason for Classification:
04/07/2021 05:41 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:
该偏差发生原因明确，由于人员疏忽导致操作错误。截至目前已经商业化生产了19批，未发生类似事件，因此判断为一起人员操作失误的偶发性事件，对产品无影响，暂不考虑制定相关CAPA，故不需要进一步调查。

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：由于人员疏忽导致操作错误。

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

原因描述 Cause Description:
由于人员疏忽导致操作错误。

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:
生产人员在执行完IBI308 DS2101013DCS程序后发现，该程序涉及的管道T0332-03和T0333-03的状态未由Process Out切换为Dirty。故在查看批记录和DCS程序后发现操作人员误将程序PU_CIP_AKTA_L1_PR执行为PU_CIP_AKTA_L1_OP与《信迪利单抗注射液M1b 3000L原液纯化批生产记录》要求不一致.

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

缺陷描述 Defect Description:
生产人员在执行完IBI308 DS2101013DCS程序后发现，该程序涉及的管道T0332-03和T0333-03的状态未由Process Out切换为Dirty。故在查看批记录和DCS程序后发现操作人员误将程序PU_CIP_AKTA_L1_PR执行为PU_CIP_AKTA_L1_OP与《信迪利单抗注射液M1b 3000L原液纯化批生产记录》要求不一致.

缺陷类型分类 Defect Category	缺陷类型子分类 Defect Sub-Category
Production/Process	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个月类似缺陷回顾（关键词搜索：M1b DS1、程序执行、错误），未发生类似缺陷。判断为非重复偏差。

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

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: 信迪利单抗注射液M1b 3000L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
DS30-308	DS2101013	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: 设备代码 Equipment Code

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: 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
7513	Permanent Change Control	MST M1b信迪利单抗注射液原液生产新增Tris-HCl和氢氧化钠 add new Tris-HCl and NaOH to Sintilimab Injection drug substance manufacture in M1b	Pending Post-Actions Comp
11510	Permanent Change Control	MFG 信迪利单抗注射液原液新增纸板囊式过滤器用于澄清和吸附深层过滤 MFG Introduce new filter to Sintilimab DS clarification and ADF	Pending Post-Actions Comp

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:	2021.04.06 14:35
Classify Completed By:	李, 四弟	Classify Completed On:	2021.04.07 18:52

Department Initial Review

Department Leader 1 Reviewed By:	邓, 献存	Department Leader 1 Reviewed On:	2021.04.07 22:57
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:	邓, 陈琪	Area QA Leader Reviewed On:	2021.04.07 18:55

Quality Initial Approval

Quality Approver 1 Approved By:	管, 国兴	Quality Approver 1 Approved On:	2021.04.07 23:30
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: