偏差报告
Deviation Report

PR#: 14482 Deviation No.:D-2021-0243

Record Status: Deviation Investigation in Progress

基本信息 General Information

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

发起人 Originator: 史, 孝飞(PID-000129) 发起日期 Date Opened: 2021.05.18

简短描述 Short Description:
M1b DS1 IBI308 2nd EOPC活细胞密度超出范围 Viable cell density of EOPC for IBI308 (2nd) out of operating range in M1b DS line 1

到期日期 Date Due: 2021.06.22 关闭日期 Date Closed:

偏差信息 Deviation Information

发现人 Discovery By: 刘志达20000271 发现日期 Discovery On: 2021.05.17

汇报人Report By: 刘志达20000271 汇报日期 Report On: 2021.05.17

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

偏差描述 Deviation Description:
2021.05.17约11:40员工（05020040、20000271）在M1b细胞培养间（26D08）按照“M1b原液细胞培养终末细胞制备记录”（BPR100333-03）中“Part A4终末细胞冻存（洁净工作台中操作）”进行DS01-308B-2产品DS2103015批次EOPC冻存操作，员工（05020026）执行6.13项时对冻存液重悬细胞进行计数时发现重悬后活细胞密度为13.5x10^6个/ml与批记录中活细胞密度为（0.7-1.3）x10^7个/ml要求不符发起偏差。

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:
N/A

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: 产品所属阶段 Product Phase:

M1b Clinical

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

产品影响评估 Product Impact Assessment:
终末细胞制备时，从3000L反应器中无菌取样细胞液，将取样的细胞进行冻存操作，无菌取样过程无异常，样品冻存密度超过范围，对3000L反应器中产品无影响。

生产/检测的影响评估 Production/Testing Impact Assessment:
终末细胞冻存密度超范围，对3000L反应器生产无影响。后续需要结合终末细胞的检测结果综合评估密度超过范围对检测的影响。

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

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

偏差分级 Deviation Classification

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偏差严重性 Deviation Severity:
对产品SISPQ的影响:
终末细胞制备时，从3000L反应器中无菌取样细胞液，将取样的细胞进行冻存操作，无菌取样过程无异常，样品冻存密度超过范围，对3000L反应器中产品无影响。

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 DS1 、IBI308 2nd 、EOPC、活细胞密度、超出范围）
未发现同类型缺陷。

偏差分级 Deviation Classification: Minor

分级的理由 Reason for Classification:
05/18/2021 04:19 PM (GMT+8:00) added by 育芳 刘 (PID-000093):
该偏差还需进一步调查分析根本原因，根据根本原因考虑建立CAPA措施。

是否需要调查？ Investigation Required? : Yes

主调查人 Lead investigator: 董, 郭雨

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

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:

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

原因描述 Cause Description:

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

缺陷描述 Defect Description:
2021.05.17约11:40员工（05020040、20000271）在M1b细胞培养间（26D08）按照“M1b原液细胞培养终末细胞制备记录”（BPR100333-03）中“Part A4终末细胞冻存（洁净工作台中操作）”进行DS01-308B-2产品DS2103015批次EOPC冻存操作，员工（05020026）执行6.13项时对冻存液重悬细胞进行计数时发现重悬后活细胞密度为13.5x10^6个/ml与批记录中活细胞密度为（0.7-1.3）x10^7个/ml要求不符发起偏差。

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? :

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

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

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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:

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（二代细胞株）

产品代码 Product Code	产品批号 Batch No.:	数量 Quantity	处理决定 Disposition
DS01-308B-2	DS2103015	400kg	

受影响的物料信息 Impacted Material Information

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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

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

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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

Innovent 信达生物制药

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Initial Approval

QA Initial Review

Area QA Initial Reviewed By:	王, 杨晨	Area QA Initial Reviewed On:	2021.05.18 13:45
Classify Completed By:	刘, 育芳	Classify Completed On:	2021.05.19 19:42

Department Initial Review

Department Leader 1 Reviewed By:	康, 云	Department Leader 1 Reviewed On:	2021.05.19 19:55
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:	2021.05.20 09:29

Quality Initial Approval

Quality Approver 1 Approved By:	管, 国兴	Quality Approver 1 Approved On:	2021.05.20 10:53
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: