偏差报告
Deviation Report

PR#: 2973 Deviation No.:D-2020-0131

Record Status: Closed-Done

基本信息 General Information

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

发起人 Originator: 张, 晓菲(PID-000133) 发起日期 Date Opened: 2020.05.21

简短描述 Short Description:
生产部 尘埃粒子计数仪不符合连续三次自净结果为0 Particle counter failure to meet three consecutive self-purification results is 0

到期日期 Date Due: 2020.05.22 关闭日期 Date Closed: 2020.05.22

偏差信息 Deviation Information

发现人 Discovery By: 史孝飞 发现日期 Discovery On: 2020.05.20

汇报人Report By: 张晓菲 汇报日期 Report On: 2020.05.21

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

偏差描述 Deviation Description:
2020.05.13 14:20员工（20000131、20000165）在M1b种子构建间（37B07）准备 贝伐珠单抗二代细胞株（CHOK1SV GS-KO）（IBI305）主细胞库建库（批号:ICM202003）摇瓶扩增操作前，员工（20000131）操作设备尘埃粒子计数仪（MFG-M1b1-088）自净三次（详见附件1）：第一次0.5μm自净结果为10、5.0μm
结果为0;第二次0.5μm自净结果为0、5.0μm结果为0;第三次0.5μm自净结果为0、5.0μm结果为0，随后进行采样操作。与“ M1b车间尘埃粒子计数仪使用、清洁及维护保养标准操作规程”（SOP200531）中“ 自净结果为0时打印自净报告（未开启自动打印时），待连续三次检测0.5μm和5.0μm粒子均为0时自净合格”不符，故发
起偏差。

描述的附件 Description attachment:
附件1：尘埃粒子计数仪粒子条.jpg

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: 产品所属阶段 Product Phase:

M1b Others

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

产品影响评估 Product Impact Assessment:
偏差调查：

采样人员在查看第一次的粒子监测结果时，误将尘埃粒子计数仪自净结果 “10”看成“0”导致偏差发生，经调查操作人员（20000131）于2019.06.10通过“M1b车间细胞复苏及摇瓶扩增”岗位技能考核，获得岗位上岗证，经历IBI308、IBI305、IBI360、IBI321等产品的摇瓶扩增操作，未出现过类似人员差错。已在2020.05.22对人员（20000131）完成了 “M1b车间尘埃粒子计数仪使用、清洁及维护保养标准操作规程”（SOP200531）培训（见附件2），以减少该情况的发生。
影响评估：
2020.05.13在摇瓶扩增操作前, 操作人（20000131）按照“M1b车间尘埃粒子计数仪使用、清洁及维护保养标准操作规程”（SOP200531）对尘埃粒子计数仪（MFG-M1b1-088）连续自净检测三次，检测结果显示：第一次0.5μm自净结果为10、5.0μm结果为0;第二次0.5μm自净结果为0、5.0μm结果为0;第三次0.5μm自净结

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果为0、5.0μm结果为0。操作人员查看尘埃粒子计数仪自净检测结果时，误将第一次0.5μm自净结果“10”看成“0”，故判断自净结果合格。随后使用该设备对BSC内环境监测，监测结果： BSC-NV1位点 0.5μm为0、5.0μm为0， BSC-NV2位点0.5μm为0、5.0μm为0。即尘埃粒子计数仪（MFG-M1b1-088）连续自净三次显示有粒子的情况下对BSC内环境进行监测， 监测结果显示无粒子。
尘埃粒子计数仪连续自净三次结果显示为0，说明包括采样软管在内的监测设备内部无粒子存在，排除设备本身内部自带粒子影响后续环境监测结果，然后使用自净合格的尘埃粒子计数仪对BSC内环境监测，监测结果才能真实反映BSC中的生产操作环境，本次偏差中连续自净时，有粒子存在，不能排除BSC监测前尘埃粒子计数仪内部无粒子存在。但是在第一次自净监测时存在0.5μm粒子10，后续连续两次自净中没有监测到粒子，说明尘埃粒子计数仪内部有粒子的可能性很低，最终监测的BSC中环境监测结果也无粒子，则说明尘埃粒子计数仪内部和BSC内环境中无粒子， BSC内环境中无粒子符合生产操作要求，故本偏差对建库产品无影响。

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

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

初步影响评估附件 Initial Impact Assessment Attachment:
D-2020-0131原因调查 附件2.pdf

偏差分级 Deviation Classification

偏差严重性 Deviation Severity:
尘埃粒子计数仪连续自净三次结果显示为0，说明包括采样软管在内的监测设备内部无粒子存在，排除设备本身内部自带粒子影响后续环境监测结果，然后使用自净合格的尘埃粒子计数仪对BSC内环境监测，监测结果才能真实反映BSC中的生产操作环境，本次偏差中连续自净时，有粒子存在，不能排除BSC监测前尘埃粒子计数仪内部无粒子存在。但是在第一次自净监测时存在0.5μm粒子10，后续连续两次自净中没有监测到粒子，说明尘埃粒子计数仪内部有粒子的可能性很低，最终监测的BSC中环境监测结果也无粒子，则说明尘埃粒子计数仪内部和BSC内环境中无粒子，
BSC内环境中无粒子符合生产操作要求，故本偏差对建库产品无影响。

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：细胞建库、尘埃粒子计数仪、自净不合格）
未发生同类型缺陷。

偏差分级 Deviation Classification: Minor

分级的理由 Reason for Classification:
05/22/2020 05:10 PM (GMT+8:00) added by 育芳 刘 (PID-000093):
该偏差原因明确，无需进行进一步调查。
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:
该偏差已经原因明确，且对导致偏差人员的培训已经完成。

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:

采样人员在查看第一次的粒子监测结果时，误将尘埃粒子计数仪自净结果 “10”看成“0”导致偏差发生

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

原因描述 Cause Description:
人员查看时看错

原因分类 Cause Category	原因子分类 Cause Sub-Category	原因归属部门 Cause Department
Human	Personal	M1b DS1

缺陷描述 Defect Description:
细胞建库尘埃粒子计数仪自净不合格

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个月未发生同类型偏差。

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: Other

产品代码 Product Code	产品批号 Batch No.:	数量 Quantity	处理决定 Disposition
Other	ICM202003	400支	

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

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:	王, 沛芳	Area QA Initial Reviewed On:	2020.05.21 15:01
Classify Completed By:	刘, 育芳	Classify Completed On:	2020.05.22 17:17

Department Initial Review

Department Leader 1 Reviewed By:	邓, 献存	Department Leader 1 Reviewed On:	2020.05.22 17:51
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:	2020.05.22 17:27

Quality Initial Approval

Quality Approver 1 Approved By:	周, 峥	Quality Approver 1 Approved On:	2020.05.22 18:03
Quality Approver 2 Approved By:	管, 国兴	Quality Approver 2 Approved On:	2020.05.22 17:54
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: