偏差报告
Deviation Report

PR#: 15236 Deviation No.:D-2021-0267

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: 万, 雅雯(PID-000300) 发起日期 Date Opened: 2021.06.04

简短描述 Short Description:
M1b DS1 IBI308摇瓶内壁有异物 Foreign matter in the inner wall of shake flask for IBI308 in M1b DS1

到期日期 Date Due: 2021.07.09 关闭日期 Date Closed:

偏差信息 Deviation Information

发现人 Discovery By: 崔宵 20000803 发现日期 Discovery On: 2021.06.02

汇报人Report By: 史孝飞 05020003 汇报日期 Report On: 2021.06.02

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

偏差描述 Deviation Description:
2021.06.02 15:30 M1b 生产员工（20000803、20002681）在种子扩增间（26C04）进行信迪利单抗注射液M1b 3000L原液（DS2105004批次）2000ml 摇瓶扩增阶段，向第一个2000ml摇瓶移入90ml细胞液后，发现摇瓶内壁上有异物，故发起偏差调查。

描述的附件 Description attachment:
附件1：DS2105004-信迪利单抗注射液M1b 3000L原液细胞培养摇瓶扩增批生产记录.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:
06/04/2021 04:16 PM (GMT+8:00) added by 雅雯 万 (PID-000300):
将存在异物的2000 ml摇瓶隔离，并从种子扩增间（26C04）通过传递窗（MGF-M1b2-002）传出至细胞培养间（26D08）废液处理，重新按剩余细胞液计算种子悬液体积和培养基体积。/生产部/2021.06.02

即时措施附件 Immediately Action Attachment:

附件2：MFG-M1b2-002传递窗使用记录-废弃细胞液处理记录.jpg

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:
偏差初步调查：
1、操作人员（工号：20000803）在生产前已经检查2000 ml摇瓶，未发现破损和异物；
2、辅操人员（工号：20002681）将1000ml摇瓶从摇床中取出后，查看细胞悬液，未发现存在异物；操作人员（工号：20000803）对1000ml摇瓶进行复核确认及吸取细胞悬液时，均未发现细胞液中存在异物；
3、生产操作前对生物安全柜（MFG-M1b2-110）状态进行检查确认，设备验证有效期：2021.06，计量有效期：2022.01.18，没有发现异常。

对产品的初步影响评估：
发现异物后，立即将2000 ml摇瓶拿出生物安全柜（MFG-M1b2-110）隔离，重新更换新的2000 ml摇瓶，在检查确认无异物后，从1000 ml摇瓶中吸取剩余细胞悬液，继续进行传代操作。并将有异物的2000 ml摇瓶从种子扩增间（26C04）通过传递窗（MGF-M1b2-002）传出至细胞培养间（26D08）废液处理。因此DS2105004批次2000 ml摇瓶扩增不会收到影响，不影响产品质量。

生产/检测的影响评估 Production/Testing Impact Assessment:
发现异物后，立即将2000 ml摇瓶拿出生物安全柜（MFG-M1b2-110）隔离；重新更换新的2000 ml摇瓶，按剩余细胞液计算种子悬液

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体积和培养基体积，实际接种密度为1#：0.38 x10^6个/ml、2#：0.38x10^6个/ml、3# 0.35x10^6个/ml，符合接种密度在(0.3~0.5)x10^6个/ml的要求，继续进行传代操作，对生产无影响。

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

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

偏差分级 Deviation Classification

偏差严重性 Deviation Severity:
对产品SISPQ的影响：
发现异物后，立即将2000 ml摇瓶拿出生物安全柜（MFG-M1b2-110）隔离，重新更换新的2000 ml摇瓶，在检查确认无异物后，从1000 ml摇瓶中吸取剩余细胞悬液，继续进行传代操作。并将有异物的2000 ml摇瓶从种子扩增间（26C04）通过传递窗（MGF-M1b2-002）传出至细胞培养间（26D08）废液处理。因此DS2105004批次2000 ml摇瓶扩增不会收到影响，不影响产品质量。

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、摇瓶内壁有异物）
噶回顾周期内未发现同类型缺陷。

偏差分级 Deviation Classification: Minor

分级的理由 Reason for Classification:
06/07/2021 04:06 PM (GMT+8:00) added by 育芳 刘 (PID-000093):
该偏差还需进一步分析根本原因，根据根本原因考虑建立CAPA措施。
综上，该偏差定义为次要偏差。

是否需要调查？ Investigation Required? : Yes

主调查人 Lead investigator: 张, 允虎

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

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缺陷描述 Defect Description:
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缺陷类型分类 Defect Category	缺陷类型子分类 Defect Sub-Category
Production/Process	Process Validation

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:

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:

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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

产品代码 Product Code	产品批号 Batch No.:	数量 Quantity	处理决定 Disposition
DS30-308	DS2105004	2000 ml	

受影响的物料信息 Impacted Material Information

物料名称 Material Name: 2000ml一次性无菌锥形瓶

物料代码 Product Code	批号 Batch No.:	数量 Quantity
W02040049	2011112	1个

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: 生物安全柜 设备代码 Equipment Code MFG-M1b2-110

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:

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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

Innovent 信达生物制药

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Initial Approval

QA Initial Review

Area QA Initial Reviewed By:	赵, 琰	Area QA Initial Reviewed On:	2021.06.04 19:14
Classify Completed By:	刘, 育芳	Classify Completed On:	2021.06.07 16:26

Department Initial Review

Department Leader 1 Reviewed By:	康, 云	Department Leader 1 Reviewed On:	2021.06.07 19:50
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:	2021.06.07 16:53

Quality Initial Approval

Quality Approver 1 Approved By:	管, 国兴	Quality Approver 1 Approved On:	2021.06.07 20:30
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: