

PR#: 14343

Deviation No.:D-2021-0239

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: 刘, 晶晶(PID-000080)

发起日期 Date Opened: 2021.05.14

简短描述 Short Description:

M1b DS1 IBI308 2nd VF收集液蛋白检测数据丢失 Protein detection data of IBI308 2nd VF pool was lost

到期日期 Date Due: 2021.06.18

关闭日期 Date Closed:

偏差信息 Deviation Information

发现人 Discovery By: 刘晶晶20000454

发现日期 Discovery On: 2021.05.12

汇报人 Report By: 刘晶晶20000454

汇报日期 Report On: 2021.05.12

发生部门 Occurred Department: M1b DS1

汇报部门 Report Department: M1b DS1

偏差描述 Deviation Description:

2021.05.12 21:32 纯化人员 (20000454) 在进行VF蛋白检测读取a1、a2、b1、b2紫外数据过程中, 读取到b1数据时, 发现b1数据将a2数据覆盖。上报QA、MST、上级, 讨论后保存当前图谱文件, 后续联系AIS审核历史数据, 确认数据是否丢失。于2021.05.13 15:24 AIS及生产人员针对该时间段进行历史数据审核后, 发现纯化操作人员实际读取三次数据, 但是图谱中只保存了a1和b1两个数据, a2数据缺失(见附件1), 故发起偏差对改事件进行调查。

描述的附件 Description attachment:

附件1 异常蛋白检测图谱及记录.docx

是否及时上报? Reporting in Time?: Yes

未及时上报的理由 Reason for not in Time:

2021.05.12 21:32异常事件发生后, 上报现场QA、MST、上级, 讨论后于2021.05.13由AIS审核历史记录, 查看被覆盖数据是否仍然存在; 2021.05.13 15:24AIS人员查看历史记录后, 发现a2数据丢失, 生产人员于2021.05.13 17:27针对该数据丢失, 已线下上报现场QA。

已采取的即时措施 Immediately Action Taken:

05/14/2021 04:22 PM (GMT+8:00) added by 晶晶 刘 (PID-000080):

- 1、保存当前图谱文件 (见附件1) /MFG/2021.05.12
- 2、重启电脑及紫外分光光度计后, 重新进行系统适应性检测 (见附件2), 重新进行蛋白浓度检测 (见附件3)。MFG/2021.05.12

即时措施附件 Immediately Action Attachment:

附件2 重启设备后适应性检测图谱.pdf

附件3 设备重启后VF蛋白浓度检测图谱.pdf

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:

本偏差影响到VF收集液的蛋白检测, 不涉及工艺和生产操作的偏离, 同时设备重启后, 系统适应性和蛋白检测正常, 因此对产品质量无影响。

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

紫外分光光度计: 设备编号为MFG-M1b2-132, 设备的计量有效期至2022.04.26, 设备的PM有效期至2021.05.15 (缓冲期60天), 设备处于正常状态。根据即时措施判断, 偏差发生后, 重启设备后可正常使用, 且设备从2019.07投产至偏差发生期间, 未发生类似情况。评估得出设备再次发生故障的可能性较低, 且异常能够立即识别, 考虑到该区域只有一台紫外分光光度计, 如果使用其他房间的设备进行蛋白检测, 可能存在交叉污染的风险, 因此可继续使用该设备用于蛋白检测, 同时为防止检测过程再次发生数据被覆盖的情况, 要求生产人员进行蛋白检测过程, 读取的每一个数据都需截图保存。用于后续偏差调查评估使用。

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

生产人员在进行VF收集液蛋白检测依次读取a1、a2、b1、b2 UV280检测数据过程中，读取b1数据时，发现b1数据将a2数据覆盖，导致a2数据丢失。根据审计追踪，确认操作人员检测了a1、a2、b1，但是打开保存的结果文件，确认只有a1和b1的数据，因此该偏差对VF蛋白检测的数据完整性产生影响，需要对该偏差调查。

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：

本偏差影响到VF收集液的蛋白检测，不涉及工艺和生产操作的偏离，同时设备重启后，系统适应性和蛋白检测正常，因此对产品质量无影响。

但是该偏差存在产品批次生产数据的丢失，可能存在数据可靠性的问题，需要进一步调查分析。

偏差发生率 Reoccurrence Probability of Deviation:

过去12个月该区域同类型缺陷回顾（关键词搜索：M1b DS1、IBI308 2nd、VF收集液蛋白检测、数据丢失）未发现同类型缺陷。

偏差分级 Deviation Classification: Major

分级的理由 Reason for Classification:

05/17/2021 07:04 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，该偏差定义为主要偏差。

是否需要调查？ Investigation Required?: Yes

主调查人 Lead investigator: 邱 明

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: 2021.05.12 21:32 纯化人员在进行VF蛋白检测读取a1、a2、b1、b2紫外数据过程中，读取到b1数据时，发现b1数据将a2数据覆盖。上报QA、MST、上级，讨论后保存当前图谱文件，后续联系AIS审核历史数据，确认数据是否丢失。于2021.05.13 15:24 AIS及生产人员针对该时间段进行历史数据审核后，发现纯化操作人员实际读取三次数据，但是图谱中只保存了a1和b1两个数据，a2数据缺失，故发起偏差对改事件进行调查。 | |
| 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? :

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（二代细胞株）

产品代码 Product Code:DS01-308B-2产品批号 Batch No.:DS2103014数量 Quantity:3000L处理决定 Disposition:

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

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 |
|-----|-------------|------------------------|---------------|
|-----|-------------|------------------------|---------------|

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Initial Approval

QA Initial Review

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|------------------------------|-------|------------------------------|------------------|
| Area QA Initial Reviewed By: | 吴, 烜 | Area QA Initial Reviewed On: | 2021.05.14 18:05 |
| Classify Completed By: | 刘, 育芳 | Classify Completed On: | 2021.05.17 19:06 |

Department Initial Review

| | | | |
|----------------------------------|-------|----------------------------------|------------------|
| Department Leader 1 Reviewed By: | 康, 云 | Department Leader 1 Reviewed On: | 2021.05.17 20:51 |
| 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: | 2021.05.18 10:56 |

Quality Initial Approval

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|---------------------------------|-------|---------------------------------|------------------|
| Quality Approver 1 Approved By: | 管, 国兴 | Quality Approver 1 Approved On: | 2021.05.18 11:04 |
| 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

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|--|--|
| 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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Deviation Report

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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: