

PR#: 3564

Deviation No.:D-2020-0187

Record Status: Closed-Done

基本信息 General Information

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

发起人 Originator: 胡, 君寅(PID-000150)

发起日期 Date Opened: 2020.06.23

简短描述 Short Description:

M1b DS1冷藏冷冻箱验证中使用了错误的温度探头 Incorrect Datalogger was used in fridge qualificaition in M1b DS1

到期日期 Date Due: 2020.06.24

关闭日期 Date Closed: 2020.06.24

偏差信息 Deviation Information

发现人 Discovery By: 姜观龙20000225

发现日期 Discovery On: 2020.06.23

汇报人 Report By: 胡君寅05080017

汇报日期 Report On: 2020.06.23

发生部门 Occurred Department: M1b DS1

汇报部门 Report Department: QE

偏差描述 Deviation Description:

2020.06.23 09:00AM, 验证部员工 (ID:20000225)在整理校验报告时发现, M1b DS1 冷藏冷冻箱 (设备编号: MFG-M1b3-126) 在执行确认时 (验证方案号: RQP00125) 11#布点探头 (探头编号: 37028609) 的校准温度范围为0~50°C, 而验证确认的温度范围为-15~-25°C, 探头校准温度不能覆盖验证范围, 因此产生偏差。经扩展查看,另外两台设备 (设备编号: MFG-M1b2-127, MFG-M1b2-134) 所用探头存在同样情况。

描述的附件 Description attachment:

附件1: 校准记录及验证温度要求.rar

是否及时上报? Reporting in Time?: Yes

未及时上报的理由 Reason for not in Time:

已采取的即时措施 Immediately Action Taken:

06/23/2020 04:33 PM (GMT+8:00) added by 君寅 胡 (PID-000150):

重新选择合适温度探头, 打印验证方案RQP00125 11页 (附录3: 测试仪器仪表的校验), 15页 (附录6: 温度探头位置布点图), 16-17页 (附录7: 负载温度分布测试) 后重新执行温度分布确认。在执行附录3确认时, 需写明温度探头的校准温度范围。

即时措施附件 Immediately Action Attachment:

附件2: 即时措施扫描件.pdf

厂房设施名称 Facility Name:

产品所属阶段 Product Phase:

M1b

Commercial+Clinical

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

产品影响评估 Product Impact Assessment:

该设备验证有效期至2020.06.30, 目前处于再验证状态, 本偏差对设备状态无影响。

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

该设备验证有效期至2020.06.30, 目前在验证状态内, 再验证执行不影响生产及检测。

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

2020.06.23 09:00发现偏差后, 当天12:30汇报给区域QA, 经讨论确认分析, 该偏差的根本原因及影响评估如下:

根本原因分析: 设备确认时, 根据确认范围 (-15至-25°C) 选择了合适量程的探头, 验证所使用的探头量程均为-30-70°C, 且按照方案 (附录3仪器仪表的校验RQP00125) 对探头的校验有效期及校验证书编号进行了确认。但验证人员未对探头校准证书中的校准范围进行确认, 故误使用了校准范围为0~50摄氏度校准范围的探头。故附录3仪器仪表的校验 (RQP00125) 中未设计仪器仪表校准范围确认的内容是造成本偏差的根本原因。

影响评估: 本偏差仅影响到设备验证数据的有效性, 对设备性能无影响。

同步确认了即时措施。

PR#: 3564

Deviation No.:D-2020-0187

Record Status: Closed-Done

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:

该设备验证有效期至2020.06.30，目前处于再验证状态，本偏差对设备状态无影响。原因明确，不涉及产品质量影响。

偏差发生率 Reoccurrence Probability of Deviation:

过去12个月未发生类似偏差。（冷冻冷藏箱，验证，温度探头）

偏差分级 Deviation Classification: Minor

分级的理由 Reason for Classification:

06/24/2020 08:39 AM (GMT+8:00) added by 晓军 吴 (PID-000095):

根据偏差管理规程定义为次要偏差。

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:

该偏差原因明确，且已完成纠正措施，无后续影响，因此无需进一步调查。

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:

验证方案模板不充分

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

原因描述 Cause Description: 记录设计不充分		
原因分类 Cause Category Method/procedure	原因子分类 Cause Sub-Category Insufficiency	原因归属部门 Cause Department QE
缺陷描述 Defect Description: 冷藏冷冻箱验证探头使用错误		
缺陷类型分类 Defect Category Others	缺陷类型子分类 Defect Sub-Category Human execution error	
缺陷描述 Defect Description: 冷藏冷冻箱验证探头使用错误		
缺陷类型分类 Defect Category Facility/Utility/Equipment/Instrument	缺陷类型子分类 Defect Sub-Category Validation	

偏差报告 Deviation Report

PR#: 3564

Deviation No.:D-2020-0187

Record Status: Closed-Done

是否是重复偏差 Repeat Deviation?: No

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

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
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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:

偏差报告

Deviation Report

PR#:3564Deviation No.:D-2020-0187

Record Status: Closed-Done

产品代码 Product Code产品批号 Batch No.:数量 Quantity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: 冷藏冷冻箱设备代码 Equipment Code MFG-M1b2-134

设备名称 Equipment Name: 冷藏冷冻箱设备代码 Equipment Code MFG-M1b2-127

设备名称 Equipment Name: 冷藏冷冻箱设备代码 Equipment Code MFG-M1b3-126

偏差处理措施 Deviation Action Items

PR#:3566

责任人 Assigned To: 胡, 君寅(PID-000150)部门 Department: QE

截止日期 Date Due: 2020.06.24完成日期 Completed Date: 2020.06.24

确认人 Verified By: 吴, 晓军(PID-000095)确认日期 Verified On: 2020.06.24

行动项详细描述 Action Description:
在验证方案模板附录3 仪器仪表的校验中增加校准范围列。
在验证方案模板附录4 执行前检查中增加校准范围能覆盖验证测试范围的确认。

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:

PR#:3564

Record Status: Closed-Done

Deviation No.:D-2020-0187

纠正与预防措施 CAPA

PR#:

责任人 Assigned To:

截止日期 Date Due:

行动项详细描述 Action Description:

部门 Department:

附件 File Attachments

关联记录 Reference Records

PR#	Record Type	简短描述 Short Description	Record Status
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相关子记录 Related children

PR#	Record Type	简短描述 Short Description	Record Status
3566	Deviation Action Items	更新验证方案模板附录Update the appendix of validation protocol template	Closed-Done

偏差报告 Deviation Report

PR#: 3564

Deviation No.:D-2020-0187

Record Status: Closed-Done

Initial Approval

QA Initial Review

Area QA Initial Reviewed By:	刘, 小云	Area QA Initial Reviewed On:	2020.06.23 17:05
Classify Completed By:	吴, 晓军	Classify Completed On:	2020.06.24 19:00

Department Initial Review

Department Leader 1 Reviewed By:	刘, 焱	Department Leader 1 Reviewed On:	2020.06.24 20:33
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:	刘, 小云	Area QA Leader Reviewed On:	2020.06.24 20:25

Quality Initial Approval

Quality Approver 1 Approved By:	王, 海霞	Quality Approver 1 Approved On:	2020.06.24 22:23
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:
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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:

偏差报告 Deviation Report

PR#: 3564

Deviation No.:D-2020-0187

Record Status: Closed-Done

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: