

#1

COMPLETE

Collector: Email Invitation 1 (Email)
Started: Friday, March 19, 2021 1:04:49 AM
Last Modified: Friday, March 19, 2021 1:19:47 AM
Time Spent: 00:14:58
Email:
IP Address:

Page 1

Q1

Please enter the unique individual Survey Monkey code provided to you by Julian Arbuckle:

1003

Q2

No

Is your biorepository inventory management system deemed as a GxP IT system?

Q3

What were the reasons that contributed to the GxP or non-GxP designation?

- 1- The system amalgamates inventory information from multiple vendors, and is not the system of record for any of the data it contains (i.e. the system is a shadow system of data created and maintained in vendor GxP systems).
 - 2- The system is a stand-alone system that is not interfaced with any other GxP system.
 - 3- System is a SaaS solution, performance of which has been validated by the vendor.
 - 3- We are not currently intending to submit data contained within the system for any regulatory findings. Any chain of custody documentation will be furnished by our vendors.
-

Q4

If GxP-designated, how many FTE is allocated to maintaining the system to GxP standards?

n/a

Q5

Respondent skipped this question

Is there any other feedback or comments that you would like to provide to us in relation to LIMS and GxP processes?

#2

COMPLETE

Collector: Email Invitation 1 (Email)
Started: Monday, March 22, 2021 4:31:52 PM
Last Modified: Monday, March 22, 2021 4:55:23 PM
Time Spent: 00:23:31
Email:
IP Address:

Page 1

Q1

Please enter the unique individual Survey Monkey code provided to you by Julian Arbuckle:

4001

Q2

Yes

Is your biorepository inventory management system deemed as a GxP IT system?

Q3

What were the reasons that contributed to the GxP or non-GxP designation?

Our LIMS system supports both CLIA and other Clinical (GCP/GCLP) studies.

Q4

If GxP-designated, how many FTE is allocated to maintaining the system to GxP standards?

2 - 3 FTE (IT and Administration)
Other FTE (Lab Staff for testing/use)

Q5

Is there any other feedback or comments that you would like to provide to us in relation to LIMS and GxP processes?

It's a bit hard to answer without further context: you trying to build new GxP, considering whether you need to be GxP, do you already have a LIMS? Are you sending samples to GxP lab? Would be happy to provide further thoughts based on context. :) Depending on the LIMS you are using or choosing, internal expertise is critical to continued functionality and oversight.

#3

COMPLETE

Collector: Email Invitation 1 (Email)
Started: Wednesday, March 24, 2021 11:22:25 PM
Last Modified: Wednesday, March 24, 2021 11:23:24 PM
Time Spent: 00:00:59
Email:
IP Address:

Page 1

Q1 Respondent skipped this question

Please enter the unique individual Survey Monkey code provided to you by Julian Arbuckle:

Q2 No

Is your biorepository inventory management system deemed as a GxP IT system?

Q3
What were the reasons that contributed to the GxP or non-GxP designation?

unknown

Q4
If GxP-designated, how many FTE is allocated to maintaining the system to GxP standards?

n/a

Q5
Is there any other feedback or comments that you would like to provide to us in relation to LIMS and GxP processes?

no

#4

COMPLETE

Collector: Email Invitation 1 (Email)
Started: Thursday, March 25, 2021 12:18:52 AM
Last Modified: Thursday, March 25, 2021 12:25:27 AM
Time Spent: 00:06:35
Email:
IP Address:

Page 1

Q1

Please enter the unique individual Survey Monkey code provided to you by Julian Arbuckle:

1011

Q2

Yes

Is your biorepository inventory management system deemed as a GxP IT system?

Q3

What were the reasons that contributed to the GxP or non-GxP designation?

Internal regulatory compliance group's interpretation of GCP guidelines

Q4

If GxP-designated, how many FTE is allocated to maintaining the system to GxP standards?

10 on a day-to-day basis, more if validation work is needed on a project basis

Q5

Is there any other feedback or comments that you would like to provide to us in relation to LIMS and GxP processes?

Some of FTE is based on the number of studies in the system (Biobanking staff), rest is system support and testing documentation that is independent of number of studies in the system (Systems staff).

#5

COMPLETE

Collector: Email Invitation 1 (Email)
Started: Thursday, March 25, 2021 2:09:00 AM
Last Modified: Thursday, March 25, 2021 2:14:46 AM
Time Spent: 00:05:46
Email:
IP Address:

Page 1

Q1

Please enter the unique individual Survey Monkey code provided to you by Julian Arbuckle:

2531

Q2

No

Is your biorepository inventory management system deemed as a GxP IT system?

Q3

What were the reasons that contributed to the GxP or non-GxP designation?

we do not have such system yet

Q4

If GxP-designated, how many FTE is allocated to maintaining the system to GxP standards?

None

Q5

Respondent skipped this question

Is there any other feedback or comments that you would like to provide to us in relation to LIMS and GxP processes?

#6

COMPLETE

Collector: Email Invitation 1 (Email)
Started: Thursday, March 25, 2021 5:10:35 PM
Last Modified: Thursday, March 25, 2021 5:16:47 PM
Time Spent: 00:06:11
Email:
IP Address:

Page 1

Q1

Please enter the unique individual Survey Monkey code provided to you by Julian Arbuckle:

3444

Q2

Yes

Is your biorepository inventory management system deemed as a GxP IT system?

Q3

What were the reasons that contributed to the GxP or non-GxP designation?

Management of clinical trial samples

Q4

If GxP-designated, how many FTE is allocated to maintaining the system to GxP standards?

Difficult to answer this question, the system needs to evolve so we have a dedicated IT team for change requests management & implementation as well as keeping all of the documentation in order. This is at least 3 FTE.

Q5

Respondent skipped this question

Is there any other feedback or comments that you would like to provide to us in relation to LIMS and GxP processes?

#7

COMPLETE

Collector: Email Invitation 1 (Email)
Started: Monday, March 29, 2021 1:45:33 PM
Last Modified: Monday, March 29, 2021 1:57:48 PM
Time Spent: 00:12:15
Email:
IP Address:

Page 1

Q1

Please enter the unique individual Survey Monkey code provided to you by Julian Arbuckle:

7333

Q2

No

Is your biorepository inventory management system deemed as a GxP IT system?

Q3

What were the reasons that contributed to the GxP or non-GxP designation?

We don't have a single biorepository yet and so not all inventory systems are GxP. We are piloting an external biorepository solution in the 2021/2022 timeframe and GxP compliance is part of the evaluation.

Q4

If GxP-designated, how many FTE is allocated to maintaining the system to GxP standards?

n/a

Q5

Is there any other feedback or comments that you would like to provide to us in relation to LIMS and GxP processes?

No

#8

COMPLETE

Collector: Email Invitation 1 (Email)
Started: Monday, March 29, 2021 2:04:25 PM
Last Modified: Monday, March 29, 2021 3:46:50 PM
Time Spent: 01:42:24
Email: 1
IP Address:

Page 1

Q1

Please enter the unique individual Survey Monkey code provided to you by Julian Arbuckle:

5965

Q2

No

Is your biorepository inventory management system
deemed as a GxP IT system?

Q3

What were the reasons that contributed to the GxP or non-GxP designation?

We did not initiate GxP/non-GxP-compliant designated biorepositories

Q4

If GxP-designated, how many FTE is allocated to maintaining the system to GxP standards?

NA

Q5

Is there any other feedback or comments that you would like to provide to us in relation to LIMS and GxP processes?

In our perspective it is better to have GxP-compliant LIMS and biorepositories, which provide additional quality/accuracy

#9

COMPLETE

Collector: Web Link 3 (Web Link)
Started: Monday, March 29, 2021 6:03:21 PM
Last Modified: Monday, March 29, 2021 6:06:51 PM
Time Spent: 00:03:30
IP Address:

Page 1

Q1

Please enter the unique individual Survey Monkey code provided to you by Julian Arbuckle:

8008

Q2

No

Is your biorepository inventory management system deemed as a GxP IT system?

Q3

What were the reasons that contributed to the GxP or non-GxP designation?

genomic studies are being performed as exploratory. We continue to evaluate this internally.

Q4

If GxP-designated, how many FTE is allocated to maintaining the system to GxP standards?

NA

Q5

Respondent skipped this question

Is there any other feedback or comments that you would like to provide to us in relation to LIMS and GxP processes?

#10

COMPLETE

Collector: Email Invitation 1 (Email)
Started: Monday, March 29, 2021 10:28:15 PM
Last Modified: Monday, March 29, 2021 10:33:36 PM
Time Spent: 00:05:21
Email:
IP Address:

Page 1

Q1

Please enter the unique individual Survey Monkey code provided to you by Julian Arbuckle:

2276

Q2

No

Is your biorepository inventory management system deemed as a GxP IT system?

Q3

What were the reasons that contributed to the GxP or non-GxP designation?

External biorepository

Q4

If GxP-designated, how many FTE is allocated to maintaining the system to GxP standards?

Not applicable

Q5

Is there any other feedback or comments that you would like to provide to us in relation to LIMS and GxP processes?

No

#11

COMPLETE

Collector: Email Invitation 1 (Email)
Started: Tuesday, March 30, 2021 4:56:00 AM
Last Modified: Tuesday, March 30, 2021 4:57:51 AM
Time Spent: 00:01:50
Email:
IP Address:

Page 1

Q1

Please enter the unique individual Survey Monkey code provided to you by Julian Arbuckle:

4099

Q2

Yes

Is your biorepository inventory management system deemed as a GxP IT system?

Q3

What were the reasons that contributed to the GxP or non-GxP designation?

Our inventory management system was designed to support GxP decision making, such as authorized use of residual or exploratory samples, without the user having to cross-reference with a validated GxP system. Therefore, we consider this system GxP.

Q4

If GxP-designated, how many FTE is allocated to maintaining the system to GxP standards?

Three.

Q5

Is there any other feedback or comments that you would like to provide to us in relation to LIMS and GxP processes?

Agency guidance is often ambiguous when it comes to systems that support the management of specimen inventory but do not capture clinical data. Our team continues to evaluate what aspects of our systems should influence the validated state of the system.

#12

COMPLETE

Collector: Email Invitation 1 (Email)
Started: Tuesday, March 30, 2021 6:24:20 PM
Last Modified: Tuesday, March 30, 2021 6:37:55 PM
Time Spent: 00:13:34
Email:
IP Address:

Page 1

Q1

Please enter the unique individual Survey Monkey code provided to you by Julian Arbuckle:

8354

Q2

Yes

Is your biorepository inventory management system deemed as a GxP IT system?

Q3

What were the reasons that contributed to the GxP or non-GxP designation?

The system contains sample information for GCP and GLP studies, as well as result data from GCP studies. Sample and result data may also be transferred from the sample management system to the clinical trial database for GCP studies. System is CFR Part 11 compliant and maintains an audit trail of each sample.

Q4

If GxP-designated, how many FTE is allocated to maintaining the system to GxP standards?

3 FTE - system has been in place for several years so less FTE are needed now for continued maintenance

Q5

Is there any other feedback or comments that you would like to provide to us in relation to LIMS and GxP processes?

LIMS system in place is highly customized to our process, and system has undergone significant enhancements to meet our specific needs.

#13

COMPLETE

Collector: Email Invitation 1 (Email)
Started: Tuesday, March 30, 2021 8:12:06 PM
Last Modified: Tuesday, March 30, 2021 8:20:00 PM
Time Spent: 00:07:54
Email:
IP Address:

Page 1

Q1

Please enter the unique individual Survey Monkey code provided to you by Julian Arbuckle:

2772

Q2

Yes

Is your biorepository inventory management system deemed as a GxP IT system?

Q3

What were the reasons that contributed to the GxP or non-GxP designation?

We did not choose whether it would be GxP or non-GxP. The vendor we use happens to have a GxP system so that's what is used for our company. The vendor is GxP because they manage samples for primary and secondary endpoints in clinical trials.

Q4

If GxP-designated, how many FTE is allocated to maintaining the system to GxP standards?

Not known-- this information is internal to our biorepository vendor.

Our company has a department that "audits" vendors' systems-- but this may be different from what the question is asking about. Not sure how much FTE to allocate to auditing our biorepository IT system.

Q5

Is there any other feedback or comments that you would like to provide to us in relation to LIMS and GxP processes?

We prefer processes/IT systems to be GxP because it provides flexibility to manage a variety of samples, some of which may require GxP.

#14

COMPLETE

Collector: Web Link 2 (Web Link)
Started: Wednesday, March 31, 2021 8:19:42 AM
Last Modified: Wednesday, March 31, 2021 8:21:31 AM
Time Spent:
IP Address:

Page 1

Q1

Please enter the unique individual Survey Monkey code provided to you by Julian Arbuckle:

0921

Q2

Yes

Is your biorepository inventory management system deemed as a GxP IT system?

Q3

What were the reasons that contributed to the GxP or non-GxP designation?

To be compliant with Belgian regulations

Q4

If GxP-designated, how many FTE is allocated to maintaining the system to GxP standards?

One

Q5

Is there any other feedback or comments that you would like to provide to us in relation to LIMS and GxP processes?

The system is GxP compliant, but not certified

#15

COMPLETE

Collector: Email Invitation 1 (Email)
Started: Saturday, April 03, 2021 3:14:27 AM
Last Modified: Saturday, April 03, 2021 3:16:01 AM
Time Spent: 00:01:34
Email:
IP Address:

Page 1

Q1

Please enter the unique individual Survey Monkey code provided to you by Julian Arbuckle:

3287

Q2

Yes

Is your biorepository inventory management system deemed as a GxP IT system?

Q3

What were the reasons that contributed to the GxP or non-GxP designation?

Compliance with downstream data feeds

Q4

If GxP-designated, how many FTE is allocated to maintaining the system to GxP standards?

2

Q5

Respondent skipped this question

Is there any other feedback or comments that you would like to provide to us in relation to LIMS and GxP processes?
