#### **ISOLOCITY SOFTWARE VALIDATION**

# EudraLex The Rules Governing Medicinal Products in the European Union Volume 4 - Good Manufacturing Practice Medicinal Products for Human and Veterinary Use Annex 11: Computerised Systems

**Legal basis for publishing the detailed guidelines:** Article 47 of Directive 2001/83/EC on the Community code relating to medicinal products for human use and Article 51 of Directive 2001/82/EC on the Community code relating to veterinary medicinal products. This document provides guidance for the interpretation of the principles and guidelines of good manufacturing practice (GMP) for medicinal products as laid down in Directive 2003/94/EC for medicinal products for human use and Directive 91/412/EEC for veterinary use.

Status of the document: revision 2

**Reasons for changes:** The Annex has been revised in response to the increased use of computerised systems and the increased complexity of these systems. Consequential amendments are also proposed for Chapter 4 of the GMP Guide.

Deadline for coming into operation: 30 June 2011

#### Principle

This annex applies to all forms of computerised systems used as part of a GMP regulated activities. A computerised system is a set of software and hardware components which together fulfill certain functionalities.

The application should be validated; IT infrastructure should be qualified.

Where a computerised system replaces a manual operation, there should be no resultant decrease in product quality, process control or quality assurance. There should be no increase in the overall risk of the process.

#### General

# 1. Risk Management

Risk management should be applied throughout the lifecycle of the computerised system considering patient safety, data integrity and product quality. As part of a risk management system, decisions on the extent of validation and data integrity controls should be based on a justified and documented risk assessment of the computerised system.

# The table below identifies any probable risks that may impact the success of the V&V (Verification & Validation) program.

Risk Type	Details	<b>Risk Rating</b>	Contingency
Human Error	QA misses' system error that required manual check	Medium	Second QA Checker & Automated Test Suite
Subsequent bugs	New builds may inadvertently create errors in other modules	High	Ensure system is updated with all test cases for test suite and releases are QA by internal staff and independent contractor.

#### 2. Personnel

There should be close cooperation between all relevant personnel such as Process Owner, System Owner, Qualified Persons, and IT. All personnel should have appropriate qualifications, level of access and defined responsibilities to carry out their assigned duties.

Role	Name	Responsibility
Operations Manager	Emily Soares	Development including enhancements and maintenance, and Customer Success
Director of Digital Marketing	Mukut Chakraborty	Marketing efforts including updates to clients on system releases
Director of Sales	Chris Budd	Sales efforts including illustrating software features and launches to prospective clients. Internal Subject matter expert.
Software Developer	Cristian Aldana	Build software enhancements based on specifications and fix bugs

Software Developer	Evan Al Diab	Build software enhancements based on specifications and fix bugs
Software Developer	Sinem Oyan	Build software enhancements based on specifications and fix bugs
Software Developer	Archana Korat	Build software enhancements based on specifications and fix bugs
Quality Assurance	Mehedi Hassan	Run Test Suite and manually QA software for each release and hotfix (including regression testing). Updates validation documentation and completes performance and operational qualification for all releases. Documents the results of the validation.

ANAGEMENT SYSTEM THAT DRIVES ITSELF

*Identify the software tools, techniques, and methodologies to be used by the verification and validation team.* 

Tool	Purpose	Details
Selenium Test Suite	Automatic QA of entire software each time code is added/altered	Run by QA and overseen by Operations. Once all test cases have been reviewed by test suite, errors found must be reviewed by Operations and resolved by the Senior Software Engineer
Manual Regression Testing	Review of software to ensure the system is working as expected and has not produced unintended outcomes in the code	Performed each quarter by QA
Validation Plan	Lists all the test plans for each module step-by-step to emphasize what is expected from the software	Update and modify validation plan as new modules are changed/added

# 3. Suppliers and Service Providers

3.1 When third parties (e.g. suppliers, service providers) are used e.g. to provide, install, configure, integrate, validate, maintain (e.g. via remote access), modify or retain a computerised system or related service or for data processing, formal agreements must exist between the

Isolocity is a CJB Consulting Ltd company Page **3** of **30**  manufacturer and any third parties, and these agreements should include clear statements of the responsibilities of the third party. IT-departments should be considered analogous.

# Isolocity terms and conditions <u>https://isolocity.com/software-terms-and-conditions/</u>

3.2 The competence and reliability of a supplier are key factors when selecting a product or service provider. The need for an audit should be based on a risk assessment.

3.3 Documentation supplied with commercial off-the-shelf products should be reviewed by regulated users to check that user requirements are fulfilled.

*Quality and Compliance complete regular reviews of Isolocity.* The next review is scheduled for 2023. <u>https://www.gualityandcompliance.com/</u>

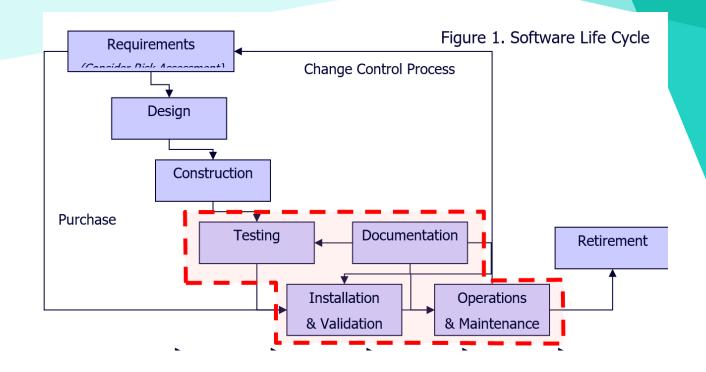
3.4 Quality system and audit information relating to suppliers or developers of software and implemented systems should be made available to inspectors on request.

AWS Agreements and security protocols can be provided upon request. Isolocity is hosted with AWS, see <u>https://aws.amazon.com/artifact/</u> for all available artifacts.

#### **Project Phase**

#### 4. Validation

4.1 The validation documentation and reports should cover the relevant steps of the life cycle. Manufacturers should be able to justify their standards, protocols, acceptance criteria, procedures and records based on their risk assessment.



4.2 Validation documentation should include change control records (if applicable) and reports on any deviations observed during the validation process.

All testing and validation steps follow these steps:

# **Requirements Phase and System Acceptance Test Specification**

This phase identifies, specifies, analyzes, and documents all the requirements that the software must satisfy regarding functionality, performance, design constraints, attributes, and external interfaces. It is important to perform a risk assessment during this phase.

# **Design Phase**

This phase develops, documents, and reviews a design that satisfies the requirements previously documented.

Answers to some key questions should be documented during formal design reviews. These include:

 $\cdot$  Have the appropriate tasks and expected results, outputs, or products been established for each software life cycle activity?

· Do the tasks and expected results, outputs, or products of each software life cycle activity:

Comply with the requirements of other software life cycle activities in terms of correctness, completeness, consistency, and accuracy?

Satisfy the standards, practices, and conventions of that activity?

Establish a proper basis for initiating tasks for the next software life cycle activity?

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#### **Construction Phase**

This phase takes each element documented in the design phase and translates it into a programming language. This phase is often known as a "coding" or "build" phase.

#### **Testing Phase**

This phase runs the software through test cases and analyzes any failure to determine which phase contributed to such error.

#### Installation and Validation Phase

This phase executes tests for the installation and integration of the software into the equipment (i.e., other software, data, hardware), and the documentation of the approval of the software for operational use. User site testing is a very important practice to consider because it helps eliminate errors (i.e., bugs) that may arise after the software is installed on different equipment.

<u>https://docs.qooqle.com/spreadsheets/d/15BUsOaqINAJRIboLUt5Z3cFxua6rWTbApfbnbj7iX10/edit#qid=</u> <u>1494046008</u> (file associated with this procedure) must be used to ensure complete assessment of all aspects of the software (especially ensuring that calculation functions are not the only item assessed) and to begin the documentation.

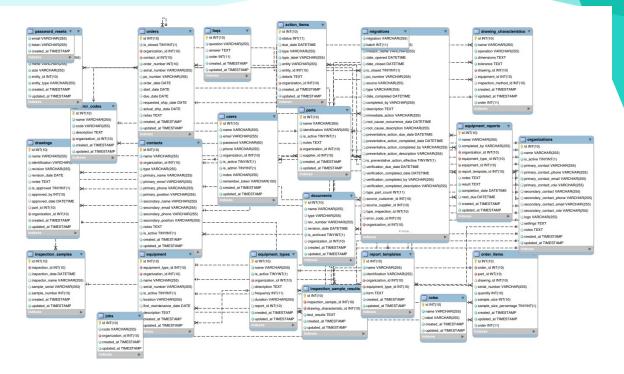
#### **Documentation Phase**

This phase handles the technical documentation of all the phases described above. Evidence must be retained in association with the methods used.

#### **Operations and Maintenance**

Once the software has been approved for operational use, routine maintenance may be performed to remove errors, to respond to new or modified equipment, or to adapt the software to changes in the operating environment. All planned changes must be approved by the Director of Operations before work is started. After any modifications, software must be verified and validated again.

4.3 An up-to-date listing of all relevant systems and their GMP functionality (inventory) should be available. For critical systems an up-to-date system description detailing the physical and logical arrangements, data flows and interfaces with other systems or processes, any hardware and software prerequisites, and security measures should be available.



4.4 User Requirements Specifications should describe the required functions of the computerised system and be based on documented risk assessment and GMP impact. User requirements should be traceable throughout the life cycle.

# Client Related Process.

#### https://isolocity.com/knowledge-base/

4.5 The regulated user should take all reasonable steps, to ensure that the system has been developed in accordance with an appropriate quality management system. The supplier should be assessed appropriately.

#### **Client related process**

4.6 For the validation of bespoke or customised computerised systems there should be a process in place that ensures the formal assessment and reporting of quality and performance measures for all the life-cycle stages of the system.

#### Not Required for Isolocity. Isolocity is an over-the-counter software.

4.7 Evidence of appropriate test methods and test scenarios should be demonstrated. Particularly, system (process) parameter limits, data limits and error handling should be considered. Automated testing tools and test environments should have documented assessments for their adequacy.

Along with our manual user driven testing utilizing the test cases in the link below, we also have an automated test suite that is running continuing.

https://docs.google.com/spreadsheets/d/15BUsOaqINAJRIboLUt5Z3cFxua6rWTbApfbnbj7iX10/e dit#qid=1494046008

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4.8 If data is transferred to another data format or system, validation should include checks that data are not altered in value and/or meaning during this migration process.

With all our integration partners, Isolocity and the partner conduct extensive testing prior to launching any integrated features. All applicable data transfers are identified here. <u>https://docs.isolocity.com/</u>

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#### **Operational Phase**

# 5. Data

Computerised systems exchanging data electronically with other systems should include appropriate built-in checks for the correct and secure entry and processing of data, in order to minimize the risks.

*Isolocity integration- API calls are verified and validated through successful and rejected gateway codes.* 

## 6. Accuracy Checks

For critical data entered manually, there should be an additional check on the accuracy of the data. This check may be done by a second operator or by validated electronic means. The criticality and the potential consequences of erroneous or incorrectly entered data to a system should be covered by risk management.

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# 7. Data Storage

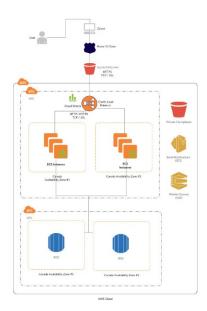
7.1 Data should be secured by both physical and electronic means against damage. Stored data should be checked for accessibility, readability and accuracy. Access to data should be ensured throughout the retention period.

AWS conducts regular backups. We verify all backup logs at regular frequencies. Furthermore, our clients databases can be exported upon request.

×
Organization Data Export
A ZIP file consisting of CSV data exports for each database table.
Select 🔻
Modules 💌

7.2 Regular back-ups of all relevant data should be done. Integrity and accuracy of backup data and the ability to restore the data should be checked during validation and monitored periodically.

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#### 8. Printouts

8.1 It should be possible to obtain clear printed copies of electronically stored data.

All modules, it is possible to download PDFs that provide a timestamp and expiration date on the PDF.

Generated by Chris Budds on July 5th 2020, 9:05:01 pm. The document is valid until the next business date.

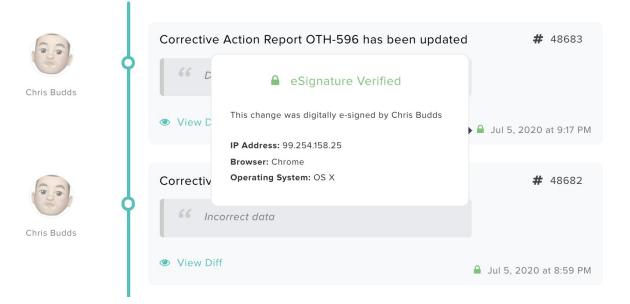
# Every form has an activity tracker that provides an audit trail of all changes made.

	Search activities	From Date	To Date
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Chris Budds	66 Data change		
	<ul> <li>View Diff</li> </ul>		🔒 Jul 5, 2020 at 9:17 PM

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 Image: Comparison of the state of the s

The changes to data are logged with a reason code along with e signature validation.



8.2 For records supporting batch release it should be possible to generate printouts indicating if any of the data has been changed since the original entry.

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# 9. Audit Trails

Consideration should be given, based on a risk assessment, to building into the system the creation of a record of all GMP-relevant changes and deletions (a system generated "audit trail").

Isolocity is a CJB Consulting Ltd company Page **14** of **30**  For change or deletion of GMP-relevant data the reason should be documented. Audit trails need to be available and convertible to a generally intelligible form and regularly reviewed.

## See example from

All modules, it is possible to download PDFs that provide a timestamp and expiration date on the PDF.

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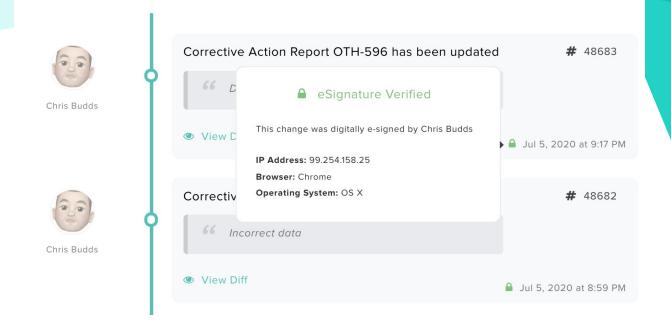
# Every form has an activity tracker that provides an audit trail of all changes made.

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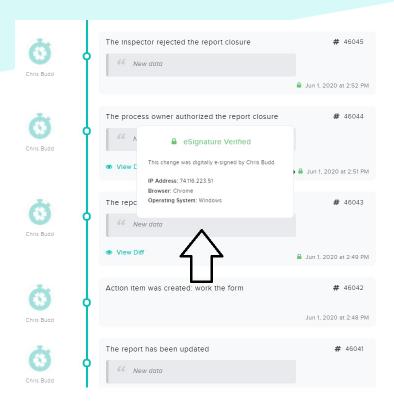
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**10. Change and Configuration Management** Any changes to a computerised system including system configurations should only be made in a controlled manner in accordance with a defined procedure.

See Isolocity QP-11 Software validation. All changes are version and revision controlled

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**11. Periodic evaluation** Computerised systems should be periodically evaluated to confirm that they remain in a valid state and are compliant with GMP. Such evaluations should include, where appropriate, the current range of functionality, deviation records, incidents, problems, upgrade history, performance, reliability, security and validation status reports.

Once the software has been approved for operational use, routine maintenance may be performed to remove errors, to respond to new or modified equipment, or to adapt the software to changes in the operating environment. All planned changes must be approved by the Director of Operations before work is started. After any modifications, software must be verified and validated again.

Table A		
Activity	3.1.1 Requirements Phase	Date/Initials
Task	Requirement Specification	
Method	Peer Review	
Check	Requirements Specification Approved	
Task	System Acceptance Test Specification	
Method	Peer Review	
Check	System Acceptance Test Specification Approved	

Table A

#### Table B

Activity	3.1.2 Design and Implementation Process	Date/Initials
Task	Design and Development Planning	
Method	Peer Review	
Task	Design Input	

Method	Peer Review	
Task	Design Output	
Method	Peer Review	
Task	Design Verification	
Method	Peer Review	
Task	Design Changes 1. Description: 2. Description:	
Method	Peer Review	
Activity	3.1.3 Construction Phase and 3.1.4 Testing Phase	Date/Initials
Task	Inspection Plan	
Method	Inspection	
Check	Inspection Approved	
Task	Test plan	
Method	Test Performance	
Check	Test Approved	

# Table C

Activity	3.1.5 Installation and Validation Phase	Date/Initials
Task	Installation Summary	
Method	Peer Review	
Task	Installation Procedure	
Method	Verification and test of installation	
Task	System acceptance test preparation	
Method	System acceptance test	
Check	System acceptance test approved	

# Table D

Activity	3.1.6 Documentation	Date/Initials
Task	Registered Anomalies	
Method	Peer Review	
Task	Precautionary Steps Taken	
Method	Verification of measures	

## Table E

Activity	3.1.7 Operations and Maintenance	Date/Initials
Task	Performance and Maintenance	
Method	Peer Review	
Task	New Versions 1. Version: 2. Version:	
Method	Peer Review 1. Action: 2. Action:	

THE QUALITY MANAGEMENT SYSTEM THAT DRIVES ITSELF

Task	Phase Out	
TASK	Phase Out	
Method	Peer Review	

#### 12. Security

12.1 Physical and/or logical controls should be in place to restrict access to computerised system to authorized persons. Suitable methods of preventing unauthorized entry to the system may include the use of keys, pass cards, personal codes with passwords, biometrics, restricted access to computer equipment and data storage areas.

12.2 The extent of security controls depends on the criticality of the computerised system.

12.3 Creation, change, and cancellation of access authorizations should be recorded.

# All user level changes, and access restrictions are recorded in our activity log.

12.4 Management systems for data and for documents should be designed to record the identity of operators entering, changing, confirming, or deleting data including date and time.

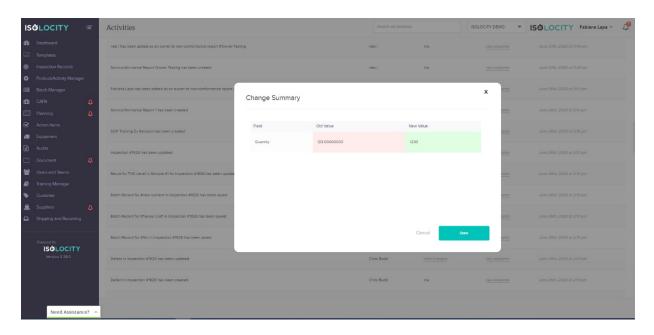
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CAPA (CAPA/ NCR/ Deviations)	~	~	~	~	
Planning (Change Control/ risk/ planning reports)	~	~	~		
Equipment	~	~	~	~	
Audits	~	~	~		
Document Manager (Initiate Change Controls)	~	~	~	~	
HR Management	~	~			
Training Activities & Doc Training	~	~	~	~	~
Data Permissions					
Create Users	~				
Reopen Reports	~				
Archive Info	~				
Create Templates	~	~			
Create Training Programs	~	~			
Adjust Organizational Settings	~				
Create Teams	~				

Isolocity User Tier & System Access | ISA) OCITY

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Dashboard     Templates	neb I has been added as an owner to non-conformance report #Owner Testing	nebl	n/a	raw snapshot	June 27th, 2020 at 11:45 am
Inspection Records	Non-conformance Report Owner Testing has been created	nebl	n/a	raw snapshot	June 27th, 2020 at 11:45 am
<ul> <li>Product/Activity Manager</li> <li>Batch Manager</li> </ul>	Fabiana Lapa has been added as an owner to non-conformance report #1	Fabiana Lapa	n/a	rew snepshot	June 26th, 2020 at 3:51 pm
CAPA Q Planning Q	Non-conformance Report 1 has been created	Fabiena Lapa	n/a	raw snepshot	June 26th, 2020 at 3:51 pm
<ul> <li>Action Items</li> <li>Equipment</li> </ul>	SQP Training Ex Revision has been created	Nidhi Dave	n/a	raw snapshot	June 26th, 2020 at 3:16 pm
<ul> <li>Audits</li> <li>Document</li> </ul>	Inspection #1526 has been updated	Chris Budd	view changes	rew snepshot	June 26th, 2020 at 2:51 pm
Users and Teams	Result for THC Level in Sample #1 for Inspection #1926 has been updated	Chris Budd	view changes	raw snapshot	June 26th, 2020 at 2:51 pm
<ul> <li>Training Manager</li> <li>Customer</li> </ul>	Batch Record for #new nutrient in Inspection #1926 has been saved	Chris Budd	view changes	rew snepshot	June 26th. 2020 at 2:51 pm
Suppliers     Shipping and Receiving	Batch Record for #flavour craft in inspection #1926 has been saved	Chris Budd	view changes	raw snapshot	June 26th, 2020 at 2:51 pm
Powered By	Batch Record for #Nic In Inspection #1926 has been saved	Chris Budd	view changes	raw snapshot	June 26th, 2020 at 2:51 pm
ISOLOCITY Version 2.38.0	Defect in Inspection #1928 has been updated	Chris Budd	view changes	raw snapshot	June 26th, 2020 at 2:51 pm
	Defect in Inspection #1926 has been created	Chris Budd	n/a	raw snapshot	June 26th. 2020 at 2:51 pm

Need Assistance? ^



ISC	LOCITY	Ŧ	Activities		Search all mode	utes	ISOLOCITY DEMO	ISOLOCITY Fabiana Lapa -	4
			neb I has been added as an owner to non-conformance report #Owner T	sting	neb l	n/a			
0			Non-conformance Report Owner Testing has been created		neb i	n/a			
			Fabiana Lapa has been added as an owner to non-conformance report	Raw Snapshot			X shot		
		4 4	Non-conformance Report 1 has been created				shot		
_			SOP Training Ex Revision has been created	{ "id": 6993, "company_id": 1, "inspection_id": "1926", 1230, "unit_of_measure": "units", "cost": 0, "order": 1,	'is_verification_check': f				
-		Д	Inspection #1926 has been updated	18:49:25", "updated_at": "2020-06-26 18:50:31", "dele	eted_at": null }		shot		
쓭		~	Result for THC Level in Sample #1 for Inspection #1926 has been update				shot		
_			Batch Record for #new nutrient in Inspection #1926 has been saved				shot		
_		4	Batch Record for #flavour craft in Inspection #1926 has been saved				shat		
		_	Batch Record for #Nic in Inspection #1926 has been saved			Cancel Don	shat		
	Version 2.38.0		Defect in Inspection #1926 has been updated		Chris Budd	view changes	rew snapshot		
			Defect in Inspection #1926 has been created		Chris Budd	n/a			
	Need Assistant	:e? ^							

# Change control:

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📸 Dashboard	Edit Change Control Report #example	Excelere to Corrective Action		The budget was approved for this report	# 46040
			O I	66 New data	
			Chris Budd	NOT GUID	
Product/Activity Manager	Status Open				Jun 1, 2020 at 2:48 Pf
				Quality Assurance department was added	# 46038
🖸 САРА 🗛	Source		Ö 👌		
	Document Revision		Chris Budd	66 Incorrect data	
	cc.#	Subject			🔒 Jun 1, 2020 at 2:47 Pl
쉽 Change Control 🚨	example	example			
A Risk Management	Revision Number	Batch Number	ð l	Catherine Jutsun has been added as an owner	# 46037
	example	1234567	Chris Budd	66 New data	
Equipment		Closure Target Date			🔒 Jun 1, 2020 at 2:47 Pl
	Jun 1. 2020	Choose Date			
			6	Action item was created: kj	# 46036
Users and Teams	Input information		_		Jun 1, 2020 at 2:46 P
Training Manager			Chris Budd		
Customer				Chris Budd has been added as an owner	# 46035
🚊 Suppliers 🔼		i i	O I		
Shipping and Receiving	Rationale for Change		Chris Budd		Jun 1, 2020 at 2:46 Pl
	work the form				
			a l	The report has been created	<b>#</b> 46034
ISOLOCITY			Chris Budd		Jun 1, 2020 at 2:46 PI
		đ.	Critis Budu		

ISOLOCITY =	Go Back Edit Change Control Report #fadlkfjlkfjac	III Escalato to Corrective Action		Search activities From 0	Date To Date
	Section 1 - Change Request				
			24	The inspector rejected the report closure	# 46045
	Status Open		🛛 🙂 🛉	66 New data	
			Chris Budd		
	Source Document Revision				Jun 1, 2020 at 2:52 PM
				The process owner authorized the report close	ure # 46044
	CC# fedikfjikfjedfi	Subject feldkijfadkisejfds	<b>O b</b>		
රි Change Control 🚨			Chris Budd	eSignature Verified	
	Revision Number fectsfactsfsad	Batch Number 1234567		View E     This change was digitally e-signed by Chris But	dd
				IP Address: 74.116.223.51 Browser: Chrome	
	Date Requested	Closure Target Date	in the	The repc Operating System: Windows	<b>#</b> 46043
	Jun 1, 2020	Choose Date	🛛 😳 🛉	66 New data	
	Description of Change(s)		Chris Budd	$\wedge$	
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			CA L	Action item was created: work the form	<b>#</b> 46042
🚊 Suppliers 🚨			u v		Jun 1, 2020 at 2:48 PM
	Rationale for Change work the form		Chris Budd		2011 () 2020 01 210 111
	work the form		24	The report has been updated	# 46041
ISOLOCITY Version 2,38.0			0 ¢	66 New data	
			Chris Budd		
				View Diff	🔒 Jun 1, 2020 at 2:48 PM
Need Assistance? ^					

#### **13. Incident Management**

All incidents, not only system failures and data errors, should be reported and assessed. The root cause of a critical incident should be identified and should form the basis of corrective and preventive actions.

ISOLOCITY =	Contact Support	ISOLOCITY Feblens Lape -	¢
	Oversion Type Select Description		
CAPA     A	Contract Seguri		
Equipment     Audits     Document			
<ul> <li>Users and Teams</li> <li>Training Manager</li> <li>Customer</li> </ul>			
Suppliers			
Need Assistance? A			

All Bugs follow an investigation and are documented in our client facing ticket system (Freshdesk) and are progressed to resolution using Asana. All bugs are provided with a rating; Critical, High, Medium and Low. All critical and High rated bugs are prioritized. As fixes are made to the

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code and pushed to the User Accepted Testing site (UaT), all fixes are peer reviewed and QA by our head of QA. Once verified through automated regression testing, the code is then merged into the production servers.

#### 14. Electronic Signature

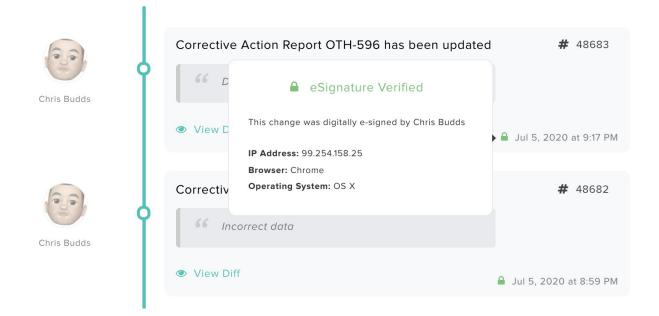
Electronic records may be signed electronically. Electronic signatures are expected to: a. have the same impact as hand-written signatures within the boundaries of the company, b. be permanently linked to their respective record, c. include the time and date that they were applied.

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Templates						
Inspection Records						
Product/Activity Ma 		Root Cause Analysis				
Batch Manager		Date Root Cause Occurred				
CAPA		May 28, 2020				
Corrective Action		Description 0				
Non-conformance		Test				
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Out Of Specificati						
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Action Items		Conclusion				
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Document						
Users and Teams		Preventative Actions				
Training Manager						
S Customer						
Suppliers		Add a preventative action				
Shipping and Rece						
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	Root Cause Analysis				
	Date Root Cause Occurred	x			
	May 28, 2020	e-Signature Required			
Corrective Actions	Description ()				
	test	Your e-signature is required for this action.			
		Password			
		Password			
	Perform a 5-Why Analyza				
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Non-conformance	Description 0					
	test	This will record your authorization of the approval action along with the current date and time.				
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Users and Teams	Preventative Actions						
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Section Customer							
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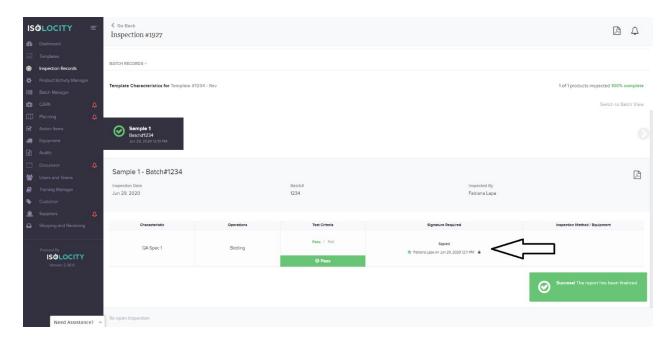


# 15. Batch release

When a computerised system is used for recording certification and batch release, the system should allow only Qualified Persons to certify the release of the batches and it should clearly identify and record the person releasing or certifying the batches. This should be performed using an electronic signature.

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ISÖL	_OCITY ≡	< Go Back				
🙆 Da		Inspection #1927				↓ ↓
lns	pection Records	Template Characteristics for Template #123	4 - Rev			1 of 1 products inspected 100% complete + Add New Sample
						ter (produce inspected terminate
						Switch to Batch View
		Sample 1 Batch#1234				
		Jun 29, 2020 12:10 PM				
						ß
		Sample 1 - Batch#1234 +Add	Photo of Sample			<b>上</b>
<b>앱</b> Up		Inspection Date		Betch#	Inspected By	
		Jun 29, 2020 12:10 PM	8	1234	Fablana Lapa	
		Characteristic	Operations	Test Criteria	Signature Required	Inspection Method / Equipment
		015 1	Bottling	@ Pass / O Fall	Add Signature	
	ISOLOCITY	QA Spec 1	Bottling	Ø Pass		
				U Pess		Delete Sample
						Develo Sample
	Need Assistance?	Delete Inspection				Save Save & Finalize



PDF Report:

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# Packaging Finished Product

Page 1 of 2

Inspection #1554

Acceptance Threshold	100%	
Part	Packaged Finished Product	
Status	Passed	
Lot Serial #	12345	
Quantity Accepted	10 units	
Defect Summary		
There were no defects logged for this inspec	ion.	
Batch Records		
#PFP-001 - Packaged Finished Product	12345	
#FP-001 - Finished Product	12345	120 unit
#Pkg-001 - Packaging Material	12345	10 unit

S	ample #1 - 12	2345		Passed
Inspection Start	Time	Octob 4:47 p	er 11th, 20 m	122
Inspected by			Budd	
Inspected Comp	leted Time			
Revision Approved By Chi Results	ris Budd on 11-10-2022 8:4	16 pm		
<u>Characteristic</u>	Operation	Criteria	Value	
Completed by	Signature of Employee Who Performed Packaging Operations	(Pass/Fail)	Pass	Signed by: Brandon Chen on 2022-16-11 4:48 pm
Verified by	Signature of Management/Lead who Verified	(Pass/Fail)	Pass	Chris Budd on 2022-10-11 4:50 pm

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# **16. Business Continuity**

For the availability of computerised systems supporting critical processes, provisions should be made to ensure continuity of support for those processes in the event of a system breakdown (e.g. a manual or alternative system). The time required to bring the alternative arrangements into use should be based on risk and appropriate for a particular system and the business process it supports. These arrangements should be adequately documented and tested.

This is a client driven process. Should have a paper-based system for back up.

# 17. Archiving

Data may be archived. This data should be checked for accessibility, readability, and integrity. If relevant changes are to be made to the system (e.g. computer equipment or programs), then the ability to retrieve the data should be ensured and tested.

*Isolocity provides archive folders for clients to store completed or obsolete data. Isolocity does not archive any data automatically, unless requested by the client.* 

#### Glossary

Application: Software installed on a defined platform/hardware providing specific functionality

**Bespoke/Customized computerised system:** A computerised system individually designed to suit a specific business process

**Commercial of the shelf software:** Software commercially available, whose fitness for use is demonstrated by a broad spectrum of users.

**IT Infrastructure:** The hardware and software such as networking software and operation systems, which makes it possible for the application to function.

**Life cycle:** All phases in the life of the system from initial requirements until retirement including design, specification, programming, testing, installation, operation, and maintenance.

Process owner: The person responsible for the business process.

**System owner:** The person responsible for the availability, and maintenance of a computerised system and for the security of the data residing on that system.

**Third Party:** Parties not directly managed by the holder of the manufacturing and/or import authorization.