

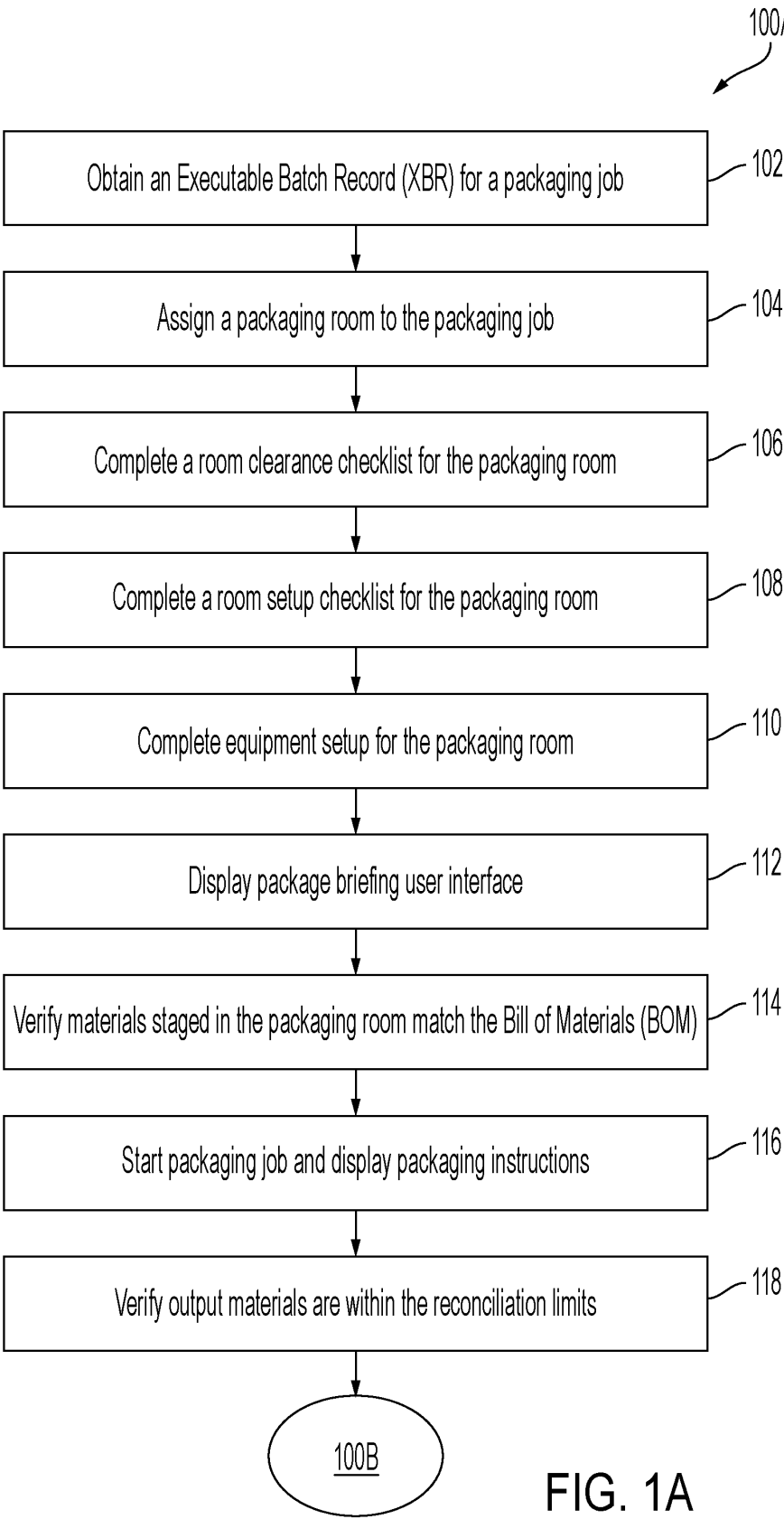


FIG. 1A

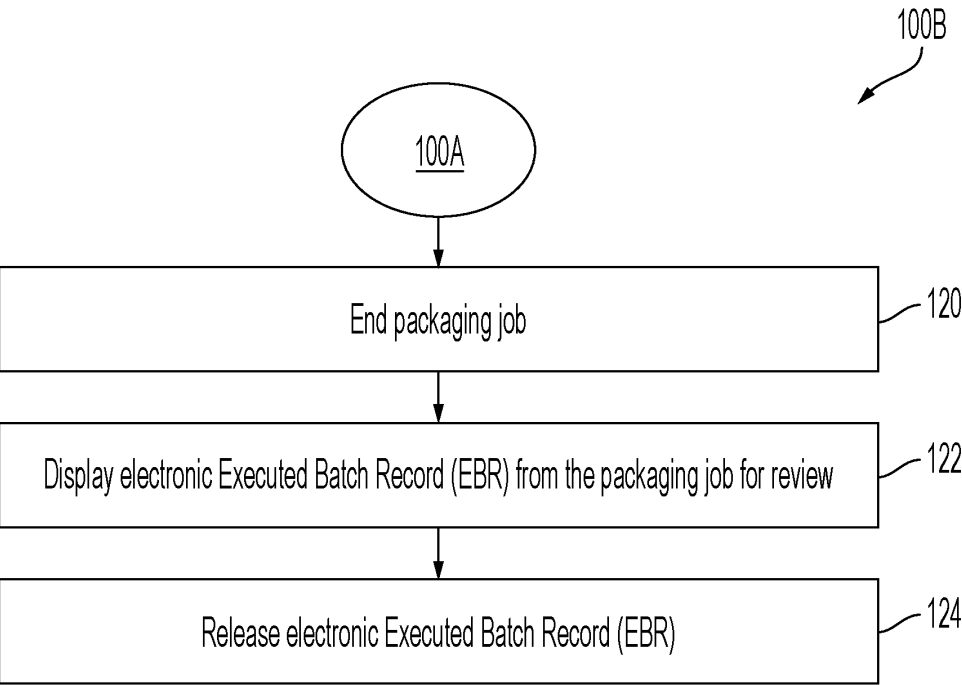


FIG. 1B



FIG. 1C

←

→

C

website

Search

Update

Sandbox: SFXQual

Search

Catalent®

Global SupplyFlex

Batch Records

PQ

Summary

WOBOM Details

Room Assignment

Room Clearance

Room Setup

Equipment Setup

Staged Log Verification

Input Reconciliation

Package Briefing

Job Actions

Comments Summary

Samples

IPC

IPC Summary

Packaging Institution

Image Capture

Fields

Information

Batch Record Name

PQ

Customer

○

SOLUSTOMER 1

Project Number

XXXX

Customer Protocol

2

Created from PSPADI

2

Medication List ID

111

Kit Number Range Start

1

Kit Number Range End

5

Sequence Number Range Start

1

Sequence Number Range End

5

Created from Packaging Request

2

General LA Note

PQ

Lot Assignment Version

1.00

LA Unique Identifier

23223

Latest SuperBom Version

○

Related XBR

○

Version

○

XBR Note

○

XBR Unique Identifier

XXX

Rooms

LSZ test room 3

Reference BRX Record

XBR Sequence Number

○

SI ID

XXX

SP Unique Identifier

XXXX-4

Batch Record Site

○

San Diego (Clinical)

SI Description

PQ Execution

SI Study Part Version

○

SI Study Part Description

PQ

Status

In Execution

Study Part

○

PQ

Packaging Type

Secondary Packaging

Blinded

No

Reason for Hold Remove

○

Blinded

☐

Hold due to quality reasons

○

Trackwise Number

○

Logged-in username : User

Edit History

12:30 PM

4/24/2023

FIG. 2A

Global SupplyFlex

Home

>

ent Items (10)

New study par

Active

Customer

Project Number

Packaging Type

Approval Status

Job Action

5003 - Descript

Active

Customer

Project Number

Packaging Type

Home

Customers

Study Information

Study Parts

Batch Records

Study Instructions

BOM

Lot Assignments

Cities

Edit

FIG. 2B

Batch Records

BRX - All

>

32 items

1

2

3

RECENT LIST VIEWS

Recently Viewed (Pinned list)

FIG. 2C

Batch Records

BRX · All ▾

Q XBR-1

item • Sorted by Status • Filtered by All batch records - Status, Last Modified Date, Current Record Type • Updated 3 minutes ago

FIG. 2D

Batch Records

BRX - All

Q XBR-1

1 item • Sorted by Status • Filtered by All batch records - Status, Last Modified Date, Current Record Type • Updated a few seconds ago

Batch Record Name	V	XBR Unique Identifier	V	Customer	V	Batch Record Site	V	Packaging Type	V	Status	↑	V	Version	V	Last Modified Date
1 1234		XBR-1		Customer 1		San Diego (CSS)		Secondary Packaging		Ready for Manufacture			1		10/26/2022

FIG. 2E

Global SupplyFlex

Batch Records

▼

XRB

▼ x

Details

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More ▼



FIG. 3A

Room Assignment Search

*Enter barcode value

123456

Search

FIG. 3B

0

Error!

Room you searched for is already occupied!

X

FIG. 3C

Room Assignment Search

*Enter barcode value

123304B

Search

Room Details

Room Name

123304B

Status ⓘ

Approved

Room Barcode Value ⓘ

123304B

Allows Light Control

☒

Room Condition

Ambient

Allows Humidity Control

☒

Site ⓘ

San Diego (CSS)

Check JDE Lots

FIG. 3D

JDE Data:

ItemNo	Description1	Description2	JDELotNo	SupplierLotNo	ExpiryDate	QuantityOnHand	UOM	
--------	--------------	--------------	----------	---------------	------------	----------------	-----	--

Output Material

Item ID	Work O...	Labeled...	JDE EXP...	Quantit...	Sample...	JDE Qty...	JDE UoM	JDE WO...
1234	Work Order Created	134556645343	07-Oct-2022	5	0	5	KT	Yes

Input Material (Drug)

Item ID	JDE Lot	Supplier Lot	JDE Lot Status	JDE Expiry Date	JDE UoM	JDE Committe...
X023	1234565	SUPLOT2		31-Aug-2025	EA	5,000,000

Input Material (Non-Drug)

Item ID	JDE Lot	Supplier Lot	JDE Lot Status	JDE Expiry Date	JDE UoM	JDE Committe...
---------	---------	--------------	----------------	-----------------	---------	-----------------

Click to Continue

Cancel

FIG. 3E

eSign

1 of 1

Catalent.

Batch record number: XBR-1
Status: Ready for Manufacture
Customer: Customer 1

Room Assignment Information

Room Name: 123304B
Room Barcode 123304B
Value: San Diego (CSS)
Site:

Rooms Conditions

Rooms Condition: Ambient
Allows Humidity

Room Description: 123304B

Allows Light

Catalent Site: San Diego (CSS)
Project Number: 123464
Protocol: 123

FIG. 3F

Catalent®

Global Supply/Flex

Equipment

▼

CST ESP-POR UAT RE... ▼ x

QA Test Batch Reco... ▼ x

Search...

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🔖

Summary

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More ▼

Change room Approval status - Approved

Enter Comments

History

Change Room

Logged-in username :USER

▼ Room Processing Conditions

Room Processing Temperature

Temperature Range

Between

Low Range in °C

15

High Range in °C

25

Room Processing Humidity

Temperature Range

Between

Low Range in %RH

30

High Range in %RH

50

Room Processing Light Conditions

Light Condition Range

Between

Light Condition Description

Room Assignment Search

Room Details

Room Name

Test room 001

Room Barcode Value ⓘ

Room001

Room Condition

Refrigerated

Site ⓘ

TESTSITE (Clinical)

Status ⓘ

Approved

Allows Light Control

☒

Allows Humidity Control

☒

FIG. 3G

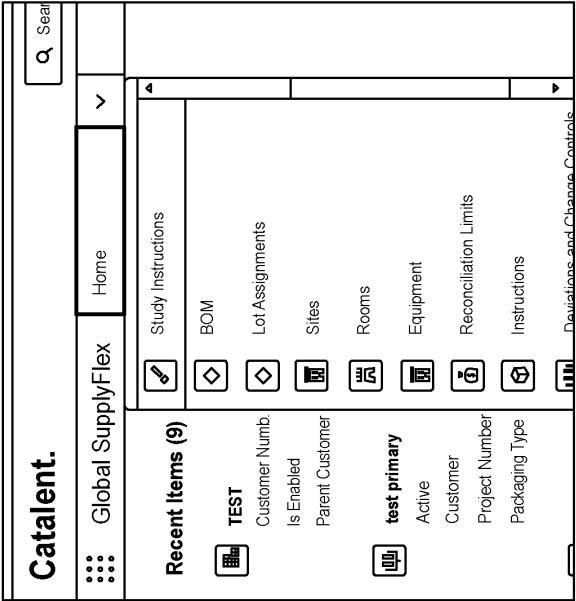


FIG. 3H

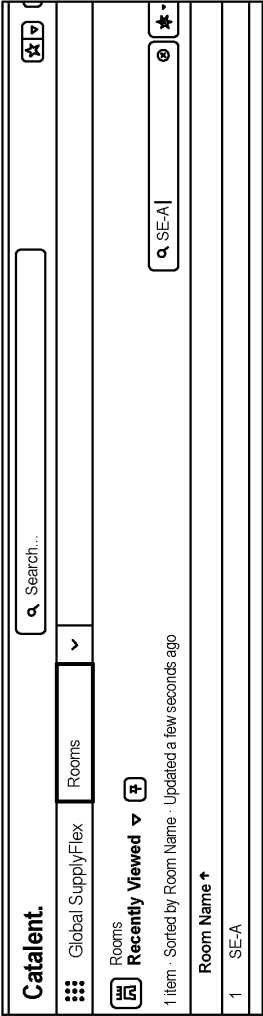


FIG. 3I

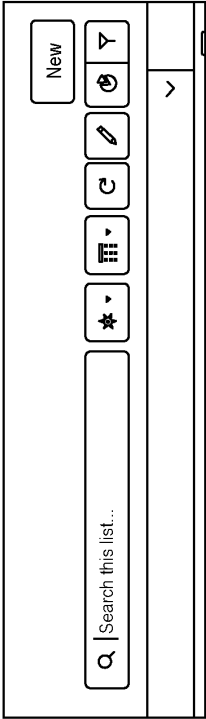


FIG. 3J

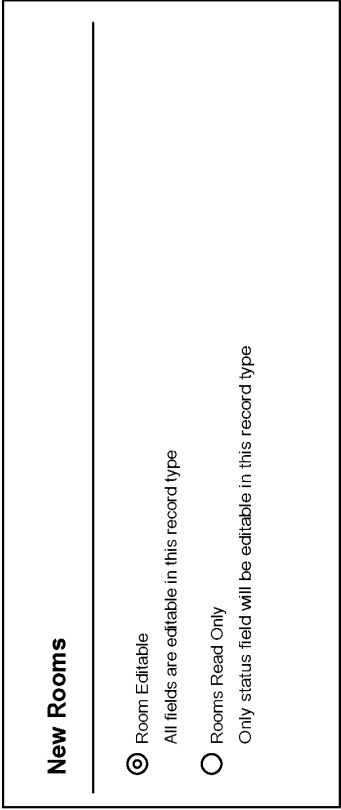


FIG. 3K

New Rooms: Room Editable

Information

* Room Name

PACKAGING ROOM 1

* Room Description

* Site

* Room Barcode Value

5

* Barcode Value #

5

Room Conditions

Room Condition

Ambient

Allows Humidity Control

Allows Light Control

Version and Status

Status

Draft

Version

1

Cancel

Save & New

Save

FIG. 3L

eSignature for Rooms

I apply my electronic signature for Rooms and all related attachments.

This signature is legally binding.

*User Login ID

Complete this field.

Comments

*Individual Signature Identifier

Approve

Cancel

FIG. 3M

Summary

WO/BOM Details

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Room Clearance Checklist

RCC Summary

JDE Work Order : 12345

EnglishGermanJapaneseChinese

Re-execute RCCEnter CommentsHistory

Logged-in username : User

Sequence	Check	Response	Comment	Blinded
1	Room log book completed	Fail N/A	Enter comments...	
2	"Special Character Test" e.g. "RCC: ! @ # \$ % ^ & * , etc.	Fail N/A	Enter comments...	
3	Room and equipment logbooks completed. Previous entry completed and correct clean indicated.	Fail N/A	Enter comments...	

Save

Second Level Approval

FIG. 4A



Error!
Comment is required for Fail Instructions.

FIG. 4B

Catalent.									
Q Search...									
Global SupplyFlex		Equipment	>	UUT CST ESP-POR UAT RE... > x	UUT QA Test Batch Record... > x				
Summary	WO/BOM Details	Room Assignment	Room Clearance	Room Setup	Equipment Setup	Staged Lot Verification	Input Reconciliation	Package Briefing	More >
<u>English</u> German Japanese Chinese									
Logged-in username : User									
Enter Comments				History					
Sequence	Check	Response	Comment						
1	Applicable documents present in the room		N/A						
2	Logbook entries (batch specific) are complete		N/A						
3	Make sure you located the piggy bank and weigh the bank		N/A						
Actual Packaging Conditions : +2 to +8°C -15 to 25°C over dry ice Other									

FIG. 5A

Actual Packaging Conditions :

+15 to +25°C

+2 to +8°C

-15 to -25°C

over dry ice

Other

Enter text...

Save

FIG. 5B

Add Comments

Record Name

1

Record Field

Actual Packaging Conditions

Field Value

+15 to +25°C

Comments

Enter|

I

Blinded/Unblinded

Blinded

Unblinded

E-Sign

E-Sign

Cancel

FIG. 5C

eSign ☰ SFX_GeneratePDFEnterComments	eSignature for Enter Comments I apply my electronic signature for QA Test Batch Record 01 and all related attachments. This signature is legally binding. *User Login ID I *Individual Signature Identifier Comments Approve Cancel							
Cat <table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td>Enter</td></tr> <tr><td>Comm</td></tr> <tr><td>Featur</td></tr> <tr><td>Blinder</td></tr> <tr><td>Record</td></tr> <tr><td>Record</td></tr> <tr><td>Field V</td></tr> </table>	Enter	Comm	Featur	Blinder	Record	Record	Field V	Approval History
Enter								
Comm								
Featur								
Blinder								
Record								
Record								
Field V								

FIG. 5D

Catalent®

Global SupplyFlex

Equipment

Q Search...

Q Search this list...

Printable View

Equipment Name	Equipment Group	Equipment Barcode	Site	Status	Record Type	Last Modified By	Last Modified Date
1 Equipment 1	SFX SIT Equipment Group	1	Site 1	Draft	Equipment	MDM	11/29/2022, 12:44 AM
2 Vial Washing Machine 1	Equipment Group_OQ1	2	Site 1	Draft	Equipment	MDM	9/7/2022, 1:46 AM
3 Vial Washing Machine 2	Equipment Group_OQ1	3	Site 1	Approved	Equipment	MDM	9/7/2022, 1:42 AM
4 Equipment 1Z3	SFX SIT Equipment Group	4	Site 1	Approved	Equipment	MDM	8/30/2022, 5:08 AM
5 SFX Equipment 2	SFX SIT Equipment Group	5	Site 1	Approved	Equipment	Person 1	10/14/2022, 3:37 AM
6 Equipment2ForNewGroup	NewEquipmentGroup-31stMarch	6	Site 2	Approved	Equipment	TeamLead	3/31/2023, 6:35 AM
7 Equip-for-Bottle-31stMarch	Bottle - Product Vision System	7	Site 2	Approved	Equipment	TeamLead	3/31/2023, 6:15 AM
8 Equipment REG1	Analytical Balance	8	Site 2	Approved	Equipment	TL SIT	3/13/2023, 6:07 AM
9 Blender	Blender	9	Site 2	Approved	Equipment	TL SIT	3/15/2023, 5:12 AM
10 Equipment 4	SFX Delivery 2	10	Site 2	Approved	Equipment	TL SIT	4/19/2023, 2:55 AM
11 Equipment 5	SFX Delivery 2A	11	Site 2	Approved	Equipment	perator1	3/15/2023, 6:09 AM
12 Equipment 2	SFX Delivery 2	12	Site 2	Approved	Equipment	Operator1	3/15/2023, 3:39 AM
13 Equipment 1	SFX Delivery 2	13	Site 2	Draft	Equipment	MDM	2/1/2023, 3:13 AM
14 Draft Equip	Analytical Balance	14	Site 2	Draft	Equipment	Operator 2	2/1/2023, 3:06 AM
15 Approved equip	Analytical Balance	15	Site 2	Approved	Equipment	TL SIT	3/14/2023, 2:10 AM
16 Analytical	Analytical Balance	16	Site 2	Approved	Equipment	TL SIT	4/21/2023, 1:01 AM
17 SFX Machine 1	SFX Delivery 2	17	Site 2	Approved	Equipment	AOPR	1/31/2023, 7:52 AM
18 Equipment 816	Packaging Job SFX	18	Site 2	In Approval	Equipment	MDM	11/28/2022, 8:47 AM
19 Tray Dryer	Packaging Job SFX	19	Site 2	Draft	Equipment	MDM	11/1/2022, 1:46 AM
20 TestEquip99	Test99	20	Site 2	Approved	Equipment	Operator	2/16/2023, 10:44 PM

FIG. 6A

Details

Room Assignment

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FIG. 6B

Q Search Barcode

Q Add Equipment

Complete this field

FIG. 6C

Scanned Equipment Details

Scanned Equipment does not belong to the Equipment Group setup in the XBR. Do you want to add it?

Equipment ...	JDE Asset ...	Equipment ...	Site	Is Clearanc...	Status
Equipment 1	Asset 1	Asset 2	San Diego (C...	No	Approved

Cancel

Add

FIG. 6D

Supervisor Approval

☐ Equipment Name	JDE Asset Number	Equipment Barcode	Status
☒ Equipment 1	Asset 1	EQ1	In Approval
☐ EQ1	AST1	EQ12	In Approval

Approve

Cancel

FIG. 6E

eSignature for Equipment

I apply my electronic signature for SD Equipment 25 and all related attachments.
This signature is legally binding.

* User Login ID

* Individual Signature Identifier

Comments

Approve

Cancel

Reject

FIG. 6F

Catalent®

Global SupplyFlex

Equipment

Q Search...

CS TESP-POR UAT RE...

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QA Test Batch Recor...

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Summary

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Equipment Setup

Staged Lot Verification

Input Reconciliation

Package Briefing

More

Q Search Barcode

Q Add Equipment

Complete this field

Enter Comments

Approval Required

History

Logged-in username : User

Equipment Group

Remove Equipment Group

Analytical Balance

Balance details

Equipment Name	JDE Asset Number	Equipment Barcode	Is Clearance Required	Equipment Setting Document	Status
Approved equip	12	EQ12	No		Approved

Equipment Group

Remove Equipment Group

Blender

Blender details

Equipment Name	JDE Asset Number	Equipment Barcode	Is Clearance Required	Equipment Setting Document	Status
Blender	bld	B1	No	Demo File.pdf	Approved

Equipment Group

Remove Equipment Group

Test09

Equipment Details

Equipment Name	JDE Asset Number	Equipment Barcode	Is Clearance Required	Equipment Setting Document	Status
Equip1	AST1	AT203	No	TestFile.pdf	Approved

▼ List of Entered Comments

Sequence	Comments	Feature Type	Blinded/Unblinded	Created By	Created Date/Time	Record Name	Record Field	Field Value
----------	----------	--------------	-------------------	------------	-------------------	-------------	--------------	-------------

FIG. 6G

Select file type

Select Select file type

Attachment

Upload Files

Or drop files

Only pdf can upload

Contains Unblinding Information

No

E sign

Close

FIG. 6H

Select file type

Select Select file type

Equipment Setup Form Checklist

Equipment Clearance Form Checklist

Others

E sign

Close

FIG. 6I

Assign Equipment Group

Equipment Group

UAT Testing

Cancel

Back

Add Equipment Group

FIG. 6J

Catalent

Global SupplyFlex

Batch Records

CST ESP-POR UAT RE

QA Test Batch Recor...

Search...

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Summary

WOBOM Details

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More

Package Briefing

Instructions

Summary

English

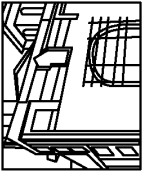
Package Instructions

Sequence

Image

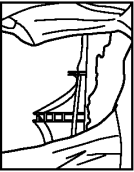
1

CST Stir together all of the crust ingredients EDITED



2

CST2 Press the crumbs into the bottom and up the sides of the pie pan



3

CST3 Mix together the room-temperature cream cheese and sugar until smooth

4

CST4 Mix in the eggs and vanilla again mixing until smooth

5

CST5 Pour the filling into the crust

6

CST6 Place the cheesecake in the oven and bake it for 20 minutes

7

CST7 Add a crust shield and bake for an additional 10 minutes

8

CST8 Remove the cheesecake from the oven

9

CST9 Serve cheesecake with fresh fruit if desired

Important Notes

Sequence

Important Notes

Attachments

Sequence

Attachments

1

TEST

Test PDF File 1.pdf.pdf

Deviation Attachments

Sequence

Attachments

E-Signature

FIG. 7A

Catalent®

Q Search...

★

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Global Supply/Flex

Batch Records

▼

CST ESP-POR UAT RE... ▼ x

QA Test Batch Recor... ▼ x

Summary

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Package Briefing

More ▼

Package Briefing

Instructions

Summary

Package Briefing

Logged-in username : User

Enter Comments

Generate PDF

Start Briefing

Edit History

Briefing Details Supervisor Approval

Sequence

Briefing Date

Briefed User

1

4/21/2023, 02:22 PM

User

List of Briefed Operators

Team Lead E-Signature

Briefing Date of Briefed User

Briefed User

Sequence

Briefing Date of Briefed User

Briefed User

1

2/9/2023, 01:14 PM

business Tester Operator1

1

3/30/2023, 05:26 PM

business Tester Operator1

2/9/2023, 01:15 PM

business Tester Teamlead1

3/30/2023, 05:27 PM

business Tester Teamlead1

List of Entered Comments

Sequence

Comments

Feature Type

Blinded/Unblinded

Created By

Created Date/Time

Record Name

Record Field

Record Value

FIG. 7B

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FIG. 7C

Package Briefing

Input Reconciliation

Job Actions

More

Generate PDF

Start Briefing

Enter Comments

FIG. 7D

Important Notes

Sequence

Attachments

Sequence

Deviation Attachments

Sequence

Important Notes

Attachments

Attachments

E-Signature

FIG. 7E

Package Briefing

Generate PDF

Start Briefing

Enter Com

Instructions

Summary

Briefing Details Supervisor Approval

Sequence	Briefing Date	Briefed User
1	11/8/2022, 12:48 AM	business Tester Operator1
2	11/8/2022, 12:49 AM	business Tester Operator2

Team Lead E-Signature

FIG. 7F

Briefing Details Supervisor Approval

Sequence	Briefing Date	Briefed User
Team Lead E-Signature		

List of Briefed Operators

Sequence	Briefing Date of Briefed User	Briefed User	Briefing Date of Briefing User	Briefing User
1	11/8/2022, 12:48 AM	business Tester Operator1	11/8/2022, 12:55 AM	business Tester Teamlead1
2	11/8/2022, 12:49 AM	business Tester Operator2	11/8/2022, 12:55 AM	business Tester Teamlead1

FIG. 7G

Catalent

Global SupplyFlex

Batch Records

▼

CST ESP-POR UAT RE...▼ x

QA Test Batch Recor...▼ x

Q Search...

Sandbox TestDeploy

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Summary

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More ▼

Logged-in username : User

Edit History

C Refresh JDE

Enter Comments

History

Output Material

Material ID	Material Description 1	Material Description 2	LCGI Destination Country	JDE Work Order	Supplier Lot	Labeled Lot	Customer Lot	Expiry Date	Quantity to be produced
1234	1234 mat		location	123456		1234 lot		2025-10-10	2

Input Material (Drug)

Source	Material ID	Material Description 1	Material Description 2	Quantity	JDE Lot #	Supplier Lot #	Customer Lot #	Status
BOM	1234	1234mat		2	1234 lot	supply 1		
JDE	1234	1234mat	Check JDE for Description	4	1234 lot	supply 1		Approved

Input Material (Non-Drug)

Source	Material ID	Material Description 1	Material Description 2	Quantity	JDE Lot #	Supplier Lot #	Customer Lot #	Status
BOM	12341	12341mat		2	12341 lot	supply 1		
JDE	12341	Check JDE for Description	Check JDE for Description	4	12341 lot	supply 1		Approved

Labels

Source	Material ID	Material Description 1	Material Description 2	JDE Lot #	Quantity	Status
BOM	1222	1222mat		1222 lot	2	
JDE	1222	Check JDE for Description	Check JDE for Description	1222 lot	1	Approved

Example Pack

Source	Material ID	Material Description 1	Material Description 2	JDE Lot #	Quantity	Status
BOM	1223	1223mat	EDITED 16NOV	1223 lot	1	
JDE	1223	Check JDE for Description	Check JDE for Description	1223 lot	1	Approved

▼ List of Entered Comments

FIG. 8

Catalent

Global SupplyFlax

Batch Records

CST ESP-POR UAT REGR 2

QA Test Batch Recor...

Search...

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Summary

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Job Actions

More

Batch Record

CST ESP-POR UAT REGR 2

Start Package Job

Execution Hold

End Package Job

BRX History

Ops Hold

End Package History

Submit for Review History

Ops Hold & Remove History

Active

Yes

Customer

Customer

Project Number

1234

Approval Status

Approved

Job Action

Ops Hold-Remove

BRX Review

Room Clearance

Room Setup

Equipment Setup

BRX Progress

Package Briefing

Staged Lot

Reconciliation

Packaging Instruction

Logged-in username :User

FIG. 9A

Summary

WO/BOM Details

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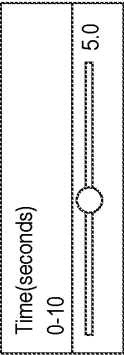
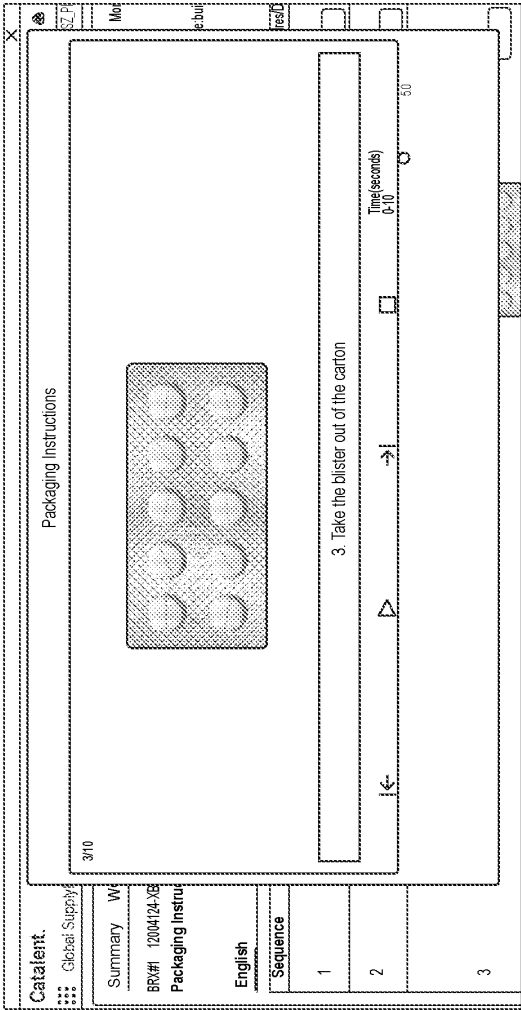
Staged Lot Verification

Input Reconciliation

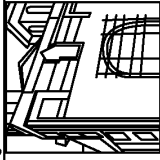
Package Instruction

More

FIG. 9B



Catalent		Search...		 	
Global SupplyFlex		CST ESP-PORT-LAT RE		OA Test Batch Recor...	
Packaging Instructions					
English					
Open Drawing Play Instructions Enter Comments History Logged-in username : User					

Sequence	Instruction	Image	Signatures	Date
1	CST Stir together all of the crust ingredients EDITED		E-Sign	
2	CST2 Press the crumbs into the bottom and up the sides of the pie pan		E-Sign	
3	CST3 Mix together the room-temperature cream cheese and sugar until smooth		E-Sign	
5	CST5 Pour the filling into the crust		E-Sign	
6	CST6 Place the cheesecake in the oven and bake it for 20 minutes		E-Sign	
7	CST7 Add a crust shield and bake for an additional 10 minutes		E-Sign	
8	CST8_Remove the cheesecake from the oven		E-Sign	
9	CST9_Serve cheesecake with fresh fruit if desired		E-Sign	

☒ Important Notes	
Sequence	Important Notes
☒ Attachments	
Sequence	Attachments

<!-- Content area -->	<!-- Attachment list --> ☐ Room clearance.pdf
--	--

1

FIG. 9F

Catalent.

Q Search...

Global SupplyFlex

Study Instructions

▼

OST ESP-POR UNIT RE...

▼ x

OCA Test Batch Recor...

▼ x

SFLA-3.5.2-SPI1

▼ x

Summary

WJBOEM Details

Room Assignment

Room Clearance

Room Setup

Equipment Setup

Staged Lot Verification

Input Reconciliation

Image Capture

More ▼

Edit History

Enter Comments

History

logged-in username : Users

BRX#: XBR-1

Image Capture

English German

Sequence	Instruction	Image
1	Ger Image Capture 1 effective	File Upload Download
2	Image Capture English effective	File Upload Download
3	Image cap 28	File Upload Download

Esign

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Click Photo

Image Name:

Blinded:

☐

Enter Image Name Here ...

Instruction Information

Sequence	Language	Instruction
1	German	Get Image Capture 1 effective

Close

FIG. 9H

Catalent

Sandbox TestDeploy

Global Supply/Flex
 Batch Records
 CST ESP-POR Unit RE...
 QA TestBatch Recor...

Summary
WOBOM Details
Room Assignment
Room Clearance
Room Setup
Equipment Setup
Staged Lot Verification
Input Reconciliation
Package Briefing
More >

Enter Comments

History

Logged-in username : User

Output Material

Item ID	Item Dos /Item Dos 2	Work Order	Produced QTY	QTY Produced Match	
'23	Item 123	45	1	false	

Input Material (Drug)

	Produced QTY	Item ID	Item Dos /Item Dos 2	JCS/Supplier Lot	BOM QTY	Issued QTY	Consumed QTY	Input Reject QTY	Sampled QTY	Returned QTY	Recon Limit	Recon%
	1	123	Check JDE for Description/Check JDE for Description	123 lot	4	10	4	0	0	61	99.7-100.3	100.0
Total -	1											

Input Material (Non-Drug)

	Produced QTY	Item ID	Item Dos /Item Dos 2	JCS/Supplier Lot	BOM QTY	Issued QTY	Consumed QTY	Input Reject QTY	Sampled QTY	Returned QTY	Recon Limit	Recon%
	0	123-4	Check JDE for Description/Check JDE for Description	123-4 lot	2	410	0	0	0	0	95-100	0
Total -	0											

Approval

FIG. 10A

Catalent

Global SupplyFlex

Batch Records

QST Esp-POR LAT RE. v x

Search...

Warning! Reconciliation percentage is not within the limits!

Success Records updated

Sandbox TestDeploy

Icons

Summary

WO/BOM Details

Room Assignment

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Room Setup

Equipment Setup

Staged Lot Verification

Input Reconciliation

Package Briefing

More v

Enter Comments

History

Logged-in username : User

Output Material

Item ID	Item Dos 1/Item Dos 2	Work Order	Produced QTY	QTY Produced Match
123	123 item	2	1	false

Input Material (Drug)

Produced QTY	Item ID	Item Dos 1/Item Dos 2	JDE/Supplier Lot	BOM QTY	Issued QTY	Consumed QTY	Input Reject QTY	Returned QTY	Recon Limit	Recon%
1	123	Check JDE for Description/Check JDE for Description	123 lot	4	10	4	0	5	99.7-100.3	90.0
Total - 1										

Input Material (Non-Drug)

Produced QTY	Item ID	Item Dos 1/Item Dos 2	JDE/Supplier Lot	BOM QTY	Issued QTY	Consumed QTY	Input Reject QTY	Returned QTY	Recon Limit	Recon%
0	1234	Check JDE for Description/Check JDE for Description	1234 lot	2	410	0	0	0	95-100	0
Total - 0										

Approval

Approval

FIG. 10B

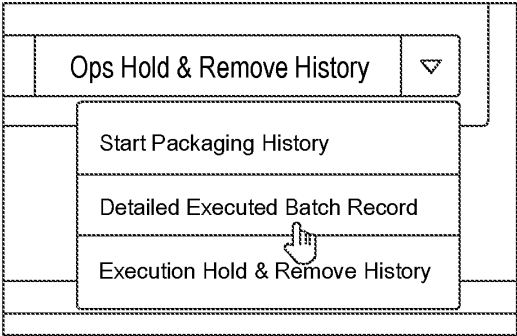


FIG. 11A

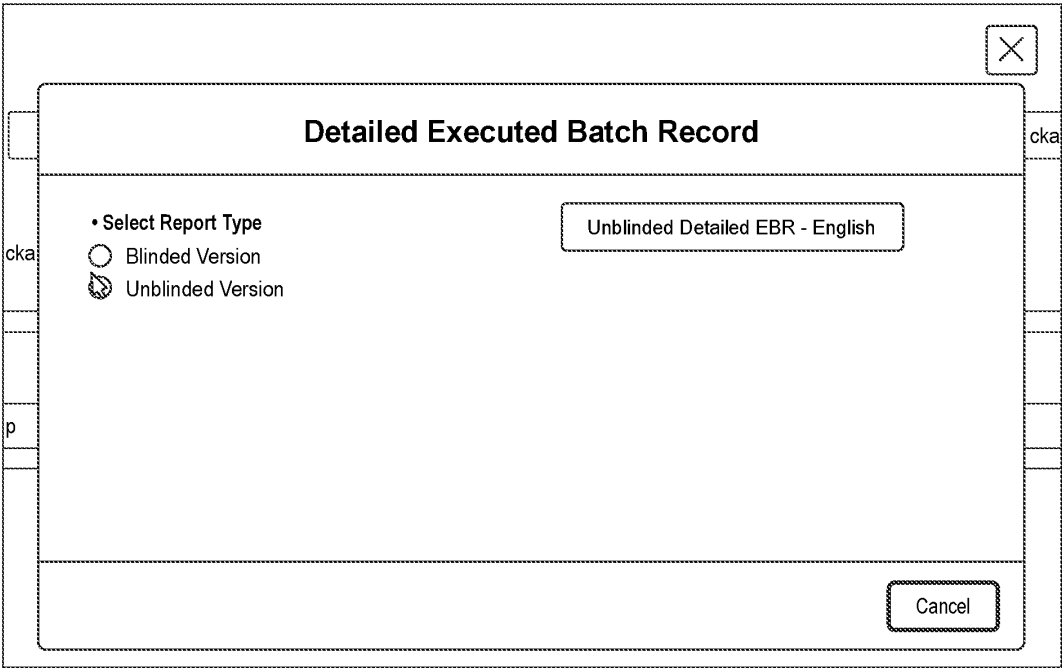


FIG. 11B

Catalent.

Blinded Executed Batch Record

SupplyFlex®

Executed Batch Record

Batch Record : XBR-1

Status: In Execution

Customer: Customer

Catalent Site: Site

Project Number: 123

Customer Protocol: 1345

1. APPROVALS

PRE-EXECUTION		POST-EXECUTION	
Created By (Pre-Production)	Name: order	Reviewed By (Production)	Printed Name:
	Title: Order		Title:
	Date of Electronic Signature: 30-Jan-2023		Signature:
	07:07:49(UTC)		Date:
Approved By (Catalent)	Name: order	Approved By (Quality)	Printed Name:
	Title: Order		Title:
	Date of Electronic Signature: 30-Jan-2023		Signature:
	07:09:14(UTC)		

Catalent.

Blinded Executed Batch Record

SupplyFlex®

Executed Batch Record

Batch Record : XBR-1

Status: In Execution

Customer: Customer

Catalent Site: Site

Project Number: 123

Customer Protocol: 1345

Related Global Trackwise Records

Record Number	Type	Short Description	Incidents recorded in Batch Record:
N/A	N/A	N/A	

DOCUMENT ERROR CODES - note codes written within the Batch Record must be CIRCLED

Code	Explanation
SP	Spelling Error
CE	Calculation Error
LE	Late Entry
CL	Clarification
DE	Data Error
WE	Writing Error
EE	Entry Error

FIG. 12

Catalent.

Blinded Executed Batch Record

SupplyFlex®
Executed Batch Record

Batch Record : XBR-1
Status: In Execution
Customer: Customer

Catalent Site: Site
Project Number: 123
Customer Protocol: 1345

OUTPUT MATERIALS							
Item Number	Item Description	Output Material Type	Destination Country/ies Label Country Group/s	Planned Output Quantity	JDE WO Number	Labeled Lot Number	Labeled Expiry Date
123	123 item	FG	Site	2	12345	12345 lot	Oct 10, 2025

STORAGE CONDITIONS				
Item Number	Item Description	Humidity Control Details	Light Control Details	Storage Temperature
123	123 item	Between 30 to 50%RH	Between 100 to 200 in lux	Between 15 to 25 in Celsius

FIG. 12
CONTINUED

Catalent.

Global SupplyFlex

Study Instructions

Q Search...

▼

ST ESP-POR UAT RE... ▼ X

FLA-3.5.2-SP1 ▼ X

Q Search...

Q Search...

Q Search...

Summary

WO/BOM Details

Room Assignment

Room Clearance

Room Setup

Equipment Setup

Staged Lot Verification

Input Reconciliation

Package Briefing

IPC

More ▼

Target Value Approval

IPC Approval

Re-execute IPC

Enter Comments

History

Logged-in username : User

Search...

Q

Add

Second Approval for Add

IPC1

Not Required

JDE Work Order #

Job Type : Assembly and Labeling

Inst Name Set : IPC 1

Inst Set Description :

Version : 1

Number of Samples Required : 3

English

German

Sequence	Check	Response Type	Target Value	Actual Value	Result
1	CST1	Pass/Fail with Value	11		Pass Fail N/A
2	CST2	Pass/Fail			Pass Fail N/A
Number of Samples taken ☐ NA					
Container Id ☐ NA					
Kit Details ☐ NA					

FIG. 13A

Summary		WO/BOM Details		Room Assignment		Room Clearance		Room Setup		Equipment Setup		Staged Lot Verification		Input Reconciliation		IPC Summary		More 		
																			Logged-in username:business Tester Operator1	
																			Enter Comments	
Sequence		JDE Work Order #		IPC Checklist Name		Remarks		Executed By		Execution Date/Time		Overall Result								
1		321		CST IPC CHEESECHECKS		samples taken as directed		business Tester OpsQA2		09-Feb-2023 15:29:32 (UTC)		Pass								
2		12345677		CST IPC CHEESECHECKS		N/A		business Tester OpsQA2		08-Mar-2023 20:05:50 (UTC)		Fail								

FIG. 13B

Please perform failure check approval before any other operations

Failure Check Approval

FIG. 13C

Select Instruction Set

Bottle filling - removal torque - In process

×

Add

Second Approval for Add

FIG. 13D

Select Instruction Set

Search...

Second Approval Required !

Q

Add

Second Approval for Add

FIG. 13E

Approval	
☒ Instruction Set Name	Status
☒ Bottle filling - removal torque - In process	In Approval
ApproveCancel	

FIG. 13F

Select IPC

Bottle filling - removal torq... ▾

Not Required

FIG. 13G

Select IPC

Bottle filling - removal torq... ▾

Marked as NOT Required

FIG. 13H

Global SupplyFlex

Study Instructions

▼

13CST ESP-POR UAT RE... ▼ ×

13 QA Test Batch Recor... ▼ ×

13 SFLA-3.5.2-SP1 ▼ ×

Q Search...

🔍 📄 📱 ? 🛡️ ⚙️

Summary

WO/BOM Details

Room Assignment

Room Clearance

Room Setup

Equipment Setup

Staged Lot Verification

Input Reconciliation

IPC Summary

More ▼

Enter Comments

Logged-in username : User

Sequence	JDE Work Order #	IPC Checklist Name	Remarks	Executed By	Execution Date/Time	Overall Result
1		CST1		TL SIT	20-Feb-2023 08:21:44 (UTC)	Pass
2	1234	CST2	24	TL SIT	20-Feb-2023 08:23:21 (UTC)	Pass

▼ List of Entered Comments

Sequence	Comments	Feature Type	Blinded/Unblinded	Created By	Created Date/Time	Record Name	Record Field	Field Value
----------	----------	--------------	-------------------	------------	-------------------	-------------	--------------	-------------

BRX Review

Room Clearance

Room Setup

Equipment Setup

BRX Progress

Package Briefing

Staged Lot

Reconciliation

Packaging Instruction

30

Catalent.

Global SupplyFlex
 Study Instructions
 CST ESP-PDR Unit RE...
 OA Test Batch Recor...
 SFLA-3.5.2.SPI

v x
 v x
 v x

Summary
 WO/BOM Details
 Room Assignment
 Room Clearance
 Equipment Setup
 Staged Lot Verification
 Input Reconciliation
 Samples
 More v

Edit History
 Enter Comments
 History
 Logged-in username : User

Output Material

Item ID	Item Des (Item Des 2)	Partial Sample(Y/N)	Required QTY	Sample Type	Sample Notes
123	123item	No	0		Take Sample

Sample taken

Sample Type	Taken QTY	Additional Sample Notes	User Date/Time

v List of Entered Comments

Sequence	Comments	Feature Type	Blinded/Unblinded	Created By	Created Date/Time	Record Name	Record Field	Field Value

BRX Review
Room Clearance
Room Setup
Equipment Setup
BRX Progress
Package Briefing
Staged Lot
Reconciliation
Packaging Instruction

FIG. 14A

UAT RE...

▼

×

QA Test Batch Recor...

▼

×

SP1

▼

×

×

Sample Table Data

*Taken QTY

1.00

*Sample LOT#

123456

Additional Notes

Enter Additional Sample Notes...

E-Sign

FIG. 14B

Add Comments

Record Name

Room20

Record Field

Room Name

Field Value

Room20

Comments

Blinded/Unblinded

☐ Blinded

☒ Unblinded

E-Sign

E-Sign

Cancel

FIG. 15

BRX Edit

BRX Edit

	Previous Value	New Value
General LA Note	Test 1	
XBR Note	Test 1	
Kit Number Range Start	1	
Kit Number Range End	5	
Sequence Number Range Start	1	
Sequence Number Range End	5	
Temperature Range Between		
Low Range in °C	15	
High Range in °C	25	
Humidity Range Between		
Low Range in %RH	1	
High Range in %RH	5	
Light Conditions Between		
Low Range in 'lux'	100	
High Range in 'lux'	200	

Cancel

Save

FIG. 16A

Output Material	
Item ID ⓘ	Item Description 1
123	123 item
Item Description 2	Supplier Lot Number ⓘ
Labeled Lot Number ⓘ	Customer Lot Number ⓘ
123 lot	
Expiry Date ⓘ	Quantity to be Manufactured
Dec 30, 2022	5
Labeled Expiry Date	
DEC30	
Save	

FIG. 16B

Input Material (Drug)	
Item ID ⓘ	Item Description 1
123	123 item
Item Description 2	BOM Quantity ⓘ
	1.000000
Supplier Lot Number ⓘ	Customer Lot Number ⓘ
SUPL0T 1	
total quantity staged	Reconciliation Limit
☒ Customer Specific	Lower Reconciliation Limit
	99.0%
Upper Reconciliation Limit	
101.0%	
Save	

FIG. 16C

OM Sample

Information

Item ID ⓘ

123

Includes Samples: Y/N

No ▾

Partial Sample

No ▾

Sample Quantity

0

Sample Type

--None-- ▾

Sample Notes

Save

FIG. 16D

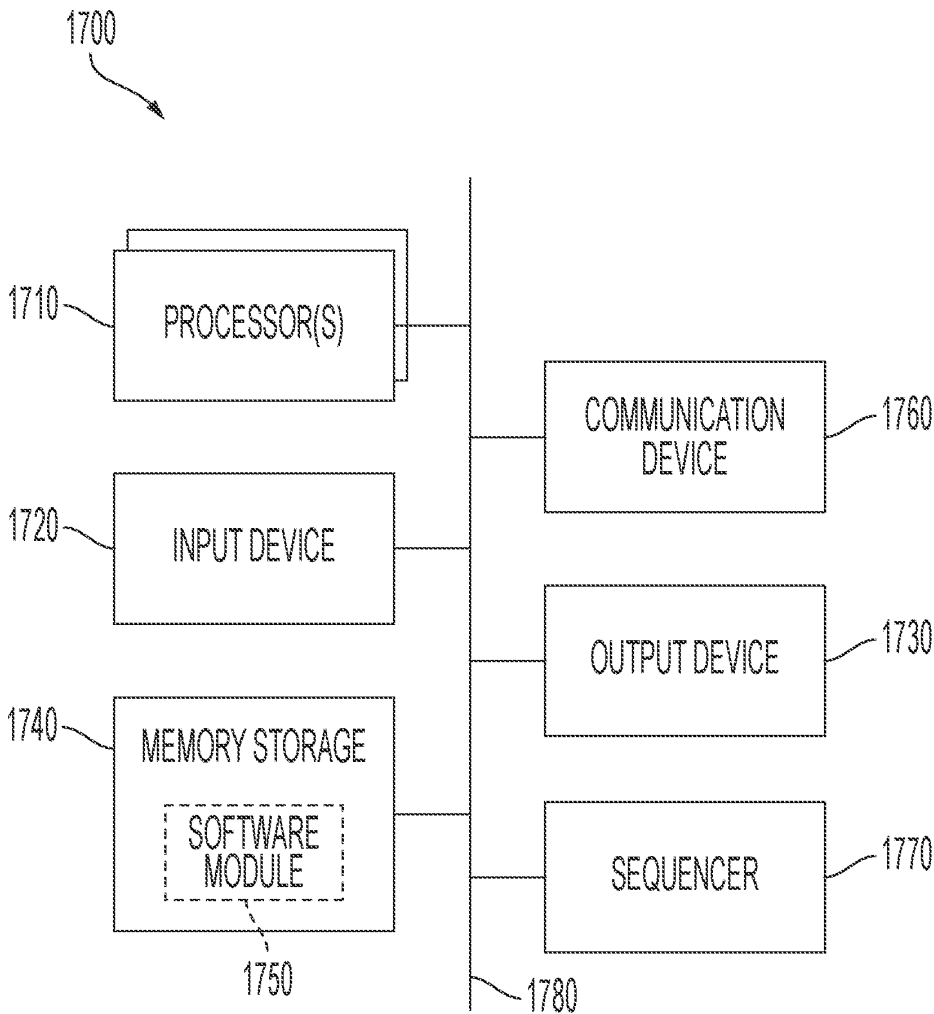


FIG. 17