

100A

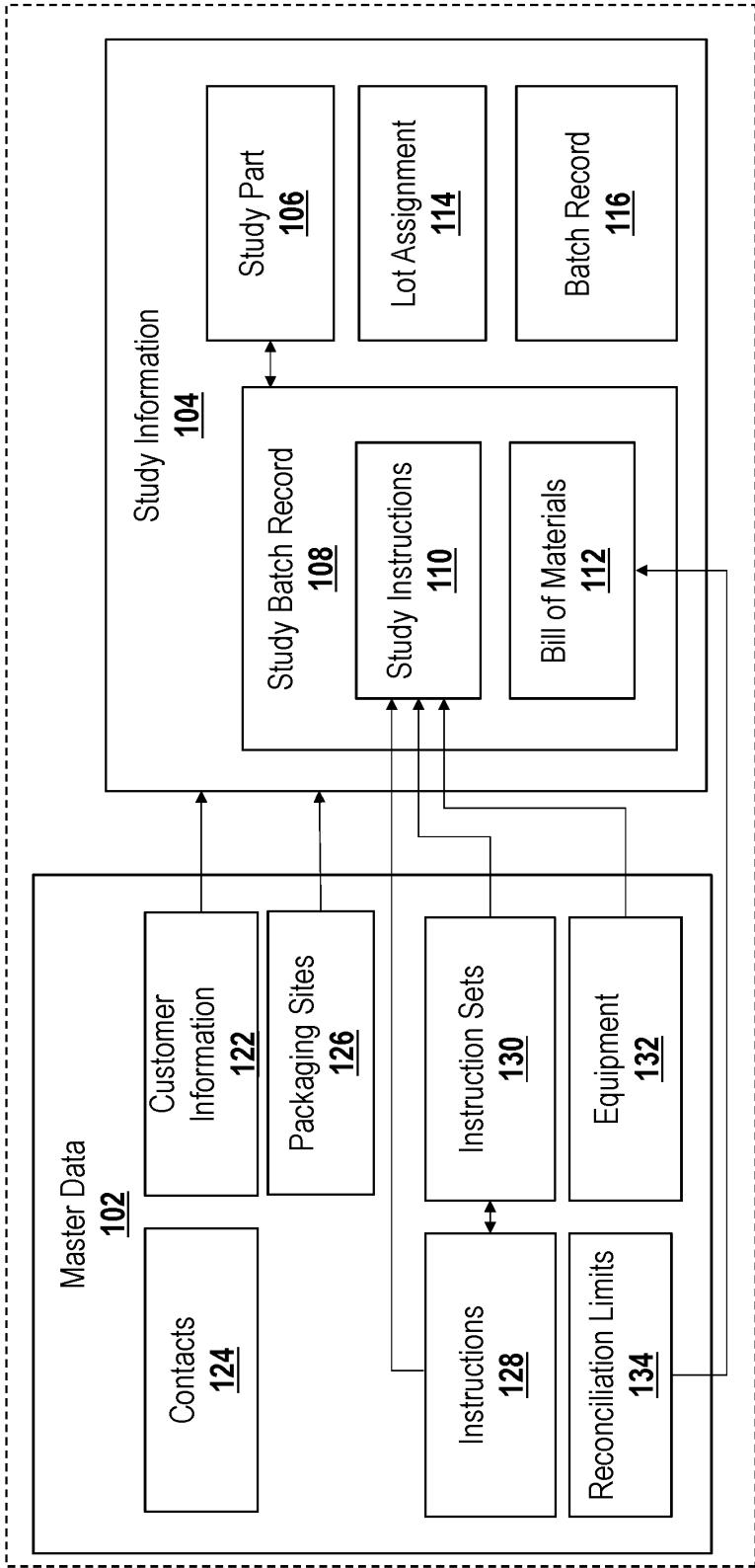


FIG. 1A

100B

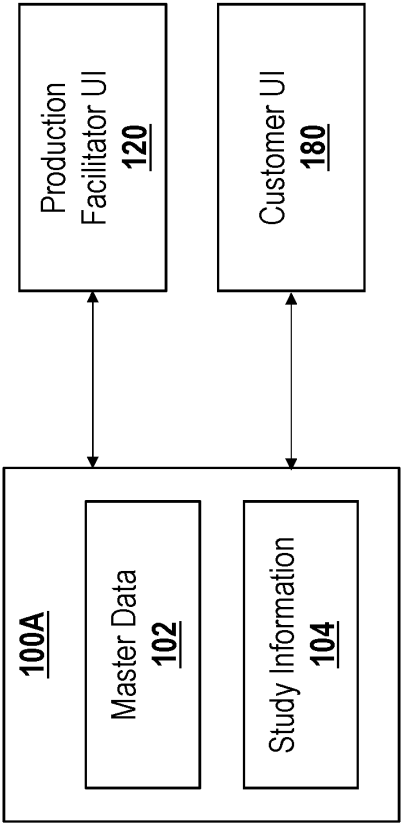


FIG. 1B

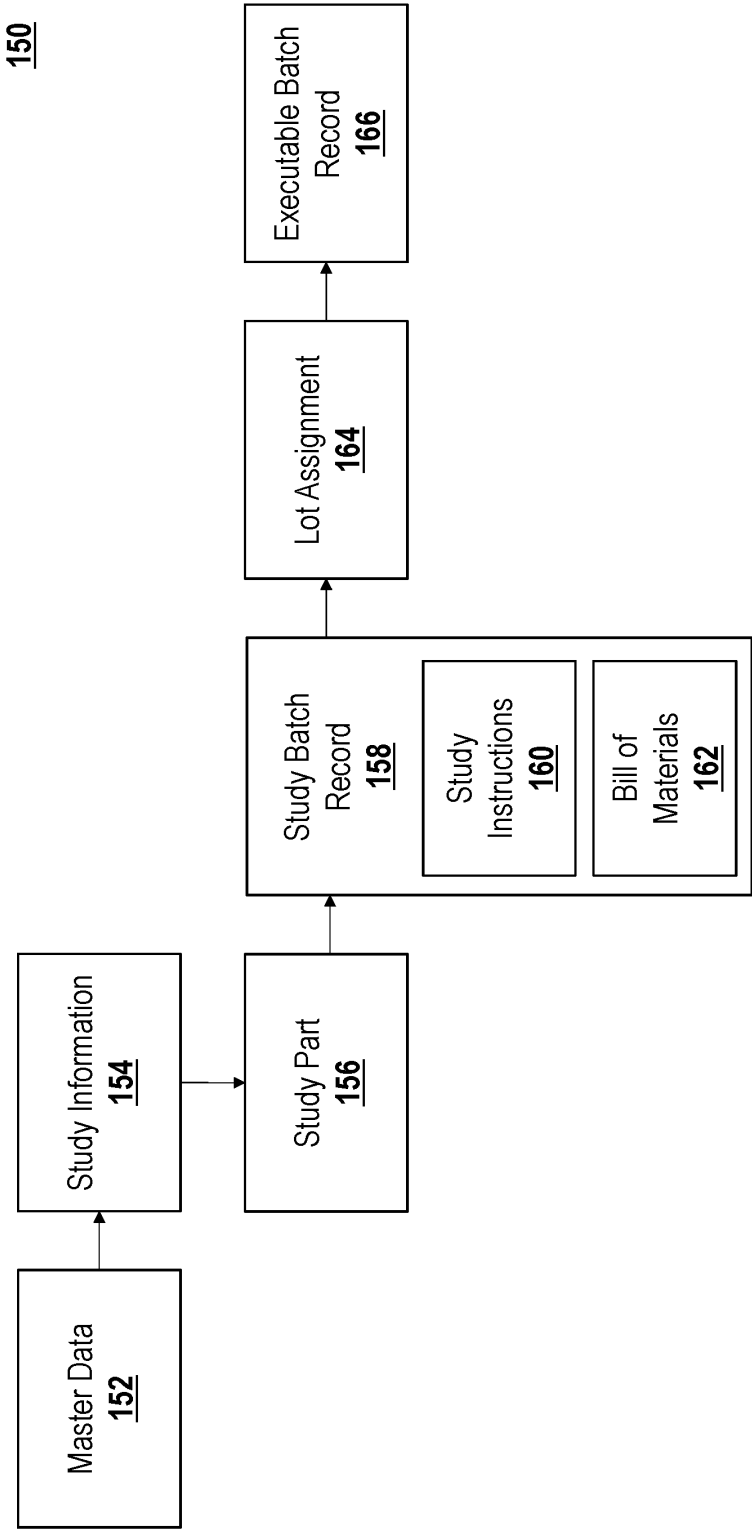


FIG. 1C

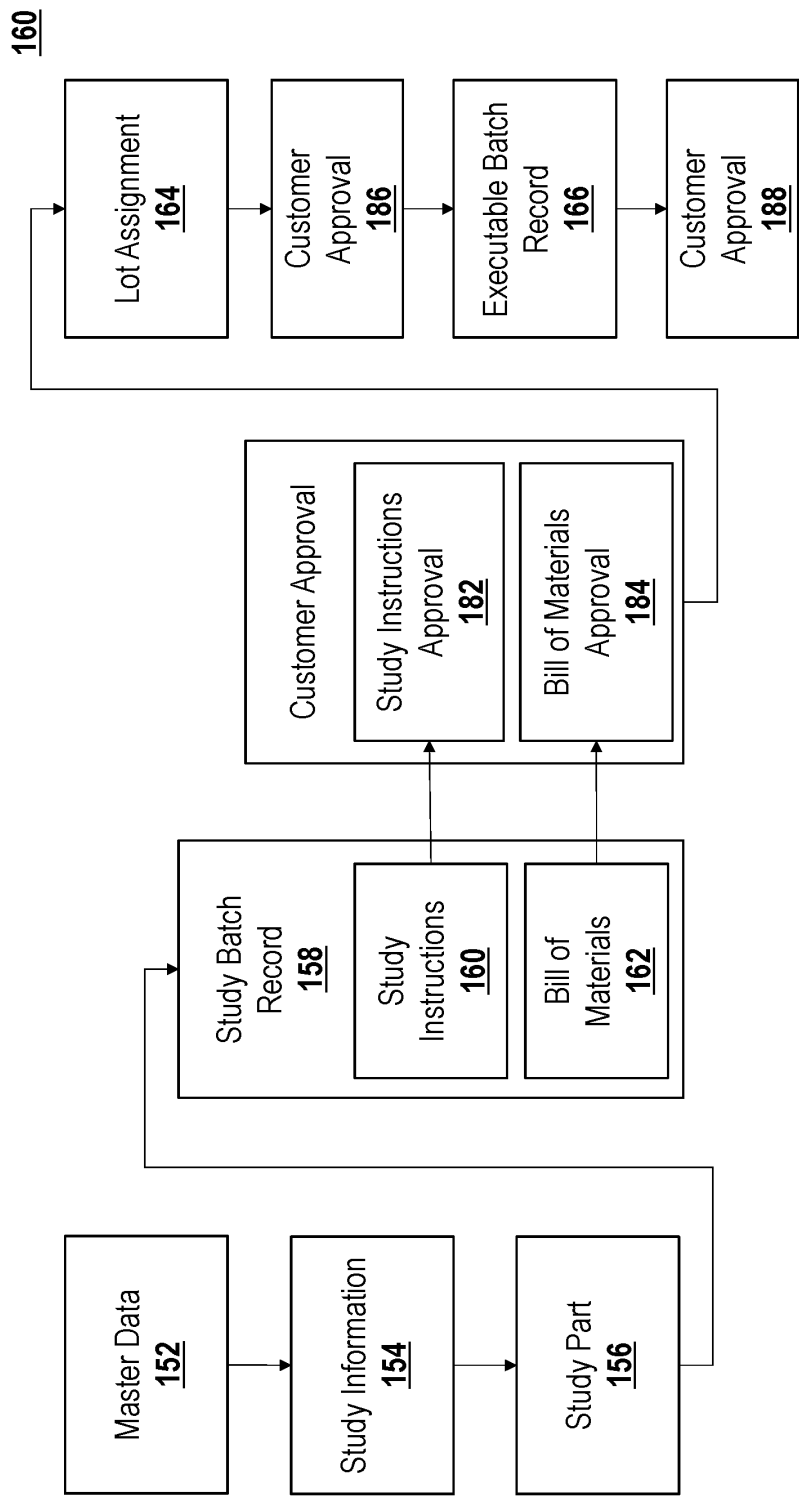


FIG. 1D

220A

228

CATALENT

SANDBOX: TESTDEPLOY

SEARCH

TESTING JOB TITLE

GLOBAL SUPPLYFLEX

INSTRUCTION SETS

SFX SIT C...

TEST COMMUNITY REJECT

AFAAQ

TESTING JOB TITLE

CUSTOMER

SFX SIT CUSTOMER 1

CUSTOMER NUMBER

422817

IS ENABLED

226A

CUSTOMER DETAILS

CONTACTS

STUDIES

CUSTOMER NAME

SFX SIT CUSTOMER 1

CUSTOMER NUMBER

422817

ENABLE DISABLE ACTION

APPROVE ENABLE

ENABLE REASON

DISABLE TO ENABLE

DISABLE REASON

CUSTOMER GROUP

CUST_GROUP23

IS ENABLED

PARTNER ACCOUNT

SYSTEM INFORMATION

CREATED BY

DEVAKI BATHALAPALLI MDM USERS

2/1/2021, 4:21 AM

CURRENT TIME

07-DEC-2021 13:30:50 (UTC)

CUSTOMER OWNER

CREATE STUDY INFORMATION

HISTORY

FIG. 2A

220B →

SANDBOX: TESTDEPLOY

CATALANT

SEARCH

TESTING JOB TITLE ? ? ? ? ?

GLOBAL SUPPLYFLEX

INSTRUCTION SETS

TEST COMMUNITY REJECT

AFAAQ

TESTING JOB TITLE

TESTING JOB TITLE

SFX SIT C...

CUSTOMER

SFX SIT CUSTOMER 1

222

224

CREATE STUDY INFORMATION

HISTORY

CUSTOMER NUMBER IS ENABLED

422817

226B

CUSTOMER DETAILS

CONTACTS

STUDIES

RELATED CONTACTS (6+)

CONTACT NAME

EMAIL

TITLE

DB1000-QA

DEVAKI.BATHALAPALLI@CAPGEMINI.COM

TESTER

DS 31819

PADMA-SREE-BANTIPALLI@CAPGEMINI.COM

PARTNER ADMIN1222222

PADMA SREE ADMIN

ADMIN KT

ERNIE BANKS

CHRIS-CUTLIP@CAPGEMINI.COM

MR CUB

PARTNER ADMIN PADMA SREE BANTIPALLI PARTNER

PADMA-SREE.BANTIPALLI@CAPGEMINI.COM

TESTER-2

VIEW ALL

FIG. 2B

220C →

SANDBOX: TESTDEPLOY

CATALOG

SEARCH

TESTING JOB TITLE

TESTING JOB TITLE

GLOBAL SUPPLYFLEX INSTRUCTION SETS

60010002

TEST COMMUNITY REJECT

AFAAQ

TESTING JOB TITLE

TESTING JOB TITLE

SFX SIT C

DB10000

CONTACT

MR. DB10000-QA

226C

HISTORY

CUSTOMER NAME

SFX SIT CUSTOMER 1

EMAIL

DEVAKI.BATHALAPALLI@CAPGEMINI.COM

DETAILS

CONTACT OWNER

DEVAKI BATHALAPALLI CATALENT SYSTEM ADMIN

NAME

MR. DB10000-QA

CUSTOMER NAME

SFX SIT CUSTOMER 1

EMAIL

DEVAKI.BATHALAPALLI@CAPGEMINI.COM

TITLE

TESTER

SYSTEM INFORMATION

CREATED BY

DEVAKI BATHALAPALLI CATALENT SYSTEM ADMIN, 7/21/2021, 9:16 AM

RELATED CUSTOMERS (3)

CUSTOMER NAME

SFX SIT CUSTOMER 1

SFX SIT CUSTOMER 2

SFX SIT CUSTOMER 8

DIRECT

☒

☐

☐

ROLES

STUDY APPROVER

STUDY APPROVER

STUDY APPROVER

VIEW ALL

FIG. 2C

220D

CATALENT

SANDBOX: TEST/DEPLOY

Q SEARCH...

TESTING JOB TITLE

TESTING JOB TITLE

GLOBAL SUPPLY/LEX

INSTRUCTION SETS

TEST COMMUNITY REJECT

AFAAQ

TESTING JOB TITLE

TESTING JOB TITLE

SFX SIT C...

DB10000

CUSTOMER

SFX SIT CUSTOMER 1

222

224

CREATE STUDY INFORMATION

HISTORY

CUSTOMER NUMBER IS ENABLED

422817

226D

CUSTOMER DETAILS

CONTACTS

STUDIES

STUDY INFORMATION (10+)

10+ ITEMS SORTED BY PROJECT NUMBER-UPDATED A FEW SECONDS AGO

PROJECT NUMBER	CUSTOMER PROTOCOL	SI DESCRIPTION	VERSION	JDE ID	STUDY PURPOSE	STATUS
1	SFX SIT SHIGA TEST	SI SHIGA TESTING	1	422817	MEDICINE	OBSOLETE
2	SFX SIT SHIGA TEST	DRYRUN XBR REPORT	2	422817	MEDICINE	APPROVED
3	SFX SIT SHIGA TEST	DRYRUN XBR REPORT	3	422817	MEDICINE	DRAFT
4	SFX SIT 1A	CUSTOMER SI TESTING	1	422817	TESTING	HOLD
5	SFX SIT 1A	CUSTOMER SI TESTING	2	422817	TESTING	HOLD
6	SFX SIT 1A	CUSTOMER SI TESTING	3	422817	TESTING	HOLD
7	SFX SIT 1A	CUSTOMER SI TESTING	3	422817	TESTING	HOLD
8	SFX SIT 1A	CUSTOMER SI TESTING	4	422817	TESTING	HOLD
9	SFX SIT 1A	CUSTOMER SI TESTING	5	422817	TESTING	HOLD

FIG. 2D

220E

SANDBOX: TESTDEPLOY

CATALENT

228

GLOBAL SUPPLYFLEX

SITES

60010002

TEST COMMUNITY REJECT

AFAA

TESTING JOB TITLE

KANSAS CITY (CSS)

SEARCH

?

?

?

226E

KANSAS CITY (CSS)

LANGUAGE

ENGLISH

224

PRINTABLE VIEW

HISTORY

DETAILS

COMMENTS

SITE NAME

KANSAS CITY (CSS)

JDE BRANCH PLANT

13201

COMPANY CODE

00132

LANGUAGE

ENGLISH

ENABLED

EXTERNAL O

COUNTRY

UNITED STATES

OP REQUIRED?

NO

MANUFACTURING AUTHORIZATION NUMBER

O

LONG ADDRESS

CATALENT PHARMA SOLUTIONS

10245 HICKMAN MILLS DR,

KANSAS CITY,

MO 64137,

UNITED STATES

ADDRESSES

ADDRESS 1

CATALENT PHARMA SOLUTIONS

10245 HICKMAN MILLS DR,

KANSAS CITY,

MO 64137,

UNITED STATES

DISTRIBUTION MAILBOX

SUPPLYFLEX-DIST-KCM@CALENT.COM

PRODUCTION MAILBOX

SUPPLYFLEX-PACK-KCM@CALENT.COM

CREATED BY

DATA LOAD USER, 1/28/2021, 2:46 PM

CURRENT TIME

07-DEC-2021 13:35:52 (UTC)

OWNER

DATA LOAD USER

2025

220F

CATALENT

228

SANDBOX: TESTDEPLOY

SEARCH

GLOBAL SUPPLYFLEX EQUIPMENT

60010002

TEST COMMUNITY REJECT

AFAAQ

TESTING JOB TITLE

KANSAS CITY (CSS)

BLENDER

EQUIPMENT BLENDER

226F

PRINTABLE VIEW HISTORY

DETAILS

RELATED EQUIPMENT

FIELD HISTORY

EQUIPMENT GROUP DETAILS

EQUIPMENT/EQUIPMENT GROUP NAME

BLENDER

RECORD TYPE

EQUIPMENT GROUP

SYSTEM INFORMATION

CREATED BY

DATA LOAD USER

1/28/2021, 2:49 PM

CURRENT TIME

07-DEC-2021 13:36:38 (UTC)

FIG. 2F

220G

CATALENT

228

SEARCH

SANDBOX: TESTDEPLOY

GLOBAL SUPPLYFLEX

RECONCILIATION LIMITS

60010002

TEST COMMUNITY REJECT

AFAAQ

TESTING JOB TITLE

KANSAS CITY (CSS)

BLENDER

BRIGHT STOCK

224

APPROVAL HISTORY

RECONCILIATION LIMIT

BRIGHT STOCK

UPPER RECONCILIATION LIMIT

101.00%

226G

LOWER RECONCILIATION LIMIT

99.00%

DETAILS

RECONCILIATION LIMIT

BRIGHT STOCK

DESCRIPTION

BRIGHT STOCK UNLABELED PACKAGED PRODUCT..COLD FORM BLISTERS

RL UNIQUE IDENTIFIER

RL-4

RECONCILIATION LIMITS

LOWER RECONCILIATION LIMIT

99.00%

UPPER RECONCILIATION LIMIT

101.00%

VERSION AND STATUS

VERSION

1

PREVIOUS VERSION

OWNER

DATA LOAD USER

CREATED BY

DATA LOAD USER

1/28/2021, 12:42 PM

STATUS

OBSOLETE

REASON FOR VERSIONING

CURRENT TIME

07-DEC-2021 13:37:36 (UTC)

FIG. 2G

220H

CATALENT228

SANDBOX: TESTDEPLOY

SEARCH...

GLOBAL SUPPLIER INSTRUCTIONS60010002TEST COMMUNITY REL. AFAAQTESTING JOB TITLEKANSAS CITY (CSS)BLENDERBRIGHT STOCKRODGERS INACTIVE INS.

INSTRUCTIONS

RODGERS INACTIVE INSTRUCTION TEST

INSTRUCTION TYPEINSTRUCTION CATEGORYLANGUAGE INACTIVEVERSION

PACKAGING INSTRUCTIONASSEMBLYENGLISH3.0

226H

224

PRINTHISTORY

ENGLISH242H

NEW VERSIONINACTIVE

GERMANJAPANESECHINESE

NEW VERSION

TEXT AND EXECUTION RESULT

TEXT
RODGERS INACTIVE INSTRUCTION TEST
RESPONSE TYPE

TEXT AND EXECUTION RESULT

TEXT
GERMAN TRANSLATION
RESPONSE TYPE

EFFECTIVE, INACTIVE OR VERSION

EFFECTIVE
INACTIVE

INSTRUCTION GROUP ID

MADE EFFECTIVE BY USER
NICK-PRE PROD RODGERS

MADE EFFECTIVE BY USERNAME
NICHOLAS.RODGERS@CAATALENT.TESTDEPLOY

EFFECTIVE COMMENTS
INACTIVE COMMENTS

EFFECTIVE, INACTIVE OR VERSION

EFFECTIVE
INACTIVE

INSTRUCTION GROUP ID

MADE EFFECTIVE BY USER
NICK-PRE PROD RODGERS

MADE EFFECTIVE BY USERNAME
NICHOLAS.RODGERS@CAATALENT.TESTDEPLOY

EFFECTIVE COMMENTS
INACTIVE COMMENTS

VERSION
3.1

INSTRUCTION GROUP ID
IGP-3723

MADE EFFECTIVE DATE
9/14/2021, 12:48 PM

EFFECTIVE COMMENTS
INACTIVE COMMENTS

FIG. 2H-1

INSTRUCTION DETAILS

LANGUAGE

INSTRUCTION TYPE

PACKAGING INSTRUCTION

INSTRUCTION CATEGORY

ASSEMBLY

CUSTOMER

SYSTEM DETAILS

INST UNIQUE IDENTIFIER

1934

CURRENT TIME

07-DEC-2021 13:38:24 (UTC)

CREATED BY ID

NICK-PRE PROD RODGERS

INSTRUCTION DETAILS

LANGUAGE

INSTRUCTION TYPE

PACKAGING INSTRUCTION

INSTRUCTION CATEGORY

ASSEMBLY

CUSTOMER

SYSTEM DETAILS

CURRENT TIME

07-DEC-2021 13:38:24 (UTC)

CREATED BY ID

NICK-PRE PROD RODGERS

TRANSLATIONS (3)

NEW

TITLE	TEXT	LANGUAGE	VERSION
GERMAN TRANSLATION	GERMAN TRANSLATION	GERMAN	3.1
JAPANESE TRANSLATION	JAPANESE TRANSLATION	JAPANESE	3.1
CHINESE TRANSLATION	CHINESE TRANSLATION	CHINESE	3.1

VIEW ALL

INSTRUCTION SETS (0)

GERMAN JAPANESE CHINESE

STUDY INSTRUCTIONS (1)

1 ITEM • UPDATED A FEW SECONDS AGO

SBR

INSTRUCTION N...

INSTRUCTION PARENT

101 RODGERS

INACTIVE INSTRUCT...

RELATED

BATCH RECORD

PRIMARY OPEN

BLISTER PACKING...

SEQUENCE

10

BLISTER PACKIN...

STATUS

DRAFT

INSTRUCTION...

VIEW ALL

FIG. 2H-2

2201

SANDBOX: TEST/DEPLOY

CATALENT

228

SEARCH...

GLOBAL SUPPLY CHAIN INSTRUCTIONS SETS

80010002

TEST COMMUL...

HEAD

TESTING JOB TL

KANSAS CITY

BLENDER

BRIGHT STOCK

RODGERS INC.

BARCODE CON

BARCODE CON

INSTRUCTION SETS

☒ BARCODE CONTENT VERIFICATION

INSTRUCTION TYPE STATUS VERSION

IN PROCESS CHECK APPROVED 1.0

2261

SELECT INSTRUCTION CATEGORY EFFECTIVE?

OTHER

YES

SEARCH

ENGLISH GERMAN JAPANESE CHINESE

TEXT

USING A BARCODE SCANNER, VERIFY BARCODE CONTENTS MATCH THE PRINT SETUP SPECIFIED IN THE BATCH RECORD

INSTRUCTIONS

USING A BARCODE SCANNER, VERIFY BARCODE CONTENTS MATCH THE PRINT SETUP SPECIFIED IN THE BATCH RECORD

EFFECTIVE, INACTIVE AND VERSION

VERSION

1.0

INACTIVE

CREATED BY

DATA LOAD USER, 1/28/2021, 9:29 PM

CURRENT TIME

07-DEC-2021 13:41:03 (UTC)

IS UNIQUE IDENTIFIER

IPC-65

INSTRUCTION GROUPINGS

NAME

BARCODE-CONTENT-VERIFICATION

DESCRIPTION

WHEN PRINTING BARCODES - ELECTRONICALLY CHECKING READABILITY AND CONTENT OF BARCODES THAT ARE PRINTED IN LINE

LANGUAGE

ENGLISH

INSTRUCTION TYPE

IN PROCESS CHECK

JOB TYPE

OTHER

INSTRUCTION SET NAME

ENGLISH-RELATED INSTRUCTION SETS

HISTORY

FIG. 21

320A

SANDBOX: TESTDEPLOY

CATALENT

SEARCH...

GLOBAL SUPPLYFLEXSTUDY INFORMATION60010002

STUDY INFORMATION60010002

324

APPROVAL NEW VERSION [CREATE LOT ASSIGNMENT] HOLD [INACTIVE]

CUSTOMER

CUSTOMER PROTOCOL

CREATED FROM PSPADI VERSION

VERSION

STATUS

SFX PQ CUSTOMER 2

SFX PQ 2

1

5

APPROVED

322-326A

STUDY INFORMATION

DESTINATION COUNTRIES LABEL...

ON GROUPS

DOSAGE CODES

STUDY APPROVERS

STUDY PARTS

PROJECT MANAGERS

BUSINESS UNIT

INFORMATION

CUSTOMER PROTOCOL

COC TYPE

CLINICAL

PROJECT NUMBER

EUDRACT NUMBER

60010002

QTA NUMBER

2222222

STUDY PURPOSE

DOUBLE BLINDED, PHASE III, MULTIDOSE STUDY TO EVALUATE, EFFICACY, SAFETY AND TOLERABILITY OF SFX SIT PRIMARY IM DRUG 1 ON SUBJECTS WITH MYELOFIBROSIS

SIDESCRIPTION

PRIMARY, OPEN, BLISTER PACKING, KCM

VERSION AND STATUS

VERSION

5

CREATED FROM PSPADI VERSION

1

PREVIOUS VERSION

60010002

REASON FOR VERSIONING

TEST

REASON REMOVE REASON

SYSTEM INFORMATION

CREATED BY

NICK-PRE PROD RODGERS, 10/8/2021, 9:56 AM

OWNER

NICK-PRE PROD RODGERS

SYSTEM ID

A14E00000064JU

FIG. 3A

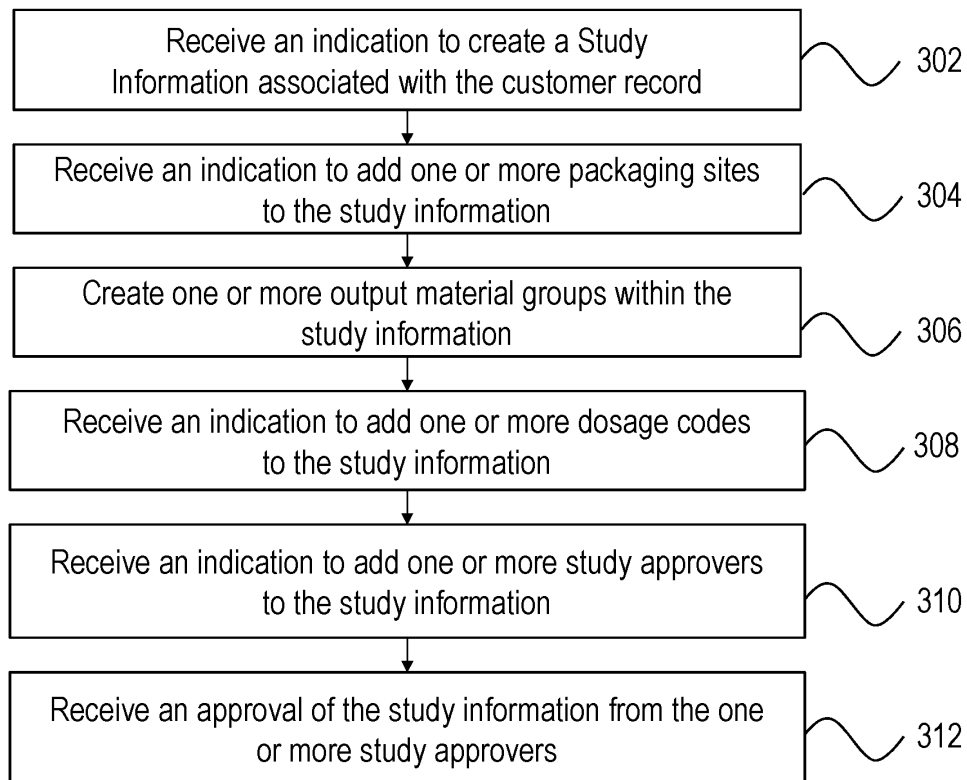
354

FIG. 3B

320C

SANDBOX: SFXQUAL

CATALENT

SEARCH...

GLOBAL SUPPLYFLEX

CUSTOMERS

JENS WOLF

SFX PQ CUSTOMER 1

90010001

STUDY INFORMATION

90010001

APPROVAL NEW VERSION HISTORY

CUSTOMER

SFX PQ CUSTOMER 1

CUSTOMER PROTOCOL

CREATED FROM PS/PADI VERSION

VERSION

3

STATUS

IN APPROVAL

332C

STUDY INFORMATION

DESTINATION COUNTRIES/LAB

ON GROUPS

DOSSAGE CODES

STUDY APPROVERS

PROJECT MANAGERS

STUDY PARTS

BUSINESS UNIT 1

326C

334C

NEW

DESTINATION COUNTRY

DESTINATION COUNTRY GROUP

COUNTRIES

SITES

JAPAN

SOUTH AFRICA

THAILAND

VIETNAM

JAPAN SOUTH AFRICA THAILAND VIETNAM

BATHGATE SHANGHAI (FREE-TRADE ZONE)

BATHGATE KANSAS CITY (CSS)

PHILADELPHIA SCHORNDORF (CSS)

SHANGHAI (FREE)

BATHGATE KANSAS CITY (CSS)

PHILADELPHIA SCHORNDORF (CSS)

SHANGHAI (FREE)

BATHGATE KANSAS CITY (CSS)

PHILADELPHIA SCHORNDORF (CSS)

SHANGHAI (FREE)

BATHGATE KANSAS CITY (CSS)

PHILADELPHIA SCHORNDORF (CSS)

SHANGHAI (FREE)

FILES (0)

ADD FILES

UPLOAD FILES

OR DROP FILES

FIG. 3C

330D

CREATE DESTINATION COUNTRY/LABEL COUNTRY GROUPS

DESTINATION COUNTRY ▾

*DESTINATION COUNTRY ⓘ

UNITED STATES ▾

***SELECT SITES**

AVAILABLE

BOLTON1	▶
BOSTON	▶
KAKEGAWA	▶
KANVAS	▶

CHOSEN

KANSAS CITY (CSS)	▲
	▼

SAVE

FIG. 3D

330E

CREATE DESTINATION COUNTRY/LABEL COUNTRY GROUPS

LABEL COUNTRY GROUPS ▾

*LABEL COUNTRY GROUP ⓘ

LCG1

***SELECT COUNTRIES**

AVAILABLE

ALGERIA	▶
	▶

CHOSEN

	▲
	▼

AN OPTION MUST BE SELECTED

***SELECT SITES**

AVAILABLE

KANSAS CITY (CSS)	▶
PHILADELPHIA	▶
SCHORNDORF	▶
SHANGHAI (FREE-TRADE ZONE)	▶

CHOSEN

BATHGATE	▲
	▼

SAVE

FIG. 3E

320F

SANDBOX: SFXQUAL

CATALENT

SEARCH

90010001

GLOBAL SUPPLYFLEX

CUSTOMERS

JENS WOLF

SFX PQ CUSTOMER 1

90010001

APPROVAL

NEW VERSION

HISTORY

STUDY INFORMATION

90010001

CUSTOMER

SFX PQ CUSTOMER 1

SFX PQ 1

DESTINATION COUNTRY LABEL

OM GROUPS

DOSSAGE CODES

STUDY APPROVERS

PROJECT MANAGERS

STUDY PARTS

BUSINESS UNIT

322

342F

OM GROUPS

OM GROUP

OM GROUP DESCRIPTION

OM GROUP TYPE

OMG-P1 5CT

OUTPUT MATERIAL A&B

PRIMARY OM GROUP

OMG-P2 4CT

OUTPUT MATERIAL C&D

PRIMARY OM GROUP

OMG-P3 4CT (2)

OUTPUT MATERIAL E&F

PRIMARY OM GROUP

OMG-S3 15CT

OUTPUT MATERIAL K&L-KIT3 LCG1

SECONDARY OM GROUP

OMG-W1 30CT

OUTPUT MATERIAL G&H-KIT1 LCG1

SECONDARY OM GROUP

OMG-S2 25CT

OUTPUT MATERIAL I&-KIT2 LCG1

SECONDARY OM GROUP

FILES (0)

ADD FILES

UPLOAD FILES

OR DROP FILES

FIG. 3F

320G

SANDBOX: SFXQUAL

CATALENT

SEARCH

90010001

SFX PQ CUSTOMER 1

JENS WOLF

CUSTOMERS

GLOBAL SUPPLYFLEX

APPROVAL

NEW VERSION

HISTORY

STUDY INFORMATION

90010001

CUSTOMER

SFX PQ CUSTOMER 1

SFX PQ 1

CUSTOMER PROTOCOL

CREATED FROM PS/PADI VERSION

VERSION

3

IN APPROVAL

STATUS

342G

STUDY INFORMATION

DESTINATION COUNTRY LABEL...

ON GROUPS

DOSAGE CODES

STUDY APPROVERS

PROJECT MANAGERS

STUDY PARTS

BUSINESS UNIT

322

DOSAGE CODES

326G

NAME

DESCRIPTION

PACKAGING TYPE

DSC-P1-OUTPUT A

OUTPUT A-2/3

PRIMARY PACKAGING

DSC-P2-OUTPUT B

OUTPUT B-3/2

PRIMARY PACKAGING

DSC-P3-OUTPUT C

OUTPUT C-2/2

PRIMARY PACKAGING

DSC-P4-OUTPUT D

OUTPUT D-2/2

PRIMARY PACKAGING

DSC-P5-OUTPUT E

OUTPUT E-3/1

PRIMARY PACKAGING

DSC-P6-OUTPUT F

OUTPUT F-1/3

PRIMARY PACKAGING

FILES (0)

ADD FILES

UPLOAD FILES

OR DROP FILES

FIG. 3G

320H

SANDBOX: SFXQUAL

CATALENT

SEARCH...

GLOBAL SUPPLYFLEX

CUSTOMERS

JENS WOLF

SFX PQ CUSTOMER 1

90010001

STUDY INFORMATION

90010001

APPROVAL | NEW VERSION | HISTORY

CUSTOMER

SFX PQ CUSTOMER 1

SFX PQ 1

CUSTOMER PROTOCOL

CREATED FROM PSIPAD | VERSION

2

VERSION

3

STATUS

IN APPROVAL

326H

342H

STUDY INFORMATION

DESTINATION COUNTRIES/LABEL...

ON GROUPS

DOSAGE CODES

STUDY APPROVERS

PROJECT MANAGERS

STUDY PARTS

BUSINESS UNIT

322

NEW

STUDY APPROVER

ROLE

PERSON APPROVING

APPROVAL AREA

BLINDED

CUSTOMER

JUSTIN PARTNER A

PRE-EXECUTION

YES

FILES (0)

UPLOAD FILES

OR DROP FILES

364H

STUDY APPROVER

ROLE

PERSON APPROVING

APPROVAL AREA

BLINDED

CUSTOMER

TYPE TEXT HERE

NONE

NONE

ON BEHALF OF

CUSTOMER

PRE-EXECUTION

POST-EXECUTION

BOTH PRE AND POST

YES

NO

SAVE

CANCEL

NEW

FIG. 3H

36

320J

SANDBOX: SFXQUAL

CATALENT

SEARCH...

320J

326J

342J

GLOBAL SUPPLYFLEX

CUSTOMERS

JENS WOLF

SFX PQ CUSTOMER 1

90010001

STUDY INFORMATION

90010001

APPROVAL

NEW VERSION

HISTORY

CUSTOMER

SFX PQ CUSTOMER 1

DESTINATION COUNTRIES LABEL...

CUSTOMER PROTOCOL

SFX PQ 1

CREATED FROM PS/PADI VERSION

2

VERSION

3

STATUS

IN APPROVAL

322

326J

342J

STUDY INFORMATION

DESTINATION COUNTRIES LABEL...

ON GROUPS

DOSAGE CODES

STUDY APPROVERS

PROJECT MANAGERS

STUDY PARTS

BUSINESS UNIT

STUDY PROJECT MANAGERS (2)

NEW

STUDY PROJECT MANAGER NUMBER

PM-C026

PM-C025

PROJECT MANAGER

AILEEN WADDELL

JAMES HUNTER

CREATED BY

JENS WOLF

JENS WOLF

CREATED DATE

9/21/2021 9:26 AM

9/21/2021 9:26 AM

VIEW ALL

FILES (0)

ADD FILES

UPLOAD FILES

OR DROP FILES

FIG. 3J

320K

SANDBOX: SFXQUAL

CATALENT

SEARCH

GLOBAL SUPPLY/EX

CUSTOMERS

JENS WOLF

SFX PQ CUSTOMER 1

90010001

APPROVAL

NEW VERSION

HISTORY

STUDY INFORMATION

90010001

CUSTOMER

SFX PQ CUSTOMER 1 SFX PQ 1

CUSTOMER PROTOCOL CREATED FROM PSIPAD VERSION 3

STATUS

IN APPROVAL

322

STUDY INFORMATION

DESTINATION COUNTRIES LABEL...

OM GROUPS

DOSAGE CODES

STUDY APPROVERS

PROJECT MANAGERS

BUSINESS UNIT

326K

SITE	BRANCH/PLANT	BUSINESS UNIT	STORAGE BUSINESS UNIT	SITE
66801	6569999999998	6569999999998	6569999999998	SHANGHAI (TANGZHEN SITE)
13101	1319999999998	1319999999998	1319999999998	PHILADELPHIA
13201	1329999999997	1329999999998	1329999999998	KANSAS CITY (CSS)
68501	6869999999997	6869999999998	6869999999998	SINGAPORE
88501	6969999999997	6969999999998	6969999999998	SHANGHAI (FREE-TRADE ZONE)
54701	3479999999997	3479999999998	3479999999998	BATHGATE
81601	3169999999997	3169999999998	3169999999998	SCHORNDORF (CSS)

FILES (0)

UPLOAD FILES

OR DROP FILES

ADD FILES

FIG. 3K

392L 

CATALENT

GLOBAL SUPPLY-LEX

STUDY INFORMATION

60010002

60010002

SEARCH...

60010002

60010002

APPROVAL

NEW VERSION

CREATE LIST ASSIGNMENT

HOLD

INACTIVE

STUDY INFORMATION

60010002

CUSTOMER

CUSTOMER PROTOCOL

CREATED FROM PSIPADI VERSION

VERSION

STATUS

326L-342L

SFX PQ CUSTOMER 2

SFX PQ 2

1

5

APPROVED

STUDY INFORMATION

DESTINATION COUNTRIES/LABEL...

OW GROUPS

DOSAGE CODES

STUDY APPROVERS

STUDY PARTS

PROJECT MANAGERS

BUSINESS UNIT

STUDY PARTS (1)

1 ITEM SORTED/DESCRIPTION UPDATED A FEW SECONDS AGO

DESCRIPTION ↑

PACKAGING TYPE

BLINDED

FAST CHAIN

STATUS

VERSION

TEST COMMUNITY REJECT

SECONDARY PACKAGING

NO

NO

APPROVED

1

VIEW ALL

360

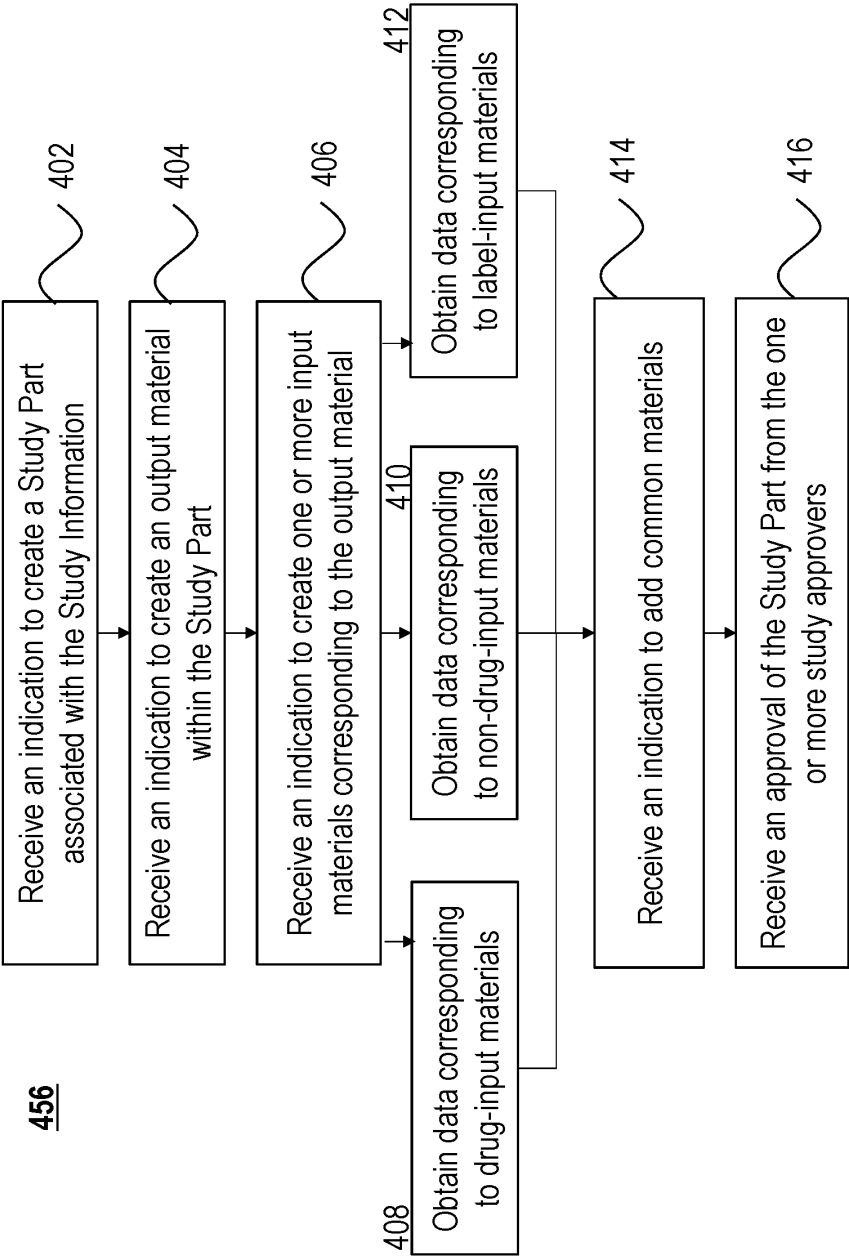


FIG. 4A

430B →

STUDY PART DETAILS

*STUDY INFORMATION ⓘ

🔍

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×

SP UNIQUE IDENTIFIER

*DESCRIPTION

LCG/DEST COUNTRY

--NONE--

▼

*PACKAGING TYPE ⓘ

SECONDARY PACKAGING

▼

*BLINDED?

--NONE--

▼

*FASTCHAIN?

--NONE--

▼

STUDY BATCH RECORD

SEARCH BATCH RECORDS...

🔍

FIG. 4B

420C

SANDBOX: TESTDEPLOY

CATALENT

GLOBAL SUPPLYFLEX

STUDY INFORMATION

60010002

TEST COM...

60010002

TEST COM...

424

422

426C

STUDY PART

TEST COMMUNITY REJECT

STUDY INFORMATION

CUSTOMER NAME

PACKAGING TYPE

VERSION

STATUS

60010002

SFX PQ CUSTOMER 2

SECONDARY PACKAGING

1

APPROVED

422

STUDY PART DETAILS

OUTPUT AND INPUT MATERIALS

COMMON

RELATED BATCH RECORDS

STUDY PART LIST

426C

STUDY PART DETAILS

STUDY INFORMATION

60010002

SP UNIQUE IDENTIFIER

60010002-6

DESCRIPTION

TEST COMMUNITY REJECT

LOG/DEST COUNTRY

DEST COUNTRY

SITES

KANSAS CITY (CSS), SCHORNDORF (CSS)

PACKAGING TYPE

SECONDARY PACKAGING

STUDY BATCH RECORD

TEST COMMUNITY REJECT

BLINDED

NO

FASTCHAIN

NO

LANGUAGES

ENGLISH, GERMAN

ADDITIONAL FIELDS

FILE UPLOAD RESTRICTION

ADD FILES FUNCTIONALITY WORKS ONLY FOR A RECORD IN DRAFT STATUS.

FILES (0)

UPLOAD FILES

OR DROP FILES

FIG. 4C

420D

SANDBOX: TESTDEPLOY

CATALENT

SEARCH...

GLOBAL SUPPLYFLEX

STUDY INFORMATION

60010002

TEST COM...

STUDY PART

TEST COMMUNITY REJECT

424

APPROVAL

NEW VERSION

CLONE

HOLD

HISTORY

STUDY INFORMATION

CUSTOMER NAME

SFX PQ CUSTOMER 2

PACKAGING TYPE

SECONDARY PACKAGING

VERSION

1

STATUS

APPROVED

422

STUDY PART DETAILS

OUTPUT AND INPUT MATERIALS

COMMON

RELATED BATCH RECORDS

STUDY PART LIST

426D

OUTPUT MATERIAL

GENERAL MATERIAL DESCRIPTION 1

GENERAL...

UOM

DESTINATION COU...

OM GROUP

DOSAGE CODE

OUTPUT MATERIAL 1

TEST 1

KT

SINGAPORE

428D

INPUT MATERIAL (DRUG)

GENERAL MATERIAL DESCRIPTION 1

GENERAL MATERIAL DESCRIPTION 2

UOM

LABELLED

ALTERNATIVE MATERIAL

DRUG 1

TEST

EA

NO

NO

434D

INPUT MATERIAL (NON-DRUG)

GENERAL MATERIAL DESCRIPTION 1

GENERAL MATERIAL DESCRIPTION 2

UOM

LABELLED

ALTERNATIVE MATERIAL

LABELS

GENERAL MATERIAL DESCRIPTION 1

GENERAL MATERIAL DESCRIPTION 2

UOM

BARCODE TYPE

FIG. 4D

420E

STUDY PART DETAILS

OUTPUT AND INPUT MATERIALS

COMMON

RELATED BATCH RECORDS

STUDY PART LIST

NEW

432E

OUTPUT MATERIAL

FIG. 4E

430F

INFORMATION

GENERAL MATERIAL DESCRIPTION 1

OM TYPE

-NONE-

GENERAL MATERIAL DESCRIPTION 2

UOM

-NONE-

OM GROUP

DOSAGE CODE N/A

SAMPLE INFORMATION

PARTIAL SAMPLE

NO

LABEL DETAILS

LABEL N/A

BARCODE TYPE

-NONE-

STORAGE TEMPERATURE

STORAGE TEMPERATURE RANGE

-NONE-

LOW RANGE IN °C

HIGH RANGE IN °C

TIME OUT ENVIRONMENT DETAILS

TIME OUT OF ENVIRONMENT

-NONE-

DOSAGE CODE NAME

TIME OUT OF ENVIRONMENT UOM

TIME FOR THIS TOE EVENT

LOW RANGE IN LUX

HIGH RANGE IN LUX

LIGHT CONTROL DETAILS

LIGHT CONDITIONS

BETWEEN

LOW RANGE IN %RH

HIGH RANGE IN %RH

HUMIDITY CONTROL DETAILS

HUMIDITY

BETWEEN

LOW RANGE IN %RH

HIGH RANGE IN %RH

ADDITIONAL TOE DETAILS

CUMULATIVE TOE

-NONE-

DESTINATION COUNTRIES / LABEL COUNTRY GROUPS

DESTINATION COUNTRIES

FIG. 4F

420G →

☒ INPUT MATERIAL (DRUG)

NEW

☐ GENERAL MATERIAL DESCRIPTION 1

UOM

▼

ALTERNATIVE MATERIAL

432G

FIG. 4G

430H →

INFORMATION		ALTERNATIVE MATERIAL		HUMIDITY CONTROL DETAILS	
*GENERAL MATERIAL DESCRIPTION 1	*UOM	*ALTERNATIVE MATERIAL		*HUMIDITY	
	-NONE-			-NONE-	▼
*GENERAL MATERIAL DESCRIPTION 2	*LABELED			*LOW RANGE IN %RH	*HIGH RANGE IN %RH
	NO	STORAGE TEMPERATURE			
CUSTOMER MATERIAL ID N/A		*STORAGE TEMPERATURE RANGE		HUMIDITY DESCRIPTION	
☐	CUSTOMER MATERIAL ID	-NONE-			
		*LOW RANGE IN °C	*HIGH RANGE IN °C		
				LIGHT CONTROL DETAILS	
DRUG CATERGORIZATIONS				*LIGHT CONDITIONS	
*CONTROLLED DRUG?	*HAZARD CATEGORY	TIME OUT ENVIRONMENT DETAILS			
NO	-NONE-			-NONE-	▼
		*TIME OUT OF ENVIRONMENT		*LOW RANGE IN LUX	*HIGH RANGE IN LUX
DANGEROUS GOODS UN N/A		-NONE-			
☐		*TIME OUT OF ENVIRONMENT UOM	*TIME FOR THIS TOE EVENT	LIGHT CONDITIONS DESCRIPTION	
*DOSAGE FORM		-NONE-			
-NONE-		*CUMULATIVE TOE	ADDITIONAL TOE DETAILS	RELATED INFORMATION	
				PARENT OUTPUT MATERIAL	
				☒ TEST	
				SAVE	

FIG. 4H

420I → ☒ INPUT MATERIAL (NO-DRUG)

GENERAL MATERIAL DESCRIPTION 1 ▾ UOM ▾ OM GROUP ▾ ALTERNATIVE MATERIAL

432I

FIG. 4I

430J →

INFORMATION

*GENERAL MATERIAL DESCRIPTION 1 *UOM

*GENERAL MATERIAL DESCRIPTION 2O

OM GROUP N/A ☐ *OM GROUP

OM GROUP DESCRIPTION OM GROUP TYPE

CUSTOMER MATERIAL ID N/AO ☐ *CUSTOMER MATERIAL IDO

ALTERNATIVE MATERIAL

*ALTERNATIVE MATERIAL

RELATED INFORMATION

*PARENT OUTPUT MATERIALO

☒ OUTPUT MATERIAL TEST 1 x

FIG. 4J

420K →

☒ LABELS

432K →

NEW

☐ GENERAL MATERIAL DESCRIPTION 1

~

LABEL COUNTRY GROUP ~

UOM ~

LABEL DESCRIPTION ~

BARCODE TYPE ~

FIG. 4K

430L →

INFORMATION

*GENERAL MATERIAL DESCRIPTION 1

*UOM

~

~NONE~

*GENERAL MATERIAL DESCRIPTION 2

LABEL DETAILS

BARCODE TYPE

~NONE~

LABEL DESCRIPTION

ALTERNATIVE MATERIAL

*ALTERNATIVE MATERIAL

NO

~

SAVE

FIG. 4L

420M →

CATALENT

SANDBOX TESTDEPLOY

SEARCH

⌕ ? 🏠

GLOBAL SUPPLYFLEX

STUDY INFORMATION

60010002

TEST COM...

60010002

TEST COMM...

STUDY PART

TEST COMMUNITY REJECT

424

APPROVAL | NEW VERSION | CLONE | HOLD | INACTIVE | HISTORY

STUDY INFORMATION

CUSTOMER NAME

PACKAGING TYPE

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60010002

SFX PQ CUSTOMER 2

SECONDARY PACKAGING

1

APPROVED

STUDY PART DETAILS

OUTPUT AND INPUT MATERIALS

COMMON

RELATED BATCH RECORDS

STUDY PART LIST

422

426M

COMMON MATERIALS

INPUT MATERIAL (DRUG)

GENERAL MATERIAL DESCRIPTION 1

GENERAL MATERIAL DESCRIPTION 2

UOM

LABELED

ALTERNATIVE MATERIAL

INPUT MATERIAL (NON-DRUG)

GENERAL MATERIAL DESCRIPTION 1

GENERAL MATERIAL DESCRIPTION 2

UOM

DESTINATION COUNTRIES

QM GROUP

ALTERNATIVE MATERIAL

LABELS

GENERAL MATERIAL DESCRIPTION 1

GENERAL MATERIAL DESCRIPTION 2

UOM

DESTINATION COUNTRIES

BARCODE TYPE

FIG. 4M

420N

☒ COMMON MATERIALS

☒ INPUT MATERIAL (DRUG)

GENERAL MATERIAL DESCRIPTION 1

UOM

DOSAGE CODES

ALTERNATIVE MATERIAL

LABELS

TEST DRUG COMMON AS

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420P →

SANDBOX: TESTDEPLOY

CATALENT

SEARCH...

60010002

60010002

TEST COM...

STUDY PART

TEST COMMUNITY REJECT

424

APPROVAL

NEW VERSION

CLONE

HOLD

INACTIVE

HISTORY

STUDY INFORMATION

CUSTOMER NAME

PACKAGING TYPE

VERSION

STATUS

60010002

SFX PQ CUSTOMER 2

SECONDARY PACKAGING

1

APPROVED

STUDY PART DETAILS

OUTPUT AND INPUT MATERIALS

COMMON

RELATED BATCH RECORDS

STUDY PART LIST

422

426P

STUDY PARTS FOR PARENT STUDY INFORMATION (1)

1 ITEM · SORTED BY DESCRIPTION · UPDATED A FEW SECONDS AGO

DESCRIPTION ↑

PACKAGING TYPE

BLINDED

FASTCHAIN

STATUS

VERSION

1

TEST COMMUNITY REJECT

SECONDARY PACKAGING

NO

NO

APPROVED

1

VIEW ALL

FIG. 4P

420Q

SANDBOX: TESTDEPLOY

CATALENT

SEARCH...

GLOBAL SUPPLYFLEX

STUDY INFORMATION

STUDY COM...

60010002

TEST COM...

424

APPROVAL

NEW VERSION

CLONE

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INACTIVE

HISTORY

STUDY PART

TEST COMMUNITY REJECT

STUDY INFORMATION

CUSTOMER NAME

PACKAGING TYPE

VERSION

STATUS

60010002

SFX PQ CUSTOMER 2

SECONDARY PACKAGING

1

APPROVED

STUDY PART DETAILS

OUTPUT AND INPUT MATERIALS

COMMON

RELATED BATCH RECORDS

STUDY PART LIST

422

426Q

BATCH RECORDS (1)

1 ITEM • UPDATED A FEW SECONDS AGO

BATCH RECORD NAME

RECORD TYPE

LAST MODIFIED BY

1

TEST COMMUNITY REJECT

SBR

NICK-PRE PROD RODGERS

VIEW ALL

FIG. 4Q

520A

SANDBOX TESTDEPLOY

SEARCH

526A

522

524

538

GLOBAL SUPPLYFLEX

STUDY PARTS

60010002

TEST FOR BUG 32357

SP_PRIMARY

080221SSP

COPY OF SECONDARY, ...

60010002

TEST COM...

TEST COM...

BATCH RECORD

TEST COMMUNITY REJECT

SBR UNIQUE IDENTIFIER

6001002-SBR-6

CUSTOMER NAME

SFX PQ CUSTOMER 2

PROJECT NUMBER

60010002

STUDY PART

TEST COMMUNITY REJECT

DETAILS

INSTRUCTIONS & EQUIPMENT OR

RELATED STUDY PARTS

RELATED

ENGLISH INSTRUCTIONS AND EQUIPMENT GROUPS

VERSION

REASON FOR VERSIONING

ACTIVE

YES

FILES (0)

UPLOAD FILES OR DROP FILES

GERMAN INSTRUCTIONS

GERMAN STATUS

APPROVED

FILES (0)

UPLOAD FILES OR DROP FILES

ROOM PROCESSING TEMPERATURE

TEMPERATURE RANGE

LESS THAN OR EQUAL TO

ROOM PROCESSING HUMIDITY

HUMIDITY RANGE

N/A

STATUS

APPROVED

HOLD REASON

SBR UNIQUE IDENTIFIER

6001002-SBR-6

HOLD REMOVE REASON

APPROVAL

NEW VERSION

HOLD

INACTIVE

HISTORY

ACTIVE

YES

APPROVAL HISTORY

538

LOW RANGE IN °C

HIGH RANGE IN °C

25

LOW RANGE IN %RH

HIGH RANGE IN %RH

FIG. 5A-1

ROOM PROCESSING LIGHT CONDITIONS	
LIGHT CONDITION RANGE	LOW RANGE IN 'LUX'
N/A	
LIGHT CONDITION DESCRIPTION	HIGH RANGE IN 'LUX'
N/A	
BATCH RECORD DETAILS	
BATCH RECORD NAME	BLINDED
TEST COMMUNITY REJECT	NO
SBR UNIQUE IDENTIFIER	STUDY PART 0
60010001-SBR-6	TEST COMMUNITY REJECT
PROJECT NUMBER	CUSTOMER 0
60010002	SFX PQ CUSTOMER 2
CREATED BY	
NICK-PRE PROD RODGERS, 12/06/2021, 10:39AM	

FIG. 5A-2

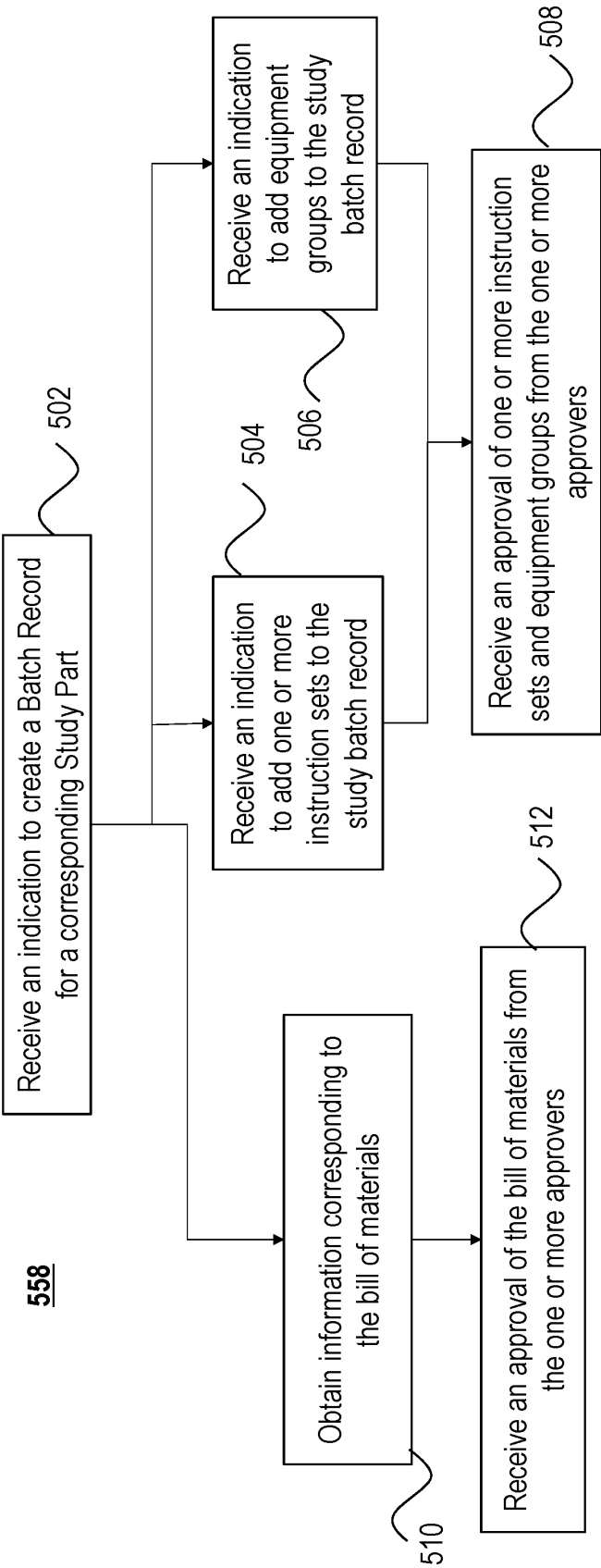


FIG. 5B

STUDY PART

TEST

CLONE

NEW VERSION

HISTORY

APPROVAL

CREATE SBR

HOLD

INACTIVE

STUDY INFORMATION

CUSTOMER NAME

PACKAGING TYPE

VERSION

STATUS

CC9899898

CC CUST0122

SECONDARY PACKAGING

1

APPROVED

FIG. 5C

520D

522

548D

542D

544D

550D

546D

DETAILS

INSTRUCTIONS & EQUIPMENT...

SUPERBOM

RELATED STUDY PARTS

RELATED XBRS

RELATED

STUDY INSTRUCTIONS

EQUIPMENT GROUPS

PACKAGING INSTRUCTIONS

IN PROCESS CHECK

IMPORTANT NOTES

IMAGE CAPTURE

SEARCH

SEARCH INSTRUCTIONS...

ADD

ENGLISH

GERMAN

SORT

NEW

FIG. 5D

520E

CATALENT

SANDBOX TEST/DEPLOY

SEARCH

PRIMARY, BLISTERING, M. x

GLOBAL SUPPLY/EX

STUDY INSTRUCTIONS

60010002

TEST FOR BUG 0257 x

SP PRIMARY x

00021SSP x

COPY OF SECONDARY ... x

PRIMARY, BLISTERING, ...

PRIMARY, ...

BATCH RECORD

PRIMARY, OPEN, BLISTER PACKING - T03

STUDY INFORMATION

80010001-SBR-3

CUSTOMER

SFX PQ CUSTOMER 1

PROJECT NUMBER

60010001

STUDY PART

PRIMARY, OPEN, BLISTER PACKING - T03

522

542E

526E

DETAILS

INSTRUCTIONS & EQUIPMENT ...

SUPEROM

RELATED STUDY PARTS

RELATED

STUDY INSTRUCTIONS

EQUIPMENT GROUPS

PACKAGING INSTRUCTIONS

IN-PROCESS CHECK

IMPORTANT NOTES

IMAGE CAPTURE

ENGLISH

GERMAN

CHINESE

SEQUENCE TEXT

IMAGE

NAME

DESCRIPTION

VER

1

VERIFY INITIAL WEIGHT AND RECORD ON INITIAL WEIGHT FORM FOR SFX SIT PRIMARY IN DRUG 1

PRIMARY, BLISTERING

UNPRINTED, THERMOFORM, NO WALLETTING OR LABELLING

1

2

VERIFY INITIAL WEIGHT AND RECORD ON INITIAL WEIGHT FORM FOR SFX SIT PRIMARY IN DRUG 2

PRIMARY, BLISTERING

UNPRINTED, THERMOFORM, NO WALLETTING OR LABELLING

1

3

RUN EMPTY PRE-FORMED BLISTERS THROUGH THE ENTIRE LENGTH OF THE MACHINE

PRIMARY, BLISTERING

UNPRINTED, THERMOFORM, NO WALLETTING OR LABELLING

1

4

OPERATOR 1: FILL APERTURES WITH PRODUCT 1. REFER TO IMAGE (PINK CAPSULES)

PRIMARY, BLISTERING

UNPRINTED, THERMOFORM, NO WALLETTING OR LABELLING

1

5

OPERATOR 2: FILL APERTURES WITH PRODUCT 2. REFER TO IMAGE (GREEN CAPSULES)

PRIMARY, BLISTERING

UNPRINTED, THERMOFORM, NO WALLETTING OR LABELLING

1

6

OPERATOR 2: FILL APERTURES WITH PRODUCT 2. REFER TO IMAGE (GREEN CAPSULES)

PRIMARY, BLISTERING

UNPRINTED, THERMOFORM, NO WALLETTING OR LABELLING

1

7

INSPECT BLISTERS ENSURING FINISHED BLISTER RESEMBLES ACCEPTABLE BLISTER

PRIMARY, BLISTERING

UNPRINTED, THERMOFORM, NO WALLETTING OR LABELLING

1

8

WEIGH ACCEPTABLE BLISTERS

PRIMARY, BLISTERING

UNPRINTED, THERMOFORM, NO WALLETTING OR LABELLING

1

9

VERIFY ACCEPTABLE BLISTER CHECKS

PRIMARY, BLISTERING

UNPRINTED, THERMOFORM, NO WALLETTING OR LABELLING

1

10

PACK ACCEPTABLE BLISTERS INTO APPROPRIATE STORAGE CONTAINERS

PRIMARY, BLISTERING

UNPRINTED, THERMOFORM, NO WALLETTING OR LABELLING

1

ON COMPLETION OF PACKAGING ALL STORAGE CONTAINERS MUST HAVE A DFE LABEL

PRIMARY, BLISTERING

UNPRINTED, THERMOFORM, NO WALLETTING OR LABELLING

1

FIG. 5E

520F

SANDBOX: TEST/DEPLOY

CATALENT

SEARCH

PRIMARY; BLISTERING, M...

GLOBAL SUPPLY/PEX

STUDY INSTRUCTIONS

60010002

TEST FOR BUG 32357

SP PRIMARY

COPY OF SECONDARY

PRIMARY, BLISTERIN...

PRIMARY

BATCH RECORD

PRIMARY, OPEN, BLISTER PACKING - TG3

SSR UNIQUE IDENTIFIER

CUSTOMER

PROJECT NUMBER

STUDY PART

60010001-SBR-3

SEY PQ CUSTOMER 1

60010001

PRIMARY, OPEN, BLISTER PACKING - TG3

522

542F

526F

DETAILS

INSTRUCTIONS & EQUIPMENT ...

SUPERBOM

RELATED STUDY PARTS

RELATED

STUDY INSTRUCTIONS

EQUIPMENT GROUPS

PACKAGING INSTRUCTIONS

IN PROCESS CHECK

IMPORTANT NOTES

IMAGE CAPTURE

ENGLISH

GERMAN

CHINESE

ROW

TEXT

RESPONSE TYPE

JOB TYPE

INS SET NAME

INS SET DESCRIPTION

VER

1

PERFORM IN PROCESS LEAK TEST

BOTTLE FILLING - MANUAL

BOTTLE FILLING - LEAK TESTING - IN PROCESS

VERIFYING SEAL INTEGRITY OF THE BOTTLE THROUGH DYE INGRESS.

1

FIG. 5F

520G

SANDBOX TEST/DEPLOY

CATALIST

SEARCH

?

GLOBAL SUPPLY/LEX

STUDY INSTRUCTIONS

60010002

TEST FOR BUG 12345

SP PRIMARY

COPY OF SECONDARY

PRIMARY; BLISTERING, M...

PRIMARY; BLISTERIN...

PRIMARY, ...

BATCH RECORD

PRIMARY, OPEN, BLISTER PACKING - TG3

SER UNIQUE IDENTIFIER

CUSTOMER

PROJECT NUMBER

STUDY PART

60010001-SR-3

SFX PQ CUSTOMER 1

60010001

PRIMARY, OPEN, BLISTER PACKING - TG3

522

542G

526G

DETAILS

INSTRUCTIONS & EQUIPMENT ...

SUPERBOM

RELATED STUDY PARTS

RELATED

STUDY INSTRUCTIONS

EQUIPMENT GROUPS

PACKAGING INSTRUCTIONS

IN PROCESS CHECK

IMPORTANT NOTES

IMAGE CAPTURE

ENGLISH

GERMAN

CHINESE

ROW #

TEXT

1

PRODUCT MUST NOT BE RECLAIMED DURING BLISTERING

2

CALL IPCT TO PERFORM SEGREGATION CHECK

3

PERFORM CAMERA EJECTION CHALLENGE AND RECORD.

4

PERFORM IN-PROCESS LEAK TESTING ON BLISTERS AND RECORD ON APPROPRIATE FORM

5

RECORD ACCEPTABLE BLISTER CHECK ON APPROPRIATE FORM

6

ON COMPLETION OF PACKAGING ALL STORAGE CONTAINERS MUST HAVE A JDE LABEL

CUSTOMER SPECIFIC

FIG. 5G

520H →

STUDY INSTRUCTIONS

EQUIPMENT GROUPS

PACKAGING INSTRUCTIONS

IN PROCESS CHECK

IMPORTANT NOTES

IMAGE CAPTURE

SEARCH FOR INSTRUCTIONS

ENGLISH

GERMAN

SEQUENCE	TEXT	IMAGE	NAME	DESCRIPTION	VER
1	INSTRUCTION EXAMPLE CHANGES		PACKAGING INSTRUCTION TEST	554H	1
2	NEW ENGLISH INSTRUCTION 11-20		PACKAGING INSTRUCTION TEST		1

FIG. 5H

5301 ↘

EDIT STUDY INSTRUCTIONS

INFORMATION

INSTRUCTION NAME

PACKAGING INSTRUCTION TEST

INSTRUCTION

TEXT ⓘ

SALESFORCE SANS

12

B

/

U

1

2

INSTRUCTION EXAMPLE CHANGES

DESCRIPTION

SALESFORCE SANS

12

B

/

U

1

2

IMAGE

⬆️

UPLOAD FILES

OR DROP FILES

SAVE

FIG. 51

520J →

DETAILS INSTRUCTIONS & EQUIPMENT... SUPERBOM RELATED STUDY PARTS RELATED XBRs

STUDY INSTRUCTIONS EQUIPMENT GROUPS

558J 556J

CREATE EQUIPMENT GROUPS

EDIT NEW

EQUIPMENT GROUP

EQUIPMENT DETAILS

FIG. 5J

530K →

DETAILS INSTRUCTIONS & EQUIPMENT... SUPERBOM RELATED STUDY PARTS RELATED XBRs

STUDY INSTRUCTIONS EQUIPMENT GROUPS

CREATE EQUIPMENT GROUPS

SAVE CANCEL NEW

EQUIPMENT GROUP

EQUIPMENT DETAILS

--NONE--

✓ --NONE--

BLISTER PACKER

NEW GROUP

THERMOMETER

INDUCTION SEALER

OVERENCAPSULATION

FIG. 5K

520L

CATALENT

SANDBOX TEST/DEPLOY

SEARCH

PRIMARY, OPEN BLISTER PACKING - TCS

526L

GLOBAL SUPPLY/FLEX

BATCH RECORD

60010002

TEST FOR BUG 3287

SP PRIMARY

COPY OF SECONDARY

SECONDARY STANDARD

PRIMARY, OPEN BLISTE

BATCH RECORD

PRIMARY, OPEN BLISTER PACKING - TCS

SER UNIQUE IDENTIFIER

60010001-SBR-3

CUSTOMER

SXP-PO CUSTOMER 1

PROJECT NUMBER

60010001

STUDY PART

PRIMARY, OPEN BLISTER PACKING - TCS

522

526L

DETAILS

INSTRUCTIONS & EQUIPMENT...

SUPERBOM

RELATED STUDY PARTS

RELATED

STUDY INSTRUCTIONS

EQUIPMENT GROUPS

EQUIPMENT GROUP

LEAK TESTER

BLISTER - FLOOD FEEDER

PRODUCT COUNTER

PRODUCT COUNTER

BOTTLE - PRODUCT VISION SYSTEM

CHECKWEIGHER

BLISTER - FLOOD FEEDER

EQUIPMENT DETAILS

SFX SIT PRIMARY IM DRUG 2

SFX SIT PRIMARY IM DRUG 2

SFX SIT PRIMARY IM DRUG 1

SFX SIT PRIMARY IM DRUG 1

FIG. 5L

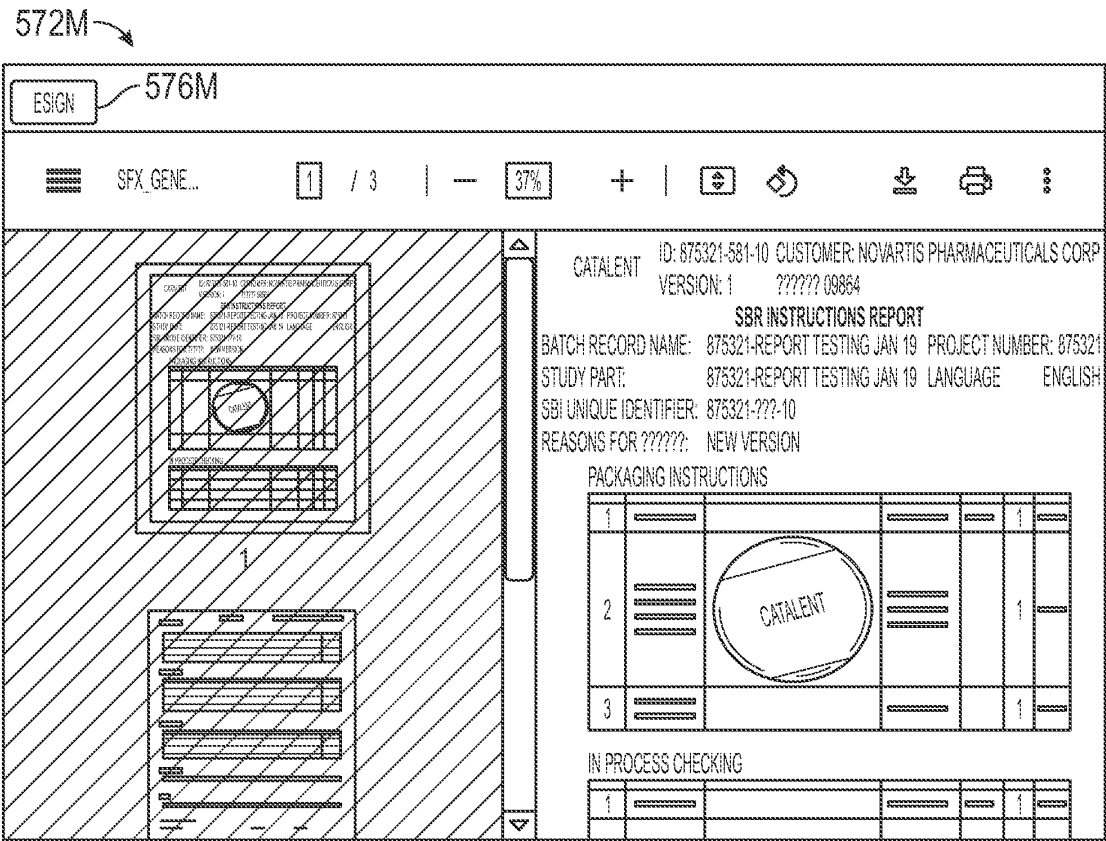


FIG. 5M

574N

ESIGNATURE FOR
I APPLY MY ELECTRONIC SIGNATURE FOR AND 875321-REPORT TESTING
JAN 19 AND ALL RELATED ATTACHMENTS.
THIS SIGNATURE IS LEGALLY BINDING.

*USER LOGIN ID *INDIVIDUAL SIGNATURE IDENTIFIER

COMMENTS

APPROVE CANCEL REJECT

FIG. 5N

5200 →

DETAILS INSTRUCTIONS & EQUIPMENT SUPERBOM RELATED STUDY PARTS RELATED XBRST 522

STATUS & VERSION

STATUS & VERSION

STATUS APPROVED

SBOM VERSION 1.0

COMMUNITY URL
HTTPS://CAPGEMINI-CATALENT.CS17.FORCE.COM/CUSTOMERS/DETAIL/AORG00000065EMI

NEW VERSION HISTORY APPROVAL REPORT COMPARE VERSIONS HOLD

OMIM COMMON

OUTPUT MATERIAL

ITEM ID GENERAL MATERIAL DESCRIPTION 1 GENERAL MATERIAL DESCRIPTION 2 LABEL COUNTRY GROUP OM GROUP JDE UNIT OF MEASURE

1 DEMO SP BOM 12/04 / 8 0 5

INPUT MATERIAL (DRUG)

ITEM ID GENERAL MATERIAL DES. LABEL QUANTITY JDE UNIT OF MEASURE NEED LABEL?

5820 DEM IM 12/04 1 / 8 0 5

INPUT MATERIAL (NON-DRUG)

ITEM ID GENERAL MATERIAL DES. LABEL QUANTITY JDE UNIT OF MEASURE NEED LABEL?

5840 DEM IM NON-DRUG 12/04 1 / 8 0 5

LABELS

ITEM ID GENERAL MATERIAL ... GENERAL MATERIAL ... LABEL LABEL COUNTRY GR... QUANTITY JDE UNIT OF MEAS NEED LABEL?

DEMO LABEL 12/04 1 / 8 0 5

EXAMPLE PACK

ITEM ID GENERAL MATERIAL DES. GENERAL MATERIAL DES. LABEL QUANTITY JDE UNIT OF MEASURE NEED LABEL?

FIG. 50

[illegible]

ESG

SANDBOX TEST DEPLOY									
SEARCH					☒ ? ☒				
CALIENT									
GLOBAL SUPPLY/EXL BATCH RECORDS > 60010002 >> < TEST FOR BUG 82087 >> < SP PRIMARY >> < WZ21SSP >> < COPY OF SECONDARY ... >> < SECONDARY STANDARD >> < PRIMARY OPEN, BLISTE... >>									
☒ BATCH RECORD ☒ PRIMARY OPEN BLISTER PACKING - TIG3 526Q									
SR UNIQ IDENTIFIER 60100H-SBR-3 CUSTOMER STYPO CUSTOMER I PROJECT NUMBER 80100H1 STUDY PART PRIMARY OPEN BLISTER PACKING - TIG3 522									
DETAILS INSTRUCTIONS & EQUIPMENT GR. SUPERBOM RELATED STUDY PARTS RELATED									
STATUS & VERSION STATUS APPROVED REASON FOR PENDING COMMUNITY URL FILES (0) SECM VERSION 1.0 HOLD REASON HTTPS://TESTER.OV-CUSTOMERS.OS16-FORCE.COM/CUSTOMERS/DETAIL/40E00000LUPK SECM UNIQ IDENTIFIER 80100H1-SBRM-3 HOLD REMOVE REASON ACTIVE YES 524									
☒ STATUS & VERSION ☒ APPROVAL ☒ NEW VERSION ☒ GET ITEMS ☒ HOLD IN ACTIVE HISTORY									
COMMON MATERIALS INPUT MATERIAL (DRUG)									
ITEM ID GENERAL MATERIAL DESCRIPTION 1 GENERAL MATERIAL DESCRIPTION 2 JOE LOON LABELLED ALTERNATIVE MATERIAL									
ITEM ID GENERAL MATERIAL DESCRIPTION 1 GENERAL MATERIAL DESCRIPTION 2 JOE LOON ALTERNATIVE MATERIAL BOM QUANTITY									
ITEM ID GENERAL MATERIAL DESCRIPTION 1 GENERAL MATERIAL DESCRIPTION 2 JOE LOON ALTERNATIVE MATERIAL BOM QUANTITY									

FILE

520R

BATCH RECORD

1234

584R

GET ITEM IDS

EDIT

APPROVAL REPORT

▼

UNIQUE IDENTIFIER	CUSTOMER	PROJECT NUMBER	STUDY PART	VERSION
SB-EY950387-43	CC CUST0122	EY950387	DENO 12/04 SAMPLE	1

2
 5
 6
 000000
 11

530S

INVENTORY ITEM ID RESPONSE

SELECT THE CHECKBOX IF YOU WANT TO UPDATE THE INFORMATION TO SUPERBOM

ITEM IDS WHICH EXIST IN JDE:

INVENTORY ITEM ID	GENERAL MATERIAL DESC...	INVENTORY DESCRIPTION 1	INVENTORY DESCRIPTION 2	GENERAL UOM	JDE UNIT OF MEASURE
☐ 119947	OUTPUT MATERIAL BLISTERING - STRIPS OF 7	6X VI CT (2024-C) PC2		AM	CT
☐ 117935	IM DRUG SMOKE BLISTERING - STRIPS OF 7	LC100358PMS201 LBL WITH	3/4" CLE 1.5"V X 6.5"H	BT	EA
☐ 119948	IM NON DRUG BLISTERING - STRIPS OF 7	6X VI PIN (10015-PIN) PC2		BD	EA
☐ 120245	LABEL BLISTERING - STRIPS OF 7	APL-2 350MG/9ML VI UNBLD			VI
☐ 120485	EXAMPLE PACKBLISTERING - STRIPS OF 7	MEDIMOP 20MM VI ADAPTER	CAT#8072036	BC	EA

CANCEL

UPDATE

SS
GLE^x

530T

EXAMPLE PACK

INFORMATION	
*GENERAL MATERIAL DESCRIPTION 1	*UOM①
	-NONE-
BOM QUANTITY①	
1	
CUSTOMER MATERIAL ID N/A ①	*GENERAL MATERIAL ID ①
☐	
JDE ITEM INFORMATION	
*ITEM ID ①	JDE UOM①
ITEM DESCRIPTION 1	
ITEM DESCRIPTION 2	
SAVE	

FIG. 5T

520U

524

DETAILS

INSTRUCTIONS & EQUIPMENT...

SUPERBOM

RELATED STUDY PARTS

RELATED XBRs

STATUS & VERSION

STATUS & VERSION

STATUS SBOM VERSION 1.0

APPROVED

COMMUNITY URL
HTTPS://CAPGEMINI-CATALENT.CS17.FORCE.COM/CUSTOMERS/DETAIL/A0RG00000065EMI

GET ITEMS

NEW VERSION

HISTORY

APPROVAL

HOLD

578U

FIG. 5U

576V

572V

574W

ESIGN

CANCEL

CATALENT.

OUTPUT MATERIAL INFORMATION

GENERAL MATERIAL DEMO SP

DESCRIPTION 1: BOM 12/04

OM GROUP:

OM GROUP DESCRIPTION:

OM GROUP TYPE:

SBOM TYPE: SECONDARY OM

ESIGNATURE FOR

I APPLY MY ELECTRONIC SIGNATURE FOR FOR.

THIS SIGNATURE IS LEGALLY BINDING.

*USER LOGIN ID

*INDIVIDUAL SIGNATURE IDENTIFIER

COMMENTS

APPROVE

CANCEL

REJECT

FIG. 5V

FIG. 5W

520X →

SANDBOX TEST/DEPLOY

CATALOG

SEARCH...

☆

+

?

🔍

🔒

GLOBAL SUPPLY

BATCH RECORDS

60010002

TEST FOR BLS 2057

SP PRIMARY

080215SP

COPY/OS SECONDARY...

SECONDARY STANDARD...

PRIMARY OPEN BLST...

BATCH RECORD

PRIMARY, OPEN, BLISTER PACKING - TGS

SSR UNIQUE IDENTIFIER

CUSTOMER

PROJECT NUMBER

STUDY PART

60010001-SBR-3

SFX PQ CUSTOMER 1

60010001

PRIMARY, OPEN, BLISTER PACKING - TGS

DETAILS

INSTRUCTIONS & EQUIPMENT GR...

SUPERBOM

RELATED STUDY PARTS

RELATED

522

STUDY PARTS (1)

DESCRIPTION

VERSION

STATUS

CREATED DATE

PRIMARY, OPEN, BLISTER PACKING - TGS

1

APPROVED

4/28/2021, 5:08 AM

VIEW ALL

526X

FIG. 5X

520Y

SANDBOX TEST/DEPLOY

SEARCH

☆ ? ⓘ

GLOBAL SUPPLIER

BATCH RECORDS

60010002

TEST FOR BUG 32357

SP PRIMARY

100021SSP

COPY OF SECONDARY

SECONDARY STANDARD

PRIMARY, OPEN BUST

BATCH RECORD

PRIMARY, OPEN, BLISTER PACKING - TG3

SRR UNIQUE IDENTIFIER

CUSTOMER

PROJECT NUMBER

STUDY PART

522

60010001-SRR-3

SFX PQ CUSTOMER 1

60010001

PRIMARY, OPEN, BLISTER PACKING - TG3

DETAILS

INSTRUCTION & EQUIPMENT GR...

SUPERBOM

RELATED STUDY PARTS

RELATED

STUDY INSTRUCTIONS (2)

2 ITEMS. UPDATED A FEW SECONDS AGO

SRR INSTRUCTION NAME

VERSION

STATUS

REASON FOR VERSIONING

CREATED DATE

1

PRIMARY, OPEN, BLISTER PACKING - TG3

1

APPROVED

4/28/2021, 9:34 AM

2

PRIMARY, OPEN, BLISTER PACKING - TG3

2

IN APPROVAL

TEST

10/5/2021, 3:04 PM

VIEW ALL

BOM RELATED SBR FOR SBOM HEADER (1)

1 ITEM. UPDATED A FEW SECONDS AGO

GENERAL MATERIAL DESCRIPTION 1

SBOM VERSION

STATUS

REASON FOR VERSIONING

CREATED DATE

1

PRIMARY, OPEN, BLISTER PACKING - TG3

1.0

APPROVED

4/28/2021, 9:34 AM

VIEW ALL

RELATED BATCH RECORDS (2)

2 ITEMS. UPDATED A FEW SECONDS AGO

BATCH RECORD NAME

RECORD TYPE

STATUS

STUDY PART

UNIQUE IDENTIFIER

VERSION

1

PRIMARY, OPEN, BLISTER PACKING - TG3

XBR READ ONLY

PROCESSED SUCCESSFULLY

PRIMARY, OPEN, BLISTER PACKING - TG3

SR-60010001

1

2

PRIMARY, OPEN, BLISTER PACKING - TG3

XBR READ ONLY

READY FOR MANUFACTURE

PRIMARY, OPEN, BLISTER PACKING - TG3

SR-60010001

1

VIEW ALL

526Y

FIG. 5Y

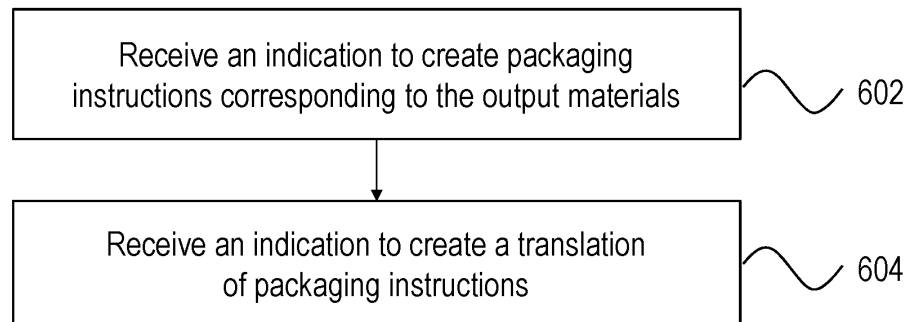
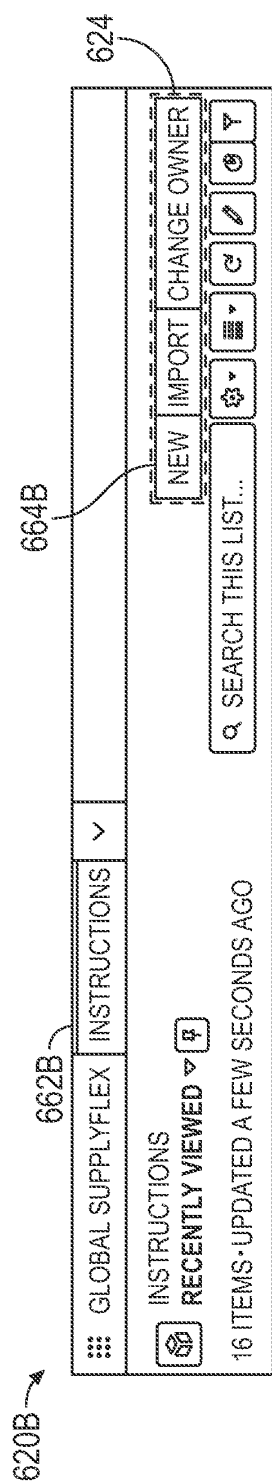
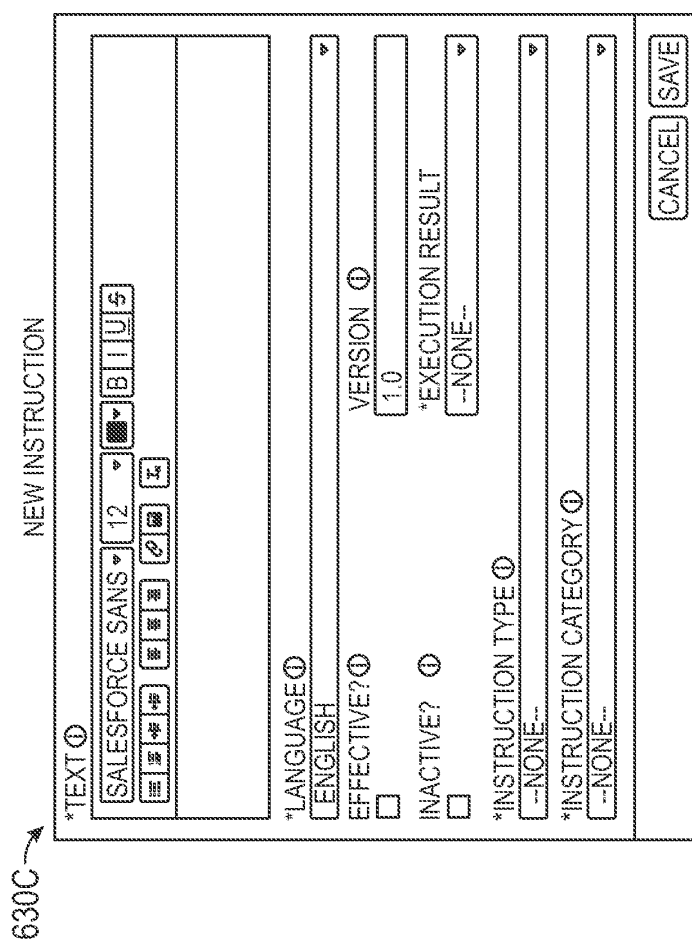
600A

FIG. 6A



உள்ளே



620D

662D

GERMAN	JAPANESE	CHINESE
NEW GERMAN		

FIG. 6D

630E

GERMAN	JAPANESE	CHINESE
SAVE CANCEL		
▼ TEXT AND EXECUTION RESULT		
*TEXT ⓘ		
SALESFORCE SANS 12 Color B I U S List Align Link Image Z		
FULO DLO FLASCHE		
EXECUTION RESULT		
PASS/FAIL ▼		
▼ EFFECTIVE, INACTIVE OR VERSION		
EFFECTIVE? ⓘ ☐	VERSION ⓘ 3.1	
INACTIVE? ⓘ ☐	INSTRUCTION GROUP ID IGP-1260	
▼ INSTRUCTION DETAILS		
LANGUAGE ⓘ GERMAN ▼		
*INSTRUCTION TYPE ⓘ IMAGE CAPTURE ▼		
INSTRUCTION CATEGORY ⓘ ASSEMBLING ▼		

FIG. 6E

ENGLISH	ENGLISH
[NEW VERSION]	[EDIT]
>TEXT AND EXECUTION RESULT	>TEXT AND EXECUTION RESULT
✓EFFECTIVE, INACTIVE OR VERSION EFFECTIVE?⓪	✓EFFECTIVE, INACTIVE OR VERSION EFFECTIVE?⓪
1.0	4.0
☒	☐

FIG. 6F

DID THE MEANING OF THE INSTRUCTION CHANGE?	
☒	[YES] [NO]

FIG. 6G

ENGLISH	ENGLISH
[SAVE] [CANCEL]	[SAVE] [CANCEL]
>TEXT AND EXECUTION RESULT	>TEXT AND EXECUTION RESULT
✓EFFECTIVE, INACTIVE OR VERSION EFFECTIVE?⓪	✓EFFECTIVE, INACTIVE OR VERSION EFFECTIVE?⓪
1.0	4.0
☒	☒

FIG. 6I

GERMAN JAPANESE CHINESE	GERMAN JAPANESE CHINESE
[NEW VERSION]	[EDIT]
>TEXT AND EXECUTION RESULT	>TEXT AND EXECUTION RESULT
✓EFFECTIVE, INACTIVE OR VERSION EFFECTIVE?⓪	✓EFFECTIVE, INACTIVE OR VERSION EFFECTIVE?⓪
1.1	3.5
☒	☐

FIG. 6J

DID THE MEANING OF THE INSTRUCTION CHANGE?	
☒	[YES] [NO]

FIG. 6K

GERMAN JAPANESE CHINESE	GERMAN JAPANESE CHINESE
[SAVE] [CANCEL]	[SAVE] [CANCEL]
>TEXT AND EXECUTION RESULT	>TEXT AND EXECUTION RESULT
✓EFFECTIVE, INACTIVE OR VERSION EFFECTIVE?⓪	✓EFFECTIVE, INACTIVE OR VERSION EFFECTIVE?⓪
1.1	3.5
☒	☒

FIG. 6M

620N

STUDY INSTRUCTIONS EQUIPMENT GROUPS					
PACKAGING INSTRUCTIONS IN PROCESS CHECK IMPORTANT NOTES IMAGE CAPTURE					
SEARCH FOR INSTRUCTIONS					
SEARCH... q					
ADD					
ENGLISH GERMAN SORT NEW					
SEQUENCE	TEXT	IMAGE	NAME	DESCRIPTION	VER
1	INSTRUCTION EXAMPLE CHANGES		PACKAGING INSTRUCTION TEST		1 edit delete
2	NEW ENGLISH INSTRUCTION 11-20		PACKAGING INSTRUCTION TEST		1 edit delete

FIG. 6N

646N

6300

EDIT STUDY INSTRUCTION

INFORMATION
INSTRUCTION NAME
PACKAGING INSTRUCTION TEST
INSTRUCTION
*TEXT ⓘ
SALESFORCE SANS 12 color B I U S bold italic underline
list link unlink
INSTRUCTION EXAMPLE CHANGES
DESCRIPTION
SALESFORCE SANS 12 color B I U S bold italic underline
list link unlink
IMAGE
upload UPLOAD FILES OR DROP FILES
SAVE

FIG. 6O

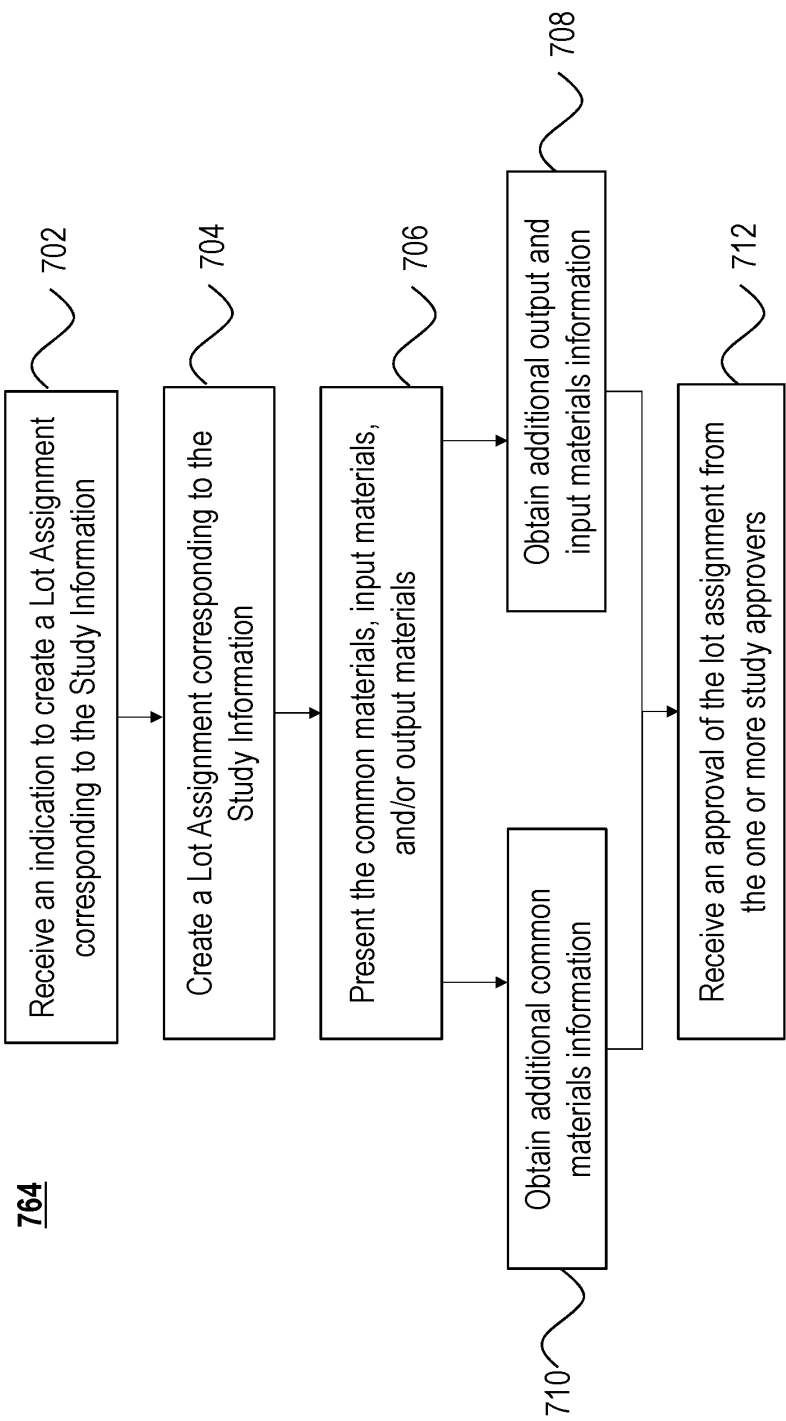


FIG. 7A

720B

STUDY INFORMATION		724				
	TEST	APPROVAL REPORT	NEW VERSION	HISTORY	CREATE LOT ASSIGNMENT	HOLD REPORT
CUSTOMER	CUSTOMER PROTOCOL	NUMBER OF STUDY PARTS	CREATED FROM PS/PADI VERSION	VERSION	STATUS	
	992211	3		1	APPROVED	

724B

FIG. 7B

730C

CREATE LOT ASSIGNMENT



*NAME

*GENERAL LA NOTE

*STUDY PART TYPE

SELECT AN OPTION

▼

*SITE

SELECT

▼

NEXT

FIG. 7C

730D

CREATE LOT ASSIGNMENT

☒ APPROVED SUPERBOMS

☒ SMOKE TEST SBR

☒ FRENCH WALLET SBR

PREVIOUS

NEXT

FIG. 7D

730E

CREATE LOT ASSIGNMENT

☐ NAME

SITE

SUPERBOM NAME

OUTPUT MATERIAL 1 SMOKE TES...

BATHGATE;

SMOKE TEST SBR

OUTPUT MATERIAL 2 SMOKE TES...

BATHGATE;

SMOKE TEST SBR

FRENCH WALLET WITH RED DOT...

BATHGATE;

FRENCH WALLET SBR

PREVIOUS

CREATE LOT ASSIGNMENT

FIG. 7E

720F

724

722

726F

TEST LA REPORT ... 875321

LOT ASSIGNMENT

TEST LA REPORT JAN 20

NEW VERSION

HISTORY

EDIT

APPROVAL

HOLD

RELATED STUDY INFORMATION

875321

PACKAGING TYPE

SECONDARY PACKAGING

1

VERSION

1

STATUS

APPROVED

DETAILS

COMMON

OUTPUT AND INPUT MATERIAL

RELATED XBR

1

LOT ASSIGNMENT NAME

TEST LA REPORT JAN 20

3035453

ETO NUMBER

0

GENERAL LA NOTE

TEST LA 101

MA-IT

ETO DESCRIPTION

0

PACKAGING TYPE

SECONDARY PACKAGING

2

CREATED FROM PS/PADI VERSION

0

LA SITE NAME

PHILADELPHIA

1

CREATED FROM PACKAGING REQUEST

0

PROTOCOL NUMBER

09864

0

RELATED STUDY INFORMATION

875321

0

LOT ASSIGNMENT DESCRIPTION

THIS IS THE LA DEMO DESCRIPTION FOR JAN 20

0

VERSION AND STATUS

STATUS

APPROVED

1

VERSION

1

REASON FOR VERSIONING

INCATIVE?

0

FIG. 7F

720G

724

◇

LOT ASSIGNMENT

1111

HISTORY

EDIT

APPROVAL

HOLD

VALIDATE ETO

RELATED STUDY INFORMATION	PACKAGING TYPE	VERSION	STATUS
EY48328	SECONDARY PACKAGING	1	DRAFT

DETAILS

COMMON

OUTPUT AND INPUT MATERIAL

RELATED XBRSL

722

742G

LOT ASSIGNMENT NAME	ETO NUMBER
1111	0
LOT ASSIGNMENT DESCRIPTION	ETO DESCRIPTION
0	0

726G

FIG. 7G

[illegible]

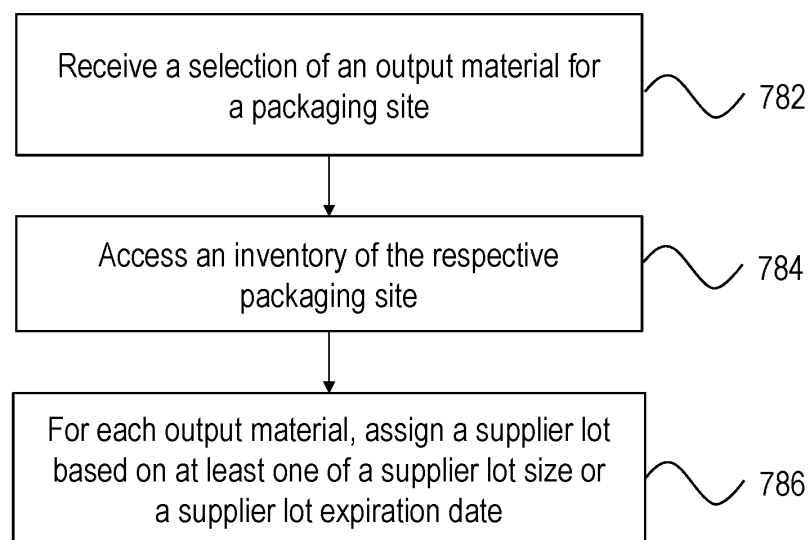
708I

FIG. 7I

720J

744J742J746J724

756J752J758J762J766J

DETAILS		COMMON		OUTPUT AND INPUT MATERIAL		RELATED XBRS	
OUTPUT MATERIAL							
ITEM ID	ITEM DE...	LABEL C...	OM GRO...	JDE UNI...	QUANTIT...	LABELED...	EXPIRY...
1 118419	JZP-258 PB...	KT LBLD		KT	5	76584380-L5	30-SEP-2022
INPUT MATERIAL (DRUG)							
ITE...	ITE...	LA...	ALT...	BO...	LOT...	JD...	SU...
1 11...	USIRO	1MG O...		1	5	KT	CLR90...
INPUT MATERIAL (NON-DRUG)							
ITE...	ITE...	LA...	ALT...	BO...	LOT...	JD...	SU...
1 CL...	TAPE...	PACKI		1	5	EA	1
LABELS							
ITE...	ITE...	LAB...	BAR...	LAB...	BO...	LOT...	JDE...
EXAMPLE PACK							
ITEM ID	ITEM DESC...	ITEM DESC...	BOM QUA...	JDE UNIT O...	LOT QUANTITY	SUPPLIER L...	

726J

FIG. 7J

730K →

EDIT OUTPUT MATERIAL

INFORMATION	
*GENERAL MATERIAL DESCRIPTION 1 OM1	OM TYPE ① FG
GENERAL MATERIAL DESCRIPTION 2 ① OM 1 DESC	*UOM ① EA - EACH
OM GROUP N/A ☐	OM GROUP ① ☒ TEST OM GRP 1 SEC
OM GROUP DESCRIPTION TEST OM GRP 1 SEC DESC	OM GROUP TYPE SECONDARY OM GROUP
DOSAGE CODE N/A ☐	*DOSAGE CODE NAME ① ☒ PBO SEC BLISTERS
CUSTOMER MATERIAL ID N/A ① ☐	*CUSTOMER MATERIAL ID ① CW-098
*QUANTITY TO BE MANUFACTURED 10	
INCLUDES SAMPLES: Y/N YES	
LOT INFORMATION	
CUSTOMER LOT NUMBER N/A 	*CUSTOMER LOT NUMBER ① 3454

FIG. 7K

730L →

INPUT MATERIAL (DRUG)

INFORMATION	
*GENERAL MATERIAL DESCRIPTION 1 IM1-OM1	UOM ⓘ BT - BOTTLE ▼
GENERAL MATERIAL DESCRIPTION 2 ⓘ IM1-OM1	LABELLED YES ▼
CUSTOMER MATERIAL ID N/A ⓘ ☒	
BOM QUANTITY ⓘ 1	
LOT INFORMATION	
CUSTOMER LOT NUMBER N/A 	*CUSTOMER LOT NUMBER ⓘ CW-519
EXPIRY DATE ⓘ DEC 2, 2021	LOT QUANTITY 10
SUPPLIER LOT NUMBER ⓘ 0000081043	
JDE ITEM INFORMATION	
*ITEM ID ⓘ CLR-WIP-9002890-013	JDE UOM ⓘ BT ▼

FIG. 7L

720M

SANDBOX: TESTDEPLOY

CATALOG

GLOBAL SUPPLY/EX LOT ASSIGNMENTS

6010002

TEST

TEST LA REPORT...

07522

TEST LOGS

PRIMARY OPEN BLIST

SUCCESS

UNDRY STANDARD

LOT ASSIGNMENT

TEST LA REPORT JAN 20

APPROVAL

NEW VERSION

HOLD

INACTIVE

HISTORY

RELATED STUDY INFORMATION

PACKAGING TYPE

VERSION

STATUS

10010007

SECONDARY PACKAGING

1

DRAFT

DETAILS

COMMON

OUTPUT AND INPUT MATERIAL

RELATED XBRS

OUTPUT MATERIAL

ITEM ID

ITEM DESCRIPTION 1

ITEM DESCRIPTION 2

LABEL COUNTRY GROUP

ORG GROUP

JOE UNIT OF MEASURE

QUERY IN THE MEA

LABELLED LOT NUMBER

EXPIRY DATE

CLA-186-790-3-2222

DALFANPSDACPACCO

LBL11600-09

LOG TWO TEST

TEST ON GRP 1 SEC

CA

3D

075321-220

075321-220

F

INPUT MATERIAL (DRUG)

ITEM ID

ITEM DESCR

ITEM DESCR

LABELLED

NUMERATE M

BOM QUANTITY

LOT QUANTITY

JDS UNIT OF

SUPPLY LOT

EXPIRY DATE

USE IS ???

1

CLDWD90

???

???

???

YES

1

10

ST

000053063

2-DE-2023

YES

075321-220

075321-220

075321-220

2

CLDWD90

???

???

???

YES

1

10

ST

000053063

2-DE-2023

YES

075321-220

075321-220

075321-220

FIG. 7M

730N

INPUT MATERIAL (NON-DRUG)

INFORMATION	
*GENERAL MATERIAL DESCRIPTION 1 IMND1-0M1	UOM ⓘ BT - BOTTLE ▼
GENERAL MATERIAL DESCRIPTION 2 ⓘ C1	LABELED ⓘ NO ▼
CUSTOMER MATERIAL ID N/A ☐	CUSTOMER MATERIAL ID ⓘ 123
CUSTOMER GOODS UN N/A ☐	DANGEROUS GOODS UN ⓘ
BOM QUANTITY ⓘ 1	
LOT INFORMATION	
*CUSTOMER LOT NUMBER TO BE ASSIGNED ▼	
SUPPLIER LOT TO BE ASSIGNED ▼	LOT QUANTITY 10
JDE ITEM INFORMATION	
*ITEM ID ⓘ CLR-WIP-9002890-013	JDE UOM ⓘ BT

FIG. 7N

7200 →

INPUT MATERIAL (LABEL)

INFORMATION	
GENERAL MATERIAL DESCRIPTION 1 10MG DIAZEPAM 1CT CARTON LABEL	UOM ⓘ EA - EACH ▼
GENERAL MATERIAL DESCRIPTION 2 ⓘ L1208990	BOM QUANTITY ⓘ 1.000000 ▼
LABEL DETAILS	
BARCODE TYPE ⓘ DOES NOT HAVE A BARCODE ▼	*JDE LABEL WO#: QUANTITY ⓘ X56:3,8AU:7
LOT INFORMATION	
LOT QUANTITY ⓘ 500.000000	
JDE ITEM INFORMATION	
ITEM ID ⓘ CLR-634-780-842582	JDE UOM ⓘ EA
ITEM DESCRIPTION 1 DIAZ.001.05 5MG 1X CTN LABEL	
ITEM DESCRIPTION 2 L1600438	

FIG. 70

720P →

EXAMPLE PACK

INFORMATION	
GENERAL MATERIAL DESCRIPTION 1 FOR_TIME_UPDATE	UOM ① BC - BLISTER CARD
BOM QUANTITY ① 1.000000	SUPERBOM TEST REQUIRED
OM GROUP N/A ☐	OM GROUP ① ☐
OM GROUP DESCRIPTION	OM GROUP TYPE
CUSTOMER MATERIAL ID N/A ① ☐	CUSTOMER MATERIAL ID ① 568
LOT INFORMATION	
CUSTOMER LOT NUMBER TO BE ASSIGNED	
SUPPLIER LOT YES	LOT QUANTITY 1.000000
SUPPLIER LOT NUMBER ① 6787	EXPIRY DATE ① 5/8/2021
JDE ITEM INFORMATION	

FIG. 7P

720Q

SANDBOX TEST DEPLOY

CATALOG

SEARCH...

TEST LOGS

GLOBAL SUPPLY/VIEW LOT ASSIGNMENTS

TEST FOR BUG 3287

ISSP PRIMARY

ISSP COPY OF SECONDARY

SECONDARY STANDARD

PRIMARY OPEN B

TEST LOGS

724

LOT ASSIGNMENT TEST LOGS

APPROVAL

NEW VERSION

HOLD

INACTIVE

HISTORY

RELATED STUDY INFORMATION

PACKAGING TYPE

VERSION

STATUS

10010007

SECONDARY PACKAGING

1

722

APPROVED

DETAILS

COMMON

OUTPUT AND INPUT MATERIAL

RELATED XBRS

SUPERBOMS

HIDE

REFERENCED INPUT MATERIALS THAT HAVE OBSOLETE RECONCILIATION LIMIT

ITEM ID

COMMON

SFXSIDRG3

FALSE

SFXSIDRG2

FALSE

COMMON MATERIALS

INPUT MATERIAL (DRUG)

ITEM ID

ITEM DESCRIPTION 1

ITEM DESCRIPTION 2

JOE UOM

LABELLED

ALTERNATIVE MATERIAL

LOT QUALITY

SUPPLIER LOT NUMBER

EXPIRY DATE

USE ON XBR

INPUT MATERIAL (NON-DRUG)

ITEM ID

ITEM DESCRIPTION 1

ITEM DESCRIPTION 2

JOE UOM

LABEL COUNTRY GROUP

DESTINATION COUNTRIES

DM GROUP

ALTERNATIVE MATERIAL

BOM QUANTITY

LOT QUANTITY

SUPPLIER LOT

EXPIRY DATE

USE IN XBR

LABELS

ITEM ID

ITEM DESCRIPTION 1

ITEM DESCRIPTION 2

JOE UOM

LABEL COUNTRY GROUP

DESTINATION COUNTRIES

DM GROUP

BARCODE TYPE

BOM QUANTITY

LOT QUANTITY

EXAMPLE PACK

ITEM ID

ITEM DESCRIPTION 1

ITEM DESCRIPTION 2

JOE UOM

LABEL COUNTRY GROUP

DESTINATION COUNTRIES

DM GROUP

BOM QUANTITY

LOT QUANTITY

SUPPLIER LOT NUMBER

EXPIRY DATE

726Q

FIG. 7Q

720R

778R

LOT ASSIGNMENT
TEST

HISTORY

EDIT

APPROVAL

RELATED STUDY INFORMATION

PACKAGING TYPE

VERSION

STATUS

TEST

PRIMARY PACKAGING

1

DRAFT

FIG. 7R

776S

ESIGN

CANCEL

CATALENT.

OUTPUT MATERIAL INFORMATION

GENERAL MATERIAL DESCRIPTION 1: DEMO SP BOM 12/04

SBOM TYPE: SECONDARY OM

OM GROUP:

OM GROUP DESCRIPTION:

OM GROUP TYPE:

772S

ESIGNATURE FOR
I APPLY MY ELECTRONIC SIGNATURE FOR FOR.
THIS SIGNATURE IS LEGALLY BINDING.

*USER LOGIN ID

*INDIVIDUAL SIGNATURE IDENTIFIER

COMMENTS

APPROVE

CANCEL

REJECT

774T

FIG. 7S

FIG. 7T

7207 →

CATALENT		SANDBOX: TESTDEPLOY					
SEARCH...							
GLOBAL SUPPLY FLEX	LOT ASSIGNMENTS	W-8010002	TEST FOR BUG 3257	CSP_PRIMARY	USGZ CSP	COPY OF SECONDARY	SECONDARY STANDARD
		PRIMARY OPEN BUST		TEST LCG'S			

LOT ASSIGNMENT TEST LCG'S	724	APPROVAL	NEW VERSION	HOLD	INACTIVE	HISTORY
RELATED STUDY INFORMATION 10010007	PACKAGING TYPE SECONDARY PACKAGING 1	VERSION STATUS APPROVED				

DETAILS	COMMON	OUTPUT AND INPUT MATERIAL	RELATED XBRS	SUPERBOMS	722
BATCH RECORDS (RELATED LA HEADER) (2)					
BATCH RECORD NAME	RELATED BATCH RECORD				
TEST LCG 2	TEST LCG 2				
TEST LCG 1	TEST LCG 1				
VIEW ALL					

U
7
G^x
E

720V

SANDBOX: TESTDEPLOY

CATALENT

GLOBAL SUPPLY FLEX

LOT ASSIGNMENTS

6010002

TEST FOR BUG 2267

SP PRIMARY

000221SSP

COPY OF SECONDARY

SECONDARY STANDARD

PRIMARY OPEN BUST

TEST LOGS

LOT ASSIGNMENT

TEST LCG'S

724

APPROVAL

NEW VERSION

HOLD

INACTIVE

HISTORY

RELATED STUDY INFORMATION

PACKAGING TYPE

VERSION STATUS

10010007

SECONDARY PACKAGING 1

APPROVED

DETAILS

COMMON

OUTPUT AND INPUT MATERIAL

RELATED XBRS

SUPERBOMS

722

726V

SUPERBOM NAME

VERSION

UNIQUE IDENTIFIER

TEST LCG 2

1.0

10010007-SBOM-25

TEST LCG 1

1.0

10010007-SBOM-24

FIG. 7V

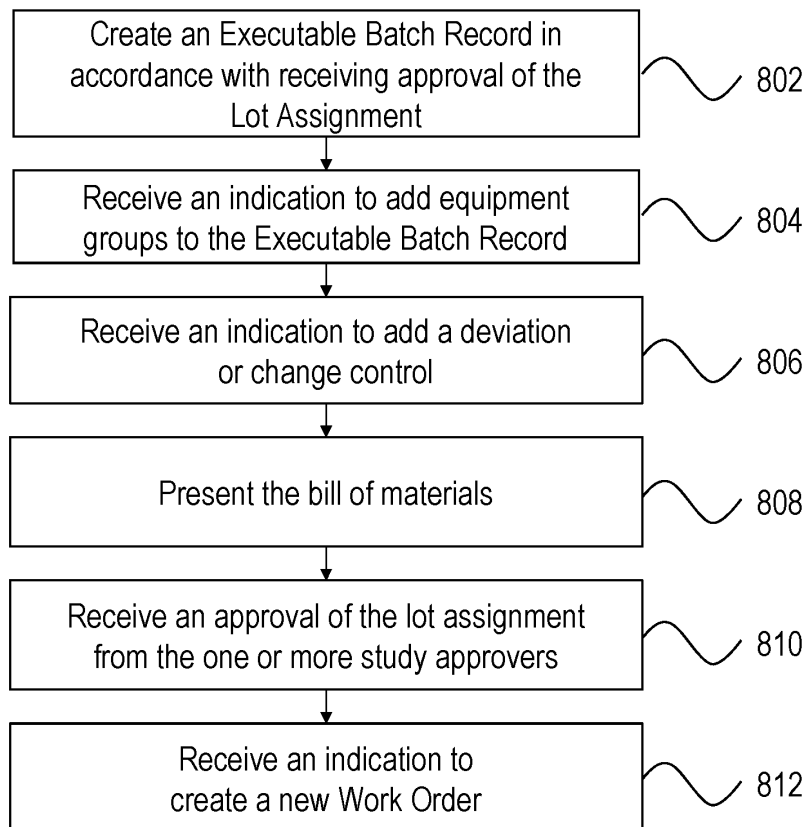
866

FIG. 8A

820B →

SANDBOX: TESTDEPLOY									
CATALENT									
SEARCH...									
GLOBAL SUPPLY FLEX LOT ASSIGNMENTS									
PRIMARY, OPEN, BL...									
PRIMARY, ...									
824									
APPROVAL NEW VERSION HOLD INACTIVE HISTORY									
BATCH RECORD									
60010001-XBR-5									
CUSTOMER PROJECT NUMBER CUSTOMER PROTOCOL PACKAGING TYPE STATUS									
SFX PQ CUSTOMER 1 60010001 SFX PQ 1 PRIMARY PACKAGING PROCESSED SUCCESSFULLY									
DETAILS EQUIPMENT GROUPS & INSTRUC... BILL OF MATERIALS DEVIATIONS & CHANGE CONTROLS WORK ORDER 822 826B									
INFORMATION									
BATCH RECORD NAME									
PRIMARY, OPEN, BLISTER PACKING - TG3									
CUSTOMER									
SFX PQ CUSTOMER 1									
PROJECT NUMBER									
60010001									
CUSTOMER PROTOCOL									
SFX PQ 1									
XBR SEQUENCE NUMBER									
1									
BLINDED									
NO									

FIG. 8B-1

STATUS	
PROCESSED SUCCESSFULLY	
REASON FOR CANCELLATION	
ERROR IN PROCESS - XBR RECREATED	
HOLD REASON	
HOLD REMOVE REASON	
▼ NOTE	
XBR NOTE ⓘ	
RETENTION SAMPLE TO BE TAKEN AT THE BEGINNING OF EACH RUN.	
RETENTION SAMPLE TO BE STORED AT 2-8°C AT CATALENT BTH	
▼ LOT INFORMATION	
RELATED LA HEADER	ETO NUMBER
3176280.03MAY2021 2	3176280
LA UNIQUE IDENTIFIER	GENERAL LA NOTE
60010001-LA-3	
LA SITE NAME	
BATHGATE	
▼ ROOM PROCESSING TEMPERATURE	
TEMPERATURE RANGE	LOW RANGE IN °C
BETWEEN	2
	HIGH RANGE IN °C
	8
▼ ROOM PROCESSING HUMIDITY	
HUMIDITY RANGE	LOW RANGE IN %RH
N/A	HIGH RANGE IN %RH

FIG. 8B-2

▼ ROOM PROCESSING LIGHT CONDITIONS

LIGHT CONDITION RANGE

N/A

LOW RANGE IN "LUX"

LIGHT CONDITIONS DESCRIPTION

HIGH RANGE IN "LUX"

▼ SYSTEM INFORMATION

CREATED BY

 SFX SYSTEM USER

XBR UNIQUE IDENTIFIER

60010001-XBR-5

STUDY PART 

PRIMARY, OPEN, BLISTER PACKING--IG3

FILE UPLOAD RESTRICTION

ADD FILES FUNCTIONALITY WORKS ONLY FOR A RECORD:

* IN DRAFT STATUS OR

* IN PENDING CUSTOMER APPROVAL STATUS IF THERE IS AT LEAST ONE STUDY APPROVER RECORD WITH OF ONBEHALFOF FOR THE STUDY OR

* IN READY FOR MANUFACTURE STATUS IF NOT BEING EXECUTED WITHIN SUPPLYFLEX.

 FILES (0)

UPLOAD FILES

OR DROP FILES

UPLOAD FILES

FIG. 8B-3

820C →

SANDBOX: TESTDEPLOY

CATALENT

SEARCH...

GLOBAL SUPPLY FLEX LOT ASSIGNMENTS

60010002

TEST FOR BUG 2267

SP PRIMARY

0000221SSP

COPY OF SECONDARY

SECONDARY STANDARD

PRIMARY, OPEN, BLIST

TEST LOGS

PRIMARY, OPEN, BL

PRIMARY

BATCH RECORD

60010001-XBR-5

824

APPROVAL

OPEN DRAWING

HOLD

CANCEL XBR

HISTORY

CUSTOMER

PROJECT NUMBER

CUSTOMER PROTOCOL

PACKAGING TYPE

STATUS

SFX PQ CUSTOMER 1

60010001

SFX PQ 1

PRIMARY PACKAGING

PROCESSED SUCCESSFULLY

DETAILS

EQUIPMENT GROUPS & INSTRUC...

BILL OF MATERIALS

DEVIATIONS & CHANGE CONTROLS

WORK ORDER

822 826C

EQUIPMENT GROUP

EQUIPMENT DETAILS

LEAK TESTER

SFX SIT PRIMARY IM DRUG 2

PRODUCT COUNTER

SFX SIT PRIMARY IM DRUG 2

PRODUCT COUNTER

SFX SIT PRIMARY IM DRUG 1

BOTTLE - PRODUCT VISION SYSTEM

CHECKWEIGHER

BLISTER - FLOOD FEEDER

SFX SIT PRIMARY IM DRUG 1

FIG. 8C-1

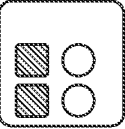
PACKAGING INSTRUCTIONS				
		IN PROCESS CHECK	IMPORTANT NOTES	IMAGE CAPTURE
ENGLISH GERMAN CHINESE				
SEQUENCE	TEXT	IMAGE	NAME	DESCRIPTION VER
1	VERIFY INITIAL WEIGHT AND RECORD ON INITIAL WEIGHT FORM FOR SIX SIX SIX PRIMARY IM DRUG 1		PRIMARY, BLISTERING	1
2	VERIFY INITIAL WEIGHT AND RECORD ON INITIAL WEIGHT FORM FOR SIX SIX SIX PRIMARY IM DRUG 2		PRIMARY, BLISTERING	1
3	RUN EMPTY PRE-FORMED BLISTERS THROUGH THE ENTIRE LENGTH OF THE MACHINE		PRIMARY, BLISTERING	1
4	OPERATOR 1: FILL APERTURES WITH PRODUCT 1. REFER TO IMAGE (PINK; CAPSULES)		PRIMARY, BLISTERING	1
5	OPERATOR 2: FILL APERTURES WITH PRODUCT 2. REFER TO IMAGE (GREEN; CAPSULES)		PRIMARY, BLISTERING	1
6	INSPECT BLISTERS ENSURING FINISHED BLISTER RESEMBLES ACCEPTABLE BLISTER		PRIMARY, BLISTERING, MIXED FILL PRODUCT	1
7	WEIGH ACCEPTABLE BLISTERS		PRIMARY, BLISTERING, MIXED FILL PRODUCT	1
8	VERIFY ACCEPTABLE BLISTER CHECKS		PRIMARY, BLISTERING, MIXED FILL PRODUCT	1
9	PACK ACCEPTABLE BLISTERS INTO APPROPRIATE STORAGE CONTAINERS		PRIMARY, BLISTERING, MIXED FILL PRODUCT	1
10	ON COMPLETION OF PACKAGING ALL STORAGE CONTAINERS MUST HAVE A JDE LABEL		PRIMARY, BLISTERING, MIXED FILL PRODUCT	1

FIG. 8C-2

840D →

CREATE EQUIPMENT GROUPS

SAVE

CANCEL

NEW

EQUIPMENT GROUP

▼

--NONE--

▼ --NONE--

BLISTER PACKER

NEW GROUP

THERMOMETER

INDUCTION SEALER

OVERENCAPSULATION

EQUIPMENT DETAILS

FIG. 8D

820E

SANDBOX: TESTDEPLOY

CATALOG

GLOBAL SUPERVIEW

LOT ASSIGNMENTS

PRIMARY, OPEN, BL...

Q SEARCH...

TEST FOR BING TEST

OUTLINE

SP PRIMARY

18022 CSP

COPY OF SECONDARY...

SECONDARY STANDARD

PRIMARY OPEN BLST

TEST LOOS

PRIMARY, OPEN, BL...

PRIMARY, ...

BATCH RECORD

60010001-XBR-5

824

APPROVAL

OPEN DRAWING

HOLD

INACTIVE

HISTORY

CUSTOMER

PROJECT NUMBER

CUSTOMER PROTOCOL

PACKAGING TYPE

STATUS

SFX PQ CUSTOMER 1

60010001

SFX PQ 1

PRIMARY PACKAGING

PROCESSED SUCCESSFULLY

DETAILS

EQUIPMENT GROUPS & INSTRUC...

BILL OF MATERIALS

DEVIATIONS & CHANGE CONT...

WORK ORDER

822

826E

DEVIATIONS AND CHANGE CONTROLS (0)

FIG. 8E

820F

DETAILS

EQUIPMENT GROUPS & INSTR...

BILL OF MATERIALS

DEVIATIONS & CHANGE CONT...

DEVIATIONS AND CHANGE CONTROLS (0)

NEW

CHANGE OWNER

FIG. 8F

830G

NEW DEVIATION AND CHANGE CONTROL

INFORMATION

*RECORD NUMBER

COMPLETE THIS FIELD

RELATED BATCH RECORD

TEST 11A

*TYPE

--NONE--

✓ --NONE--

DEVIATION

CHANGE CONTROL

SHORT DESCRIPTION

OWNER

ROHAN KAPOOR

CANCEL

SAVE & NEW

SAVE

FIG. 8G

820H

SANDBOX: TESTDEPLOY

CATALENT

Q SEARCH

TEST LOGS

PRIMARY, OPEN, BLST

SECONDARY STANDARD

COPY OF SECONDARY

SP PRIMARY

TEST FOR DRUG 2267

60010002

LOT ASSIGNMENTS

GLOBAL SUPPLY FLEX

BATCH RECORD

60010001XBR-5

APPROVAL

OPEN DRAWING

HOLD

CANCEL XBR

HISTORY

824

CUSTOMER

SFX PQ CUSTOMER 1

PROJECT NUMBER

60010001

CUSTOMER PROTOCOL

SFX PQ 1

PACKAGING TYPE

PRIMARY PACKAGING

STATUS

PROCESSED SUCCESSFULLY

DETAILS

EQUIPMENT GROUPS & INSTRUC...

BILL OF MATERIALS

DEVIATIONS & CHANGE CONTROLS

WORK ORDER

822

826H

OUTPUT MATERIAL

ITEM ID

ITEM DESCRIPTION 1

ITEM DESCRIPTION 2

JDE UOM

LABEL COUNTRY GROUP

OM GROUP

QUANTITY TO...

SUPPLIER LOT NUMBER

LABELLED EXPIRY DATE

1 SFXSITWP3 SFX SIT PM OM3

EA

OMG-P3

1000

INPUT MATERIAL (DRUG)

ITEM ID

ITEM DESCRIPTION 1

ITEM DESCRIPTION 2

JDE U...

LABELLED

BOM QUANTITY

LOT QUANTITY

SUPPLIER LOT NU...

EXPIRY DATE

SFXSIDRCA SFX SIT PM DRG1

EA

NO

2,000,000,000

2,000,000,000

675958

7-JAN-2022

SFXSIDRGS SFX SIT PM DRG2

EA

NO

2,000,000,000

2,000,000,000

345769

7-JAN-2023

INPUT MATERIAL (NON-DRUG)

ITEM ID

ITEM DESCRIPTION 1

ITEM DESCRIPTION 2

JDE U...

BOM QUANTITY

LOT QUANTITY

SUPPLIER LOT NU...

EXPIRY DATE

SFXSITM5 SFX SIT PM IM1

EA

1,000,000,000

1,000,000,000

45769

8-DEC-2021

SFXSITM6 SFX SIT PM IM2

EA

1,000,000,000

1,000,000,000

749759

8-DEC-2021

FIG. 8H

8201

BATCH RECORD
435-YBR-1378

HISTORY

EDIT

APPROVAL

▼

CUSTOMER	PROJECT NUMBER	PROTOCOL NUMBER	PACKAGING TYPE	STATUS
	435	435	SECONDARY PACKAGING	DRAFT

876J

ESIGN

CANCEL

872J

CATALOG

OUTPUT MATERIAL INFORMATION

GENERAL MATERIAL DESCRIPTION 1: DEMO SP BOM 12/04 TYPE: SECONDARY OM

OM GROUP:

OM GROUP DESCRIPTION:

OM GROUP TYPE:

874K

ESIGNATURE FOR

I APPLY MY ELECTRONIC SIGNATURE FOR FOR.

THIS SIGNATURE IS LEGALLY BINDING.

*USER LOGIN ID

*INDIVIDUAL SIGNATURE IDENTIFIER

COMMENTS

APPROVE

CANCEL

REJECT

1
 2
 3
 4
 5
 6
 7
 8
 9
 10
 11
 12
 13
 14
 15
 16
 17
 18
 19
 20
 21
 22
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36

820L 

CATALENT										SANDBOX: TESTDEPLOY									
Q SEARCH:																			
☐ GLOBAL SUPPLY FLEX		☐ LOT ASSIGNMENTS	>	☒ 60010001		☐ TEST FOR BUG 2025	>	☐ 3P PRIMARY	>	☐ 000021SSP	>	☐ COPY OF SECONDARY	>	☐ SECONDARY STANDARD	>	☐ PRIMARY OPEN, BUST	>	☐ TEST LOGS	
☒ PRIMARY OPEN, BL.		>		☒ PRIMARY		>				>				>					

☒ BATCH RECORD
60010001XBR-5

CUSTOMER PROJECT NUMBER CUSTOMER PROTOCOL STATUS
SFX PQ CUSTOMER 1 60010001 SFX PQ 1 PRIMARY PACKAGING PROCESSED SUCCESSFULLY

824

826L

822L

APPROVAL OPEN DRAWING HOLD CANCEL XBR HISTORY

DETAILS EQUIPMENT GROUPS & INSTRU... BILL OF MATERIALS DEVIATIONS & CHANGE CONTROLS WORK ORDER

ITEM ID	WORK ORDER	NO STATUS	SUPPLIER LOT NUMBER	LABELLED EXPIRY DATE	DE EXPIRY DATE	QUANTITY TO BE MANUFA.	SAMPLE QUANTITY	DE QTY TO PRODUCE	JDE UOM	JDE NO COMPLETE
SFXSITIM3	3177130	WORK ORDER CREATED 601000-PT		1000	0	1000	5A	NO		

OUTPUT MATERIAL (DRUG)

ITEM ID	JDE LOT	SUPPLIER LOT	JDE LOT STATUS	JDE EXPIRY DATE	JDE UOM	JDE COMMITTED QTY
SFXSIDRG4	3657945	679856	07-JAN-2022	EA	2,000.000000	
SFXSIDRG5	3657946	345789	07-JAN-2022	EA	2,000.000000	

INPUT MATERIAL (NON-DRUG)

ITEM ID	JDE LOT	SUPPLIER LOT	JDE LOT STATUS	JDE EXPIRY DATE	JDE UOM	JDE COMMITTED QTY
SFXSITIM5	3657948	45789	08-DEC-2021	EA	1,000.000000	
SFXSITIM6	3657949	749759	08-DEC-2021	EA	1,000.000000	

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820M

842M

 BATCH RECORD 435-XBR-1378		HISTORYHOLDXBR REPORTAPPROVAL		
CUSTOMER	PROJECT NUMBER 435	PROTOCOL NUMBER 435	PACKAGING TYPE SECONDARY PACKAGING	STATUS READY FOR MANUFACTURE

FIG. 8M

CATALENT.
SUPPLYFLEX EXECUTABLE
BATCH RECORD

RECORD NUMBER: 435-XBR-1378
STATUS: DRAFT
CUSTOMER:

CATALENT SITE:
CATALENT PROJECT: 435
CATALENT PROTOCOL: 435

APPROVALS

PRE-APPROVAL

CREATED BY
(CATALENT)

NAME:
TITLE:
DATE OF ESIGN:

POST-REVIEW

REVIEWED BY
(PRODUCTION)

NAME:
SIGNATURE:
DATE:

REVIEWED BY
(QUALITY)

NAME:
SIGNATURE:
DATE:

REVIEWED BY
(CUSTOMER)

NAME:
SIGNATURE:
DATE:

REPORT NAME: TEST BR OCT 6 ONE V1

GENERATED BY ROHAN KAPPOR
PRE-PRODUCTION PAGE 1 OF 16

MON JAN 04 07:32:38 GMT 2021
PAGE

FIG. 8N

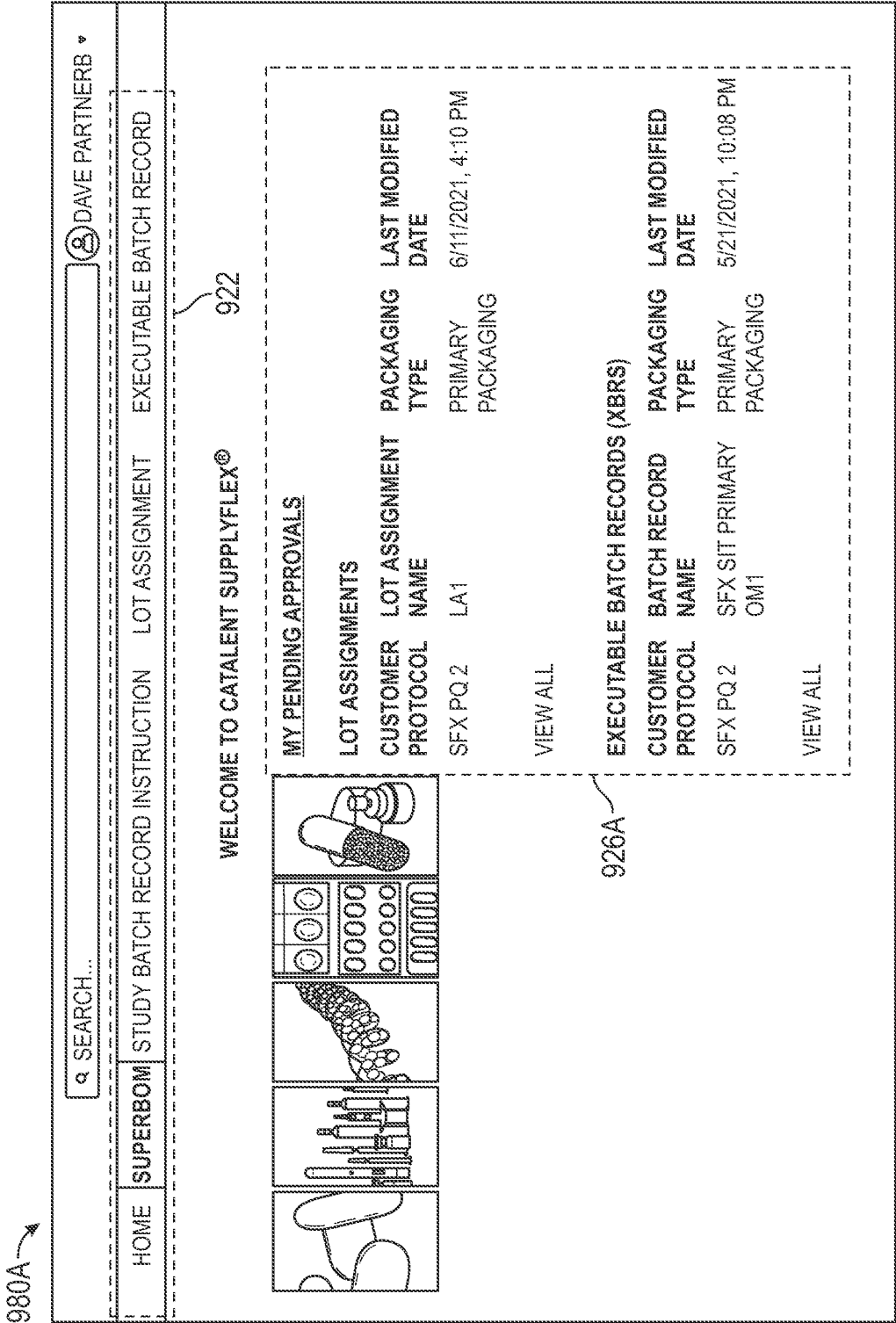


FIG. 9A

980B

SEARCH...

DAVE PARTNERB

HOME

SUPERBOM

STUDY BATCH RECORD INSTRUCTION

LOT ASSIGNMENT

EXECUTABLE BATCH RECORD

922

LOT ASSIGNMENTS

LOT ASSIGNMENTS

1 ITEM • SORTED BY CUSTOMER PROTOCOL • FILTERED BY ALL LOT ASSIGNMENTS • STATUS: UPDATED A FEW SECONDS AGO

CUSTOM...

LOT AS...

PACKAGING TYPE

LAST MODIFIED DATE

LA UNIQUE IDE...

ETO NU...

CREATE...

VERSION

STATUS

1

SFX PQ.2

LA1

PRIMARY PACKAGING

6/11/2021, 4:10 PM

6301002-LA-4

3176430

1

PENDING CUSTOMER APPROVAL

926B

FIG. 9B

980C

SEARCH

DAVE PARTNERB

HOME

SUPERBOM

STUDY BATCH RECORD INSTRUCTION

LOT ASSIGNMENT

EXECUTABLE BATCH RECORD

922

926C

LOT ASSIGNMENTS

LAI

RELATED STUDY INFORMATION

60010002

CUSTOMER PROTOCOL

SFX PQ 2

LOT ASSIGNMENT NAME

LAI

PACKAGING TYPE

PRIMARY PACKAGING

LAST MODIFIED DATE

6/11/2021

APPROVAL

928C

FILES (0)

TITLE

CONTAINS UNBLINDING INFORMATION

NO RELATED LISTS TO DISPLAY

CREATED FROM PACKAGING REQUEST

FIG. 9C

[illegible]

FIG. 10A

1020B

AUDIT HISTORY

LOGGED IN USER UTC OFFSET: (UTC+06:00)

TAB	TYPE	USERS	MATERIALS
HISTORY		ALL	ALL

LOGGED IN USER NAME	LAST MODIFIED DATE	ACTION	COMMON	GENERAL MATERIAL DESCRIPTION 1 2	ON UOM TYPE	QUANTITY BE MANUFACTURED (CM)	SCM QUANTITY	LOT QUANTITY	DOSAGE CODE ACTION NAME	DOSAGE CODE QUANTITY ACTION	ON GROUP CODE N/A	ON DESAG CODE N/A
NICHOLAS@GERSO.COM TEST DEPLOY	07 DEC 2021 14:23 (UTC)	CREATED	FALSE	INPUT 1 EA	EA	1	20		FALSE	FALSE		
NICHOLAS@GERSO.COM TEST DEPLOY	07 DEC 2021 14:23 (UTC)	CREATED	FALSE	LABEL 1 EA	EA	1	20		FALSE	FALSE		
NICHOLAS@GERSO.COM TEST DEPLOY	07 DEC 2021 14:23 (UTC)	CREATED	FALSE	DRUG 1 EA	EA	2	40		FALSE	FALSE		
NICHOLAS@GERSO.COM TEST DEPLOY	07 DEC 2021 14:23 (UTC)	CREATED	FALSE	INPUT 1 EA	EA	1	20		FALSE	FALSE		
NICHOLAS@GERSO.COM TEST DEPLOY	07 DEC 2021 14:23 (UTC)	CREATED	FALSE	DRUG 1 EA	EA	2	40		FALSE	FALSE		
NICHOLAS@GERSO.COM TEST DEPLOY	07 DEC 2021 14:23 (UTC)	CREATED	FALSE	LABEL 1 EA	EA	1	20		FALSE	FALSE		
NICHOLAS@GERSO.COM TEST DEPLOY	07 DEC 2021 14:23 (UTC)	CREATED	FALSE	OUTPUT 1 FG	FG	KT	20	0	TRUE	TRUE		
NICHOLAS@GERSO.COM TEST DEPLOY	07 DEC 2021 14:23 (UTC)	CREATED	FALSE	OUTPUT 1 FG	FG	KT	20	0	TRUE	TRUE		

4



1100A →

ESIGN

INFORMATION
THERE IS NO PENDING EVENTS FOR THIS APPROVAL FLOW.

SFX_GENERATEPDF

APPROVAL

1/11 | - 110% + | 3

↓ ↻

CATALENT

ID: 90010001-XBR-23

CUSTOMER: SFX PQ CUSTOMER 1
PROTOCOL: SFX PQ 1

BATCH RECORD NAME:
STUDY PART
CUSTOMER:
XBR UNIQUE IDENTIFIER:
PROJECT NUMBER:
PROTOCOL NUMBER:
BLINDED:
PACKAGING TYPE:
CREATED FROM PACKAGING
REQUEST:

PRIMARY, BLINDED BLISTER PACKING 4CT (2/2), BTH
PRIMARY, BLINDED BLISTER PACKING 4CT (2/2), BTH
SFX PQ CUSTOMER 1
90010001-XBR-23
90010001
SFX PQ 1
YES
PRIMARY, PACKAGING
1

MEDICATIONS LIST ID:
KIT NUMBER RANGE START:
KIT NUMBER RANGE END:
SEQUENCE NUMBER START:
SEQUENCE NUMBER END:

N/A
N/A
N/A
N/A
N/A

1100A

CREATED FROM PS/PADI:

2

LOT INFORMATION

RELATED LA HEADER:
LA SITE NAME:
GENERAL LA NOTE:

3711381-01 07SEP2021
BATHGATE
N/A

ETO NUMBER:
LA UNIQUE IDENTIFIER:

3711381
90010001-LA-20

CANCEL

FIG. 11A

1100B →

CATALENT		ID: 90010001-XBR-23	CUSTOMER: SFX PQ CUSTOMER 1 PROTOCOL: SFX PQ 1
XBR REPORT			
BATCH RECORD NAME:	PRIMARY, BLINDED, BLISTER PACKING 4CT (2/2), BTH		
STUDY PART	PRIMARY, BLINDED, BLISTER PACKING 4CT (2/2), BTH		
CUSTOMER:	SFX PQ CUSTOMER 1		
XBR UNIQUE IDENTIFIER:	90010001-XBR-23		
PROJECT NUMBER:	90010001		
PROTOCOL NUMBER:	SFX PQ 1		
BLINDED:	YES		
PACKAGING TYPE:	PRIMARY, PACKAGING		
CREATED FROM PACKAGING REQUEST:	1		
MEDICAL LIST ID:		N/A	
CREATED FROM PS/PADI:		2	
LOT INFORMATION			

1110B ↗

FIG. 11B

1130C

ADD FILE DETAILS
PQ TC035 DATA SHEET

RECORD TYPE

CONTACT VERSION

INFORMATION

*TITLE

PQ TC035 DATA SHEET

DESCRIPTION

*CONTAINS UNBLINDING INFORMATION ⓘ

YES

*CUSTOMER SIGNED APPROVAL? ⓘ

NO

*LABELED PLACEMENT AND ASSEMBLY DRAWINGS ⓘ

NO

FILE 1 OF 1

SAVE

1032C

FIG. 11C

1180D

TESTDEPLOY-CUSTOMERS/CS16/FORCE.COM/CUSTOMERS/SFX/LOT-ASSIGNMENT/AC0E0000086GGA4CTEST

SEARCH

ROBERT PARTNERD

UPDATE

HOME

SUPERBOM

STUDY BATCH RECORD INSTRUCTION

LOT ASSIGNMENT

EXECUTABLE BATCH RECORD

LOT ASSIGNMENT TEST

NO RELATED LISTS TO DISPLAY

RELATED STUDY INFORMATION

60010010

PACKAGING TYPE

PRIMARY PACKAGING

VERSION

1

CUSTOMER PROTOCOL

SFX PQ 10

STATUS

PENDING CUSTOMER APPROVAL

LOT ASSIGNMENT NAME

TEST

LA UNIQUE IDENTIFIER

60010010-LA-14

FILES (1)

TITLE

PQ TC038 DATA SHEET

CONTAINS UNBLINDING INFORMATION

YES

1112D

FIG. 11D

HOME

SUPERBOM

STUDY BATCH RECORD INSTRUCTION

LOT ASSIGNMENT

EXECUTABLE BATCH RECORD

LOT ASSIGNMENT TEST

NO RELATED LISTS TO DISPLAY

RELATED STUDY INFORMATION

60010010

PACKAGING TYPE

PRIMARY PACKAGING

VERSION

1

CUSTOMER PROTOCOL

SFX PQ 10

STATUS

PENDING CUSTOMER APPROVAL

LOT ASSIGNMENT NAME

TEST

LA UNIQUE IDENTIFIER

60010010-LA-14

FILES (1)

TITLE

PQ TC038 DATA SHEET

CONTAINS UNBLINDING INFORMATION

YES

1114D

ATTENTION!

YOU ARE ABOUT TO OPEN A FILE THAT CONTAINS UNBLINDING INFORMATION

OK

CANCEL

FIG. 11E

1200

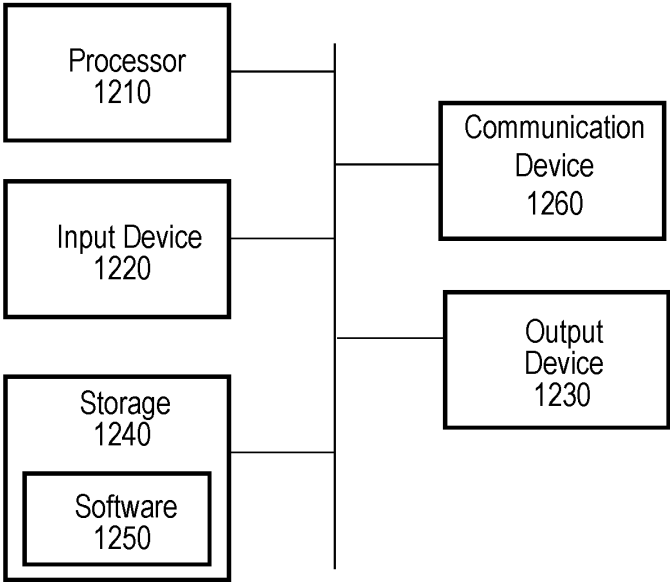


FIG. 12