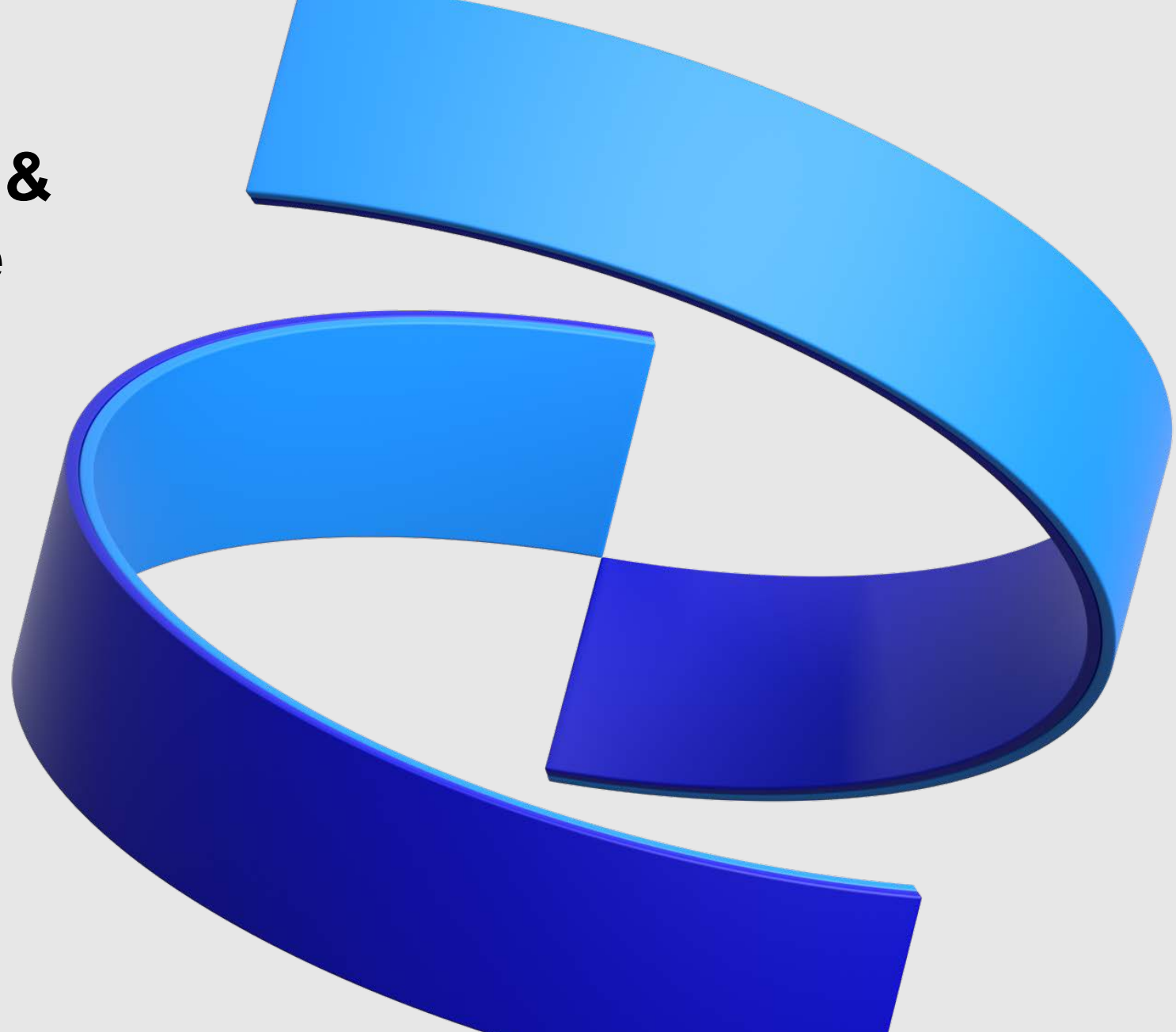

UD Short Text Format & Reason Codes Update

December 2022



Agenda

1. UD Short Text Format Update
2. Delay Reason Codes Update
3. NRFT Reason Codes Update
4. Exercises
5. Q&A

UD Short Text Format Update

Effective: 01-Jan-2023

The screenshot shows the SAP 'Change Inspection Lot: Vendor Data' interface. The 'Short text' field under the 'Description' section is highlighted with a red box. The form contains the following data:

Field	Value
Plant	NZ07 Pfizer New Zealand Limited
Inspection Lot	7513742
Material	F000117158 <input type="checkbox"/> DALACIN 150mg HFC 8x3 BLST AU
MPN Material	F000117158
Batch	B676802 1000
Vendor Batch	B676802
Insp.lot origin	01 Goods Receipt
Inspection Type	01ST Insp. for Inter CO Stock Transport PO
System Status	REL CALC SPRQ
UserStatus	
Inspection Type	01ST Insp. for Inter CO Stock Transport PO
Insp. Lot Qty	15,990 EA
No. Containers	0.000
Start date	03/18/2022
Insp. End Date	03/25/2022
Manufacturer	
Vendor	BE45 PFIZER SERVICE COMPANY BVBA
Purchasing Org.	0020 Dist planning
Short text	
Original Vendor	

Enter text in 'Short text' field as:
DDMMYY_I_ddmmyy_DRC_R/N_NRC1_NRC2_NRC3

UD Short Text Format Update

Effective: 01-Jan-2023

Format: DDMMYY_I_ddmmyy_DRC_R/N_NRC1_NRC2_NRC3_NRC4

where: **DDMMYY** = Receipt date of receiving documents in market (e.g. 02Jan22)

I = Lot Review Process Identifier (e.g. B)

F for Finished Goods

B for Products for Redressing

R for Redressed Products

O for Others

ddmmyy = Completion date of lot review of SCQ Market (or SCQ Hub as applicable) (e.g. 04Jan22)

DRC = Delay Reason Code for lots review completed beyond the agreed leadtime (e.g. 71)

R/N = Right First Time or Non-Right First Time (e.g. N)

NRC = NRFT Reason Code/s (e.g. 303_112_404)

Note: Market release lead time is 3 business days and Hub review lead time is 2 business days. Lead times may vary depending on market agreed lead time.

DRC is assigned based on the delay reason causing the longest duration of delay beyond the agreed lead time.

NRC on temperature excursion is assigned as NRC1 in case of multiple NRCs

Example: 02Jan23_B_05Jan23_15_N_303_112_404

UD Short Text Format Update

Effective: 01-Jan-2023

Effective Date	Summary of Changes
01-Jan-2023	<ul style="list-style-type: none">• Changed Business Unit & Product Type (BU.P) to Lot Review Process Identifier (I)• Added Completion date of lot review of SCQ Market (or SCQ Hub as applicable)• Changed of NRFT Reason Code format from Class.Subclass 1.Subclass2 to NRC
01-Aug-2022	<ul style="list-style-type: none">• Added Product Type for HK• Removed Upjohn as BU for AU and SG

Delay Reason Codes Update

Effective: 01-Jan-2023

DRC	Delays Reason Category	Delays Reason Sub-category	Delay Reason Definition
0	No Delay	No Delay	No delays were encountered on batch review
11	Shipment Receipt and Incidents	Inbound Documentation	Delays on inbound documentation including shipping documents, PO, receiving documents, and other inbound documentation requirement
12		Transport Incidents	Delays on product damages such as in-transit damages requiring further inspection, packaging contamination/compliance, wrong item/batch/lot, and wrong quantity.
13		Temperature Data Upload	Delays on temperature data documentation such as temperature data missing, incomplete pending temperature data upload of Forwarder/LSP/Distributor into a temperature control system
14		Temperature Logger	Delays on TMD issues including logger missing, incomplete or faulty
15		Temperature Excursion Assessment	Delays on TE documentation including temperature data assessment, supporting TE memo, site TE assessment, TE record closure and other TE related requirements
21	System	Receipt Inventory Management System	Delays on shipment receipt process in SAP system related activity such as F-code set-up, LSP system interface, manual inspection lot creation and other SAP system related issue
22		Redressing Inventory Management System	Delays on redressing receipt process in SAP system related activity such as F-code set-up, LSP system interface, manual inspection lot creation and other SAP system related issue
23		Temperature Control System	Delays on temperature data assessment on Temperature Control (TC) system issue (including RTTM shipment not created, RTTM shipment recreation, RTTM shipment manual delivery) or system unavailability
24		Artwork Management System	Delays on artwork code review due to system availability
31	Site	Site Documentation	Delays on site documentation including COA, memo and other batch documents
41	Market Release	Sample Requirement	Delays on product sampling requirement of market or local authority
42		Product Issue	Delays on product related issues including deviations, Quarantine Alert Notice (QAN), quarantine shipment
43		In Market Documentation	Delays on in-market documentation including change control, quality agreement, non-product related deviation, risk assessment, commitment tracking and other in market documentation requirement
51	Regulatory	Local Authorities Requirement	Delays on confirmation/clarification on registered information/local authority requirement including artwork, specification, COA test result, RA database information and other regulatory requirements
52		Local Authorities Approval	Delays on receipt of local authority approval (including notification, variation, vaccine release lot approval, and anti-infectives lot release approval)
53		Local Testing	Delays on local testing or mandatory drug testing on local authority requirement
61	Batch Review	Resource	Delays on product batch review completion on resource including audit involvement, local meeting/initiative, and leaves
62		Business Needs	Delays on product batch review completion on business need including volume of receipts and priority releases
63		Local Holidays	Delays on local holiday
64		Human Error Documentation	Delays on batch review due to human error including batch documents missed, SAP documentation incomplete and other human-related error on batch review
71	Repackaging	Repackaging Documentation	Delays on repackaging documentation including repackaging specification, repackaging batch records, certificate of compliance, photos and other repackaging documentation requirement
72		Repackaging Packaging Material Inventory	Delays on availability of packaging material
73		Repackaging Packaging Material Artwork Label	Delays on artwork label development
74		Product Non-routine Repackaging	Delays on product requiring non-routine repackaging such as product damages, product label issues and other product requiring repackaging
99	Others	Others	Other delays not listed in DRC listing

Delay Reason Codes Update

Effective: 01-Jan-2023

Effective Date	Summary of Changes
01-Jan-2023	<ul style="list-style-type: none">• Change Business Need and Resource into Business Need and Resource• Change Temperature Logger and System into Temperature Logger and Temperature Control System• Add Delay Reason Code on Local Testing on BOH Requirement• Add Delay Reason Code on Artwork Management System Issue,• Add Delay Reason Code on Sample Requirement,• Add Delay Reason Code on Local Holiday,• Add Delay Reason Code on Transport Incidents for delays on incidents including shortlanded/overlanded shipments• Add Delay Reason Code on Temperature Data Upload• Add Delay Reason Code on Redressing Inventory Management System for delays on GR of redressing batch in SAP• Include under Temperature Control System for delays related to RTTM issues• Include under Inbound Documentation for goods receipt impacted due to the availability of PO• Include under Regulatory Requirement or Regulatory Approval for delays on receiving a regulatory document and on confirming registered information on RA database.

Delay Reason Codes Update

Effective: 01-Jan-2023

Effective Date	Summary of Changes
01-Aug-2022	<ul style="list-style-type: none">• Added definition of DRC codes• Changed DRC 1 to scope only inbound documentation and added DRC 15 for site documentation (including COA and batch documents)• Changed DRC 3 to scope in all delays related to temperature excursion• Changed DRC 4 to scope in TMD, temperature data aside from temperature system issue• Added DRC 16 for In Market Documentation• Added DRC 17 for Others

NRFT Reason Codes Update

Effective: 01-Jan-2023

NRC	NRFT Subclass 1	NRFT Subclass 2	Definition
0	No NRFT	No NRFT	No NRFT encountered on review and release
101	Documentation	Product manufacturing document missing	Product manufacturing document required (i.e. Master Batch Record, Change History, Memo, Stability, Test Method, Packaging Record) is missing or not available
102		Product manufacturing document incorrect/incomplete	Product manufacturing document required is incorrect/incomplete
103		CoA/CoC not available	CoA/CoC on the document repository (i.e. SAP, Sharepoint) is missing or not available
104		CoA/CoC incorrect/incomplete	CoA/CoC on the document repository is incorrect (i.e. site name, destination site, product name, batch information, test limits) or incomplete (i.e. document page, test result, QP signature not available)
105		PO not available	PO is missing or not available
106		PO incorrect/incomplete	PO is incorrect/incomplete
107		Shipping document missing	Shipping document required (i.e. Commercial Invoice, Packing List, Delivery Note, Controlled Drug Importation Document) is missing or not available
108		Shipping document incorrect/incomplete	Shipping document required is incorrect/incomplete on GMP/GDP information that requires amendment prior to release
109		Transport (Forwarder) document missing	Transport (Forwarder) document required (i.e. CMR, Airway/Seaway Bill, Import License) is missing or not available
110		Transport (Forwarder) document incorrect/incomplete	Transport (Forwarder) document required is incorrect/incomplete
111		Receipt document missing	LSP/Distributor Receipt form required is missing or not available
112		Receipt document incorrect/incomplete	LSP/Distributor Receipt form required is incorrect/incomplete (i.e. incorrect TMD logger number, incomplete page, signature, reference photos)
113		Repackaging document missing	Repackaging form required is missing or not available
114		Repackaging document incorrect/incomplete	Repackaging form required is incorrect/incomplete
201	Temperature Logger and Data	TMD missing/incomplete	TMD is missing, not available, incomplete in the shipment based on the temperature logger requirement
202		TMD mixed	TMD is mixed or incorrect logger number placed on shipment
203		TMD faulty	TMD does not work properly, faulty, or data cannot be downloaded
204		TMD incorrect logger configuration	TMD has incorrect set-up (including limits does not match the transport condition of the product) or out of calibration
205		TMD not stopped	TMD is not stopped on unloading or when removed from the pallet or shipment
206		Temperature data missing/incomplete	Temperature data from logger is missing, not available (i.e. TMD not started), or incomplete (i.e. TMD has not been recording for the entire duration of the shipment)
301	Temperature Excursion	Temperature excursion supported by PQ23 Table 2	Temperature excursion within the allowable limits of temperature/time on GSOP29 Attachment 2
302		Temperature excursion supported by stability memo	Reportable temperature excursion as defined by GSOP29 supported by stability memo
303		Temperature excursion assessed by Site	Reportable temperature excursion as defined by GSOP29 assessed by Site
401	System	SAP product code data incorrect/incomplete	SAP product data is incorrect/incomplete (i.e. Incorrect F-code set-up, F-code inspection plan set-up)
402		SAP lot data missing	SAP Inspection Lot data is missing or not available in SAP or inventory management system
403		SAP lot data incorrect/incomplete	SAP Inspection Lot data is incorrect or incomplete in SAP or inventory management system
404		Temperature system data missing	Temperature system data in temperature control system is missing or not available (including RTTM shipment not created, TT4 Logger data not downloaded)
405		Temperature system data incorrect/incomplete	Temperature system data in temperature control system is incorrect/incomplete (i.e. RTTM shipment recreated, TT4 Logger data downloaded incorrect/complete)
406		Artwork system data incorrect	Artwork (carton, label, leaflet etc) system data in artwork management system is incorrect

NRFT Reason Codes Update

Effective: 01-Jan-2023

NRC	NRFT Subclass 1	NRFT Subclass 2	Definition
501	Process	Regulatory approval	Regulatory approval required (i.e. notification, variation, importation, testing) to release a batch is missing/not available for stocks received without notification from sending site
502		Repackaging specification incorrect/incomplete	Repackaging specification is incorrect/incomplete
503		Batch hold	QAN is issued for the batch on review and/or release process
504		Damages	Damaged goods during shipment (including in-transit damages or physical contamination) encountered on delivery is rejected or requires inspection prior to release
505		Product incorrect	Product received and product in documentation is encountered with discrepancy (i.e. Incorrect Product/F-code/Lot/Quantity)
506		Deviation	Deviation encountered on the review and/or release process
601	Product Dossier	Artwork missing/not available	Artwork is missing or not available in ePALMs or artwork management system
602		Artwork not approved	Artwork approval is missing or not available in ePALMS or artwork management system
603		Artwork superseded	Artwork is superseded in ePALMS or artwork management system and is beyond implementation period
604		Artwork incorrect	Artwork (carton, label, leaflet etc) is different to what is registered, or not yet registered
605		Artwork data missing/incorrect	Artwork data (batch, expiry etc) is not available/incorrect from the unit carton(s) or shipper(s)
606		Release specification not available	Release specification on the document repository is missing or not available
607		Release specification incorrect/incomplete	Release specification on the document repository is incorrect/incomplete (i.e. incorrect document version/test limits, incomplete tests) compared to what is registered
701	Local Testing	Laboratory document missing	Laboratory document on testing on local authority requirement (including local laboratory analysis exception) is missing
702		Laboratory document incorrect/incomplete	Laboratory document on testing on local authority requirement is incorrect/incomplete
703		Laboratory testing human error	Human error on laboratory testing on local authority requirement
704		Laboratory testing instrument/system issue	Instrument/system issue on laboratory testing on local authority requirement
705		Other laboratory testing issue	Other issues on laboratory testing on local authority requirement
801	Serialisation	Serialisation error	Serialization codes for the product is incorrect
999	Others	Others	Other NRFT issue not covered in other categories

NRFT Reason Codes Update

Effective: 01-Jan-2023

Effective Date	Summary of Changes
01-Jan-2023	<ul style="list-style-type: none">• Change NRFT Subclass1 from Category-Function Based into Category Based (i.e. Process, Documentation, System, Product Dossier)• Change NRFT Reason Codes on 'Incomplete' and 'Incorrect' into 'Incorrect/Incomplete'• Change NRFT Reason Codes on Site Documents (i.e. Master Batch Record, Change History, Memo, Stability, Test Method, Packaging Record) into 'Product Manufacturing Documents'• Change NRFT Reason Codes on 'COA' and 'COC' into 'COA/COC'• Change NRFT Reason Codes on Shipping Documents (i.e. Commercial Invoice, Packing List, Delivery Note, Controlled Drug Importation Documents) into 'Shipping Documents'• Change NRFT Reason Codes on Transporter Documents (i.e. CMR, Airway/Seaway Bill, Import License) into 'Transporter/Forwarder Documents'• Change NRFT Reason Codes on Temperature Logger issue on LSP/Site, Product Specification Issue on Site/Regulatory, SAP issue on LSP/GSC into general NRFT reason codes• Change NRFT Reason Codes on Temperature Excursion on PQ23-GSOP to GSOP29• Add NRFT Reason Code on Product Incorrect• Add NRFT Reason Code on Temperature Logger not Stopped• Add NRFT Reason Codes on RTTM issues• Add NRFT Reason Codes on Local Testing• Add NRFT Reason Code on F-code set-up on masterdata and inspection plan• Add NRFT Reason Code on Repackaging Specification issues• Add NRFT Reason Code on Repackaging Documentation Issues• Include NRFT Reason Code on Regulatory Approval for regulatory document not available on notification, variation, importation, testing• Remove NRFT Reason Codes on Regulatory Document, License, Certificate

Exercises

Lot A has been reported with an OOS on water content as identified by the Site and closed prior to shipment to Market. Product A Lot A was received in Market Mailbox at 6:01 pm of 12-Dec-2022. 10 units of Product A was reported in-transit damages by LSP. Market colleague completed the review of this lot for redressing on 14-Dec-2022

Answer: 13Dec22_B_14Dec22_0_N_504

Exercises

Product B Lot B was received in Hub Mailbox on a Sunday on 11-Dec-2022. Temperature excursion encountered required a Site TE assessment as per GSOP29 and completed on 15-Dec-2022. A COA typographical error was encountered, and revised COA was received on 14-Dec-2022. Hub colleague completed the review of this lot of finished goods on 15-Dec-2022

Answer: 12Dec22_F_15Dec22_15_N_303_104



Q&A

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Thank you!

