

## Pharma Enhancements

MDS User Group 2017



#### Agenda

- > HDA EDI 856/E-Pedigree Track and Trace
- > Serialization and Traceability
- > Suspicious Order Monitoring System (Excessive Product Usage)
- CSOS Options
- > Pedigree T3 Document
- > Track and Trace Options
- ARCOS and Reporting Updates



- Speed Eliminates the need to manually update the newly created pedigree
- Accuracy Information is coming directly from your vendor/manufacturer
- > Streamlined Process Saves your company time and effort



# How would you rate the operational efficiency of your track and trace system?

It is fully optimised 9.3%

It is very strong, with some fine tuning needed 24.1%

he system is functional but efficiency needs significant improvements 20.4%

The system is functional but process is inefficient in areas 13.0%

Operational efficiency is a big focus for us at the moment 16.7%

Other (please specify) 16.7%

Too early to say for the above function

Each implementation must be customized to fit the specific needs

No comparison available

Meets Reg expectations

\*Pharmaceutical Serialization and Traceability 2017 Market Trend Repo

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Meets Rag expectations

The results show that less than 10% of businesses believe they are full optimized.

\*Pharmaceutical Serialization and Traceability 2017 Market Trend Report

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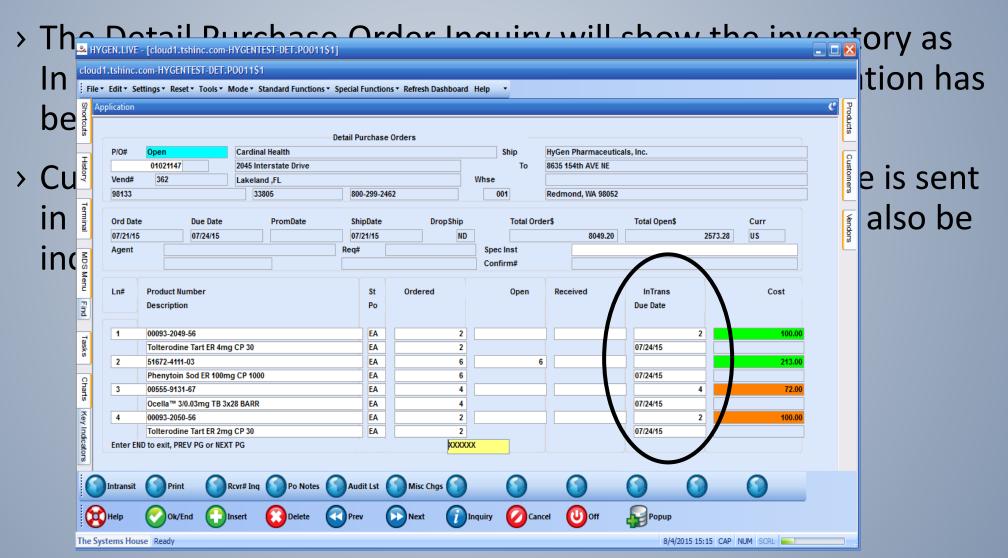
TSH is always changing to update the needs of our customers. We incorporate any and all requirements as part of our regular software updates. The goal is to have all of you in the top 10%.

\*Pharmaceutical Serialization and Traceability 2017 Market Trend Repor



- The Detail Purchase Order Inquiry will show the inventory as In Transit and the Expected Deliver Date when information has been received
- Currently, the lot information, including expiration date is sent in the EDI record. In the future, the serial number will also be included







At PO Receiving time, you will select the Intransit record that was created

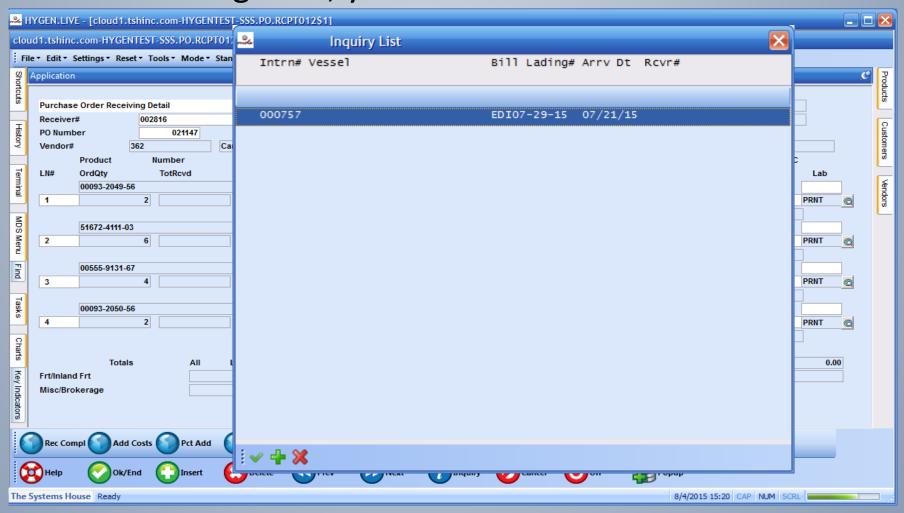


> At PO Receiving time, you will select the Intransit record that

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> At PO Receiving time, you will select the Intransit record that





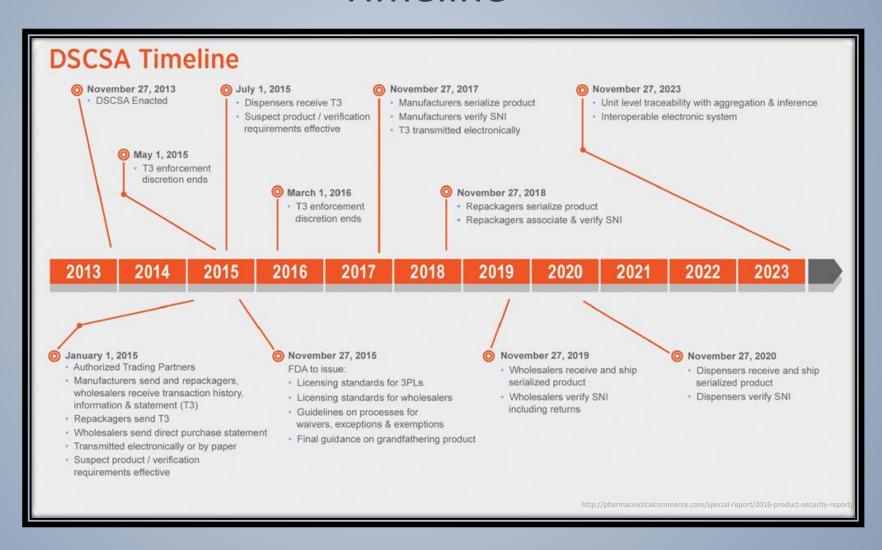
- > The Pending Pedigree Selection screen will show for any incoming Pedigree items
- > If desired, you can see detailed Pedigree information by clicking on the Pedigree Detail button



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# Federal Drug Supply Chain Security Act (DSCSA) Timeline

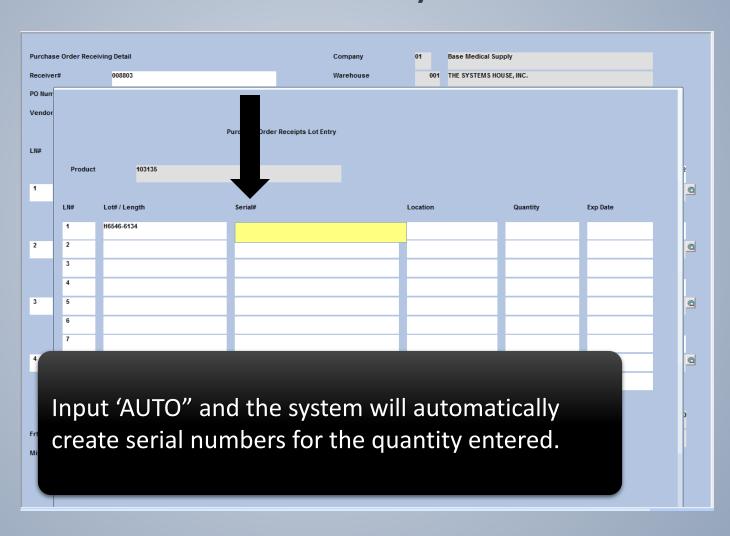




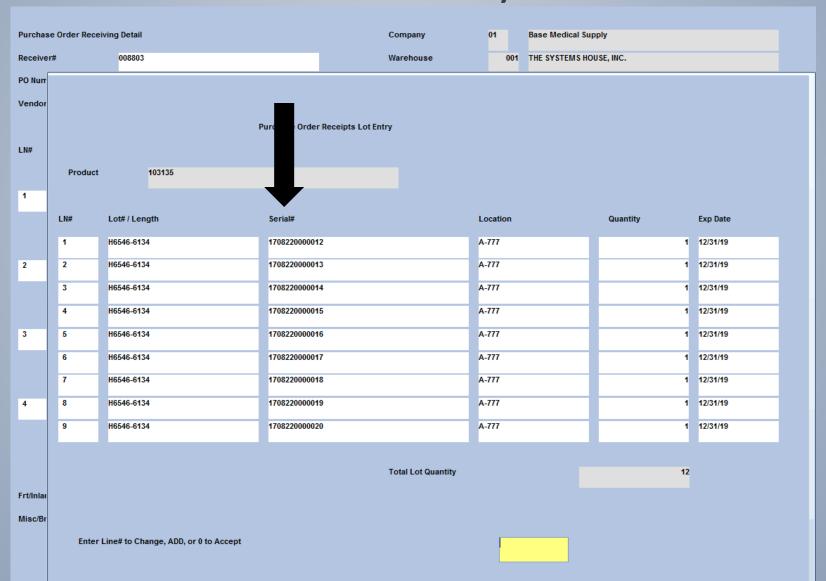
> Supply chain visibility is enabled through serialization with tracking being applied on single units.













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Page 1 of 1 Lot Tracking Report 08/22/2017 13:51:32 DATE TNX LOT NO QUANTITY **LOT SERIAL NO CUST NO** WHSE **PRODUCT** INVOICE / REL NO 001 103135 A02347 Phentoin Sodium ER 100mg 1000ct 8/22/2017 H6546-6134 1708220000012 RACHEL 01A35668001 INV 001 103135 A02347 Phentoin Sodium ER 100mg 1000ct 8/22/2017 INV H6546-6134 1708220000014 RACHEL 01A35668001 103135 A02347 001 Phentoin Sodium ER 100mg 1000ct 8/22/2017 INV H6546-6134 1708220000013 RACHEL 01A35668001



- > Utilizing GS1 Standards there are 3 components:
  - Identify Using globally unique identification keys
    - GLN Global Location Number. Your company and warehouses will have a unique GLN number. Also, all of your customers and their shipto's will have GLN numbers assigned by GS1.
    - > GTIN Global Trade Identification Number. Each item will have a unique GTIN for each saleable unit of measure.
    - SSCC Serial Shipping Container Code. Serial shipping container is used to identify items packaged together for transport.
  - Capture by utilizing barcode scanning
    - > GS1 DataMatrix barcode is read by camera-based bar code scanners.
      - Contains: GTIN, Expiration Date, Lot Number and Serial Number of the item
    - > GS1-128 line bar code. Easily read by a handheld scanner.



> Utilizing GS1 Standards there are 3 components:

Identify – Using globally unique identification keys

> GLN-Example: Use of GS1 Standards for the identification of products using a GS1 DataMatrix unique numb

> GTIN for each

> SSCC

GTIN: (01) 07046261398572

Expiry: (17) 130331 Batch / lot: (10) TEST5632

(21) 19067811811

warehouses will have a hd their shipto's will have GLN

tem will have a unique GTIN

ping container is used to

- Capture by utilizing barcode scanning
  - > GS1 DataMatrix barcode is read by camera-based bar code scanners.
    - Contains: GTIN, Expiration Date, Lot Number and Serial Number of the item
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( 01) 10222222333334( 17) 091231( 10) A1345B( 21) 1234

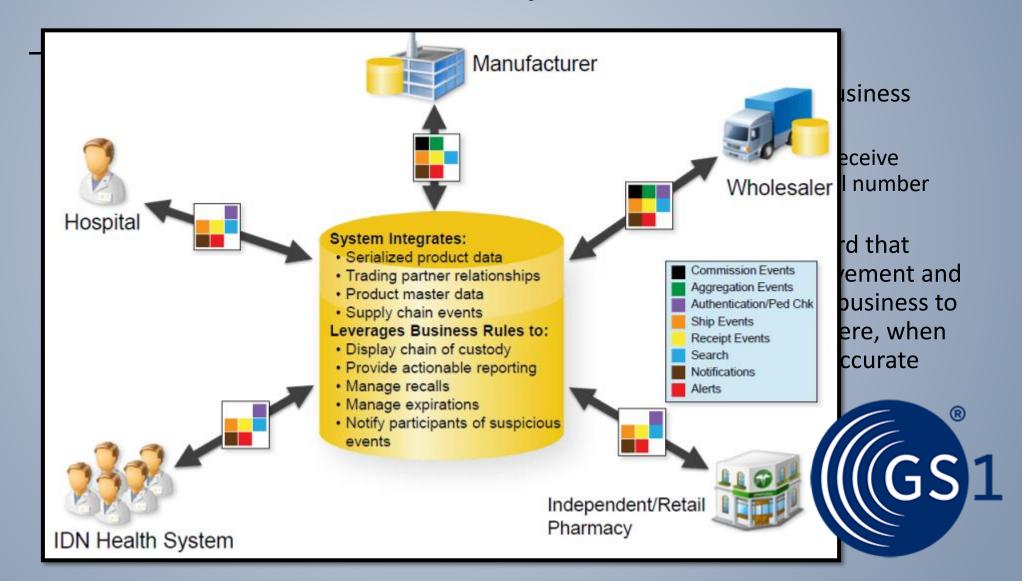
contains: Grin, expiration date, Lot Number and Serial Number of the Item

> GS1-128 line bar code. Easily read by a handheld scanner.



- Share Exchange of business-critical information
  - > EDI (Electronic Data Interchange) Is the electronic interchange of business information using a standardized format.
    - Many of our customers are utilizing this option. Currently we send and receive product information that includes the lot number. In the future the serial number will also be transmitted.
  - EPCIS Electronic Product Code Information Services is a GS1 standard that enables trading partners to share information about the physical movement and status of products as they travel throughout the supply chain – from business to business and ultimately to consumers. It helps answer the "what, where, when and why" questions to meet consumer and regulatory demands for accurate and detailed product information.







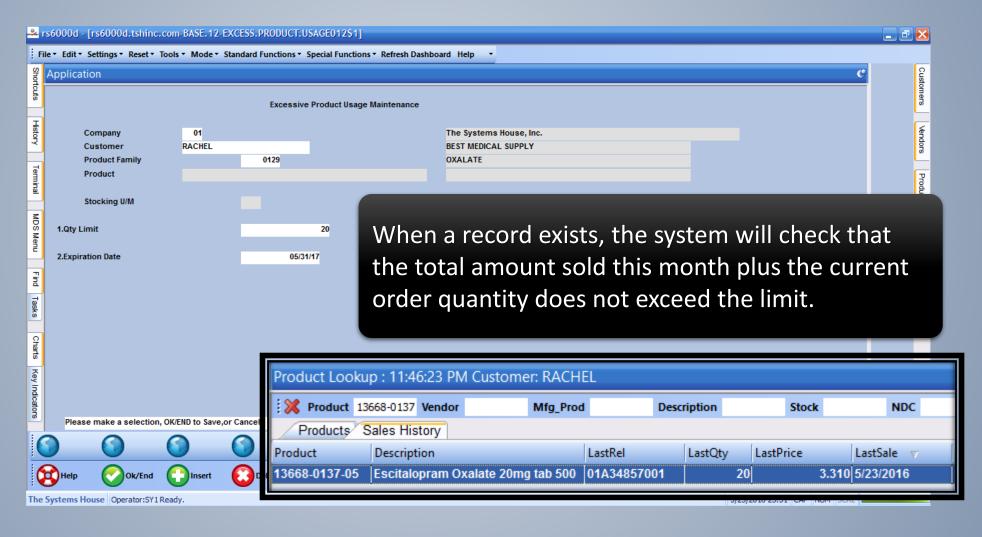
#### Suspicious Order Monitoring System

(Excessive Product Usage)

- > Typically used to monitor and control the quantity of controlled substances sold to a customer
- Can also be used for customer allocations to limit the amount of stock customer's can order. By doing this, you will be able to fulfill multiple customer orders, instead of one customer wiping out your stock
- > This is constantly being updated, as we now have expanded the options for its usage:
  - By specific customer
  - By specific product family
  - By specific product

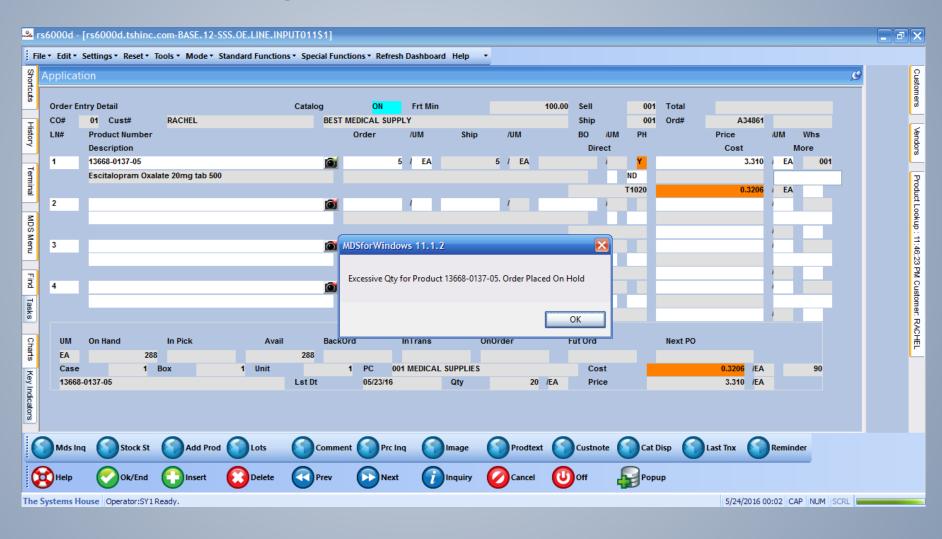


# Suspicious Order Monitoring System (Excessive Product Usage)





# Suspicious Order Monitoring System (Excessive Product Usage)

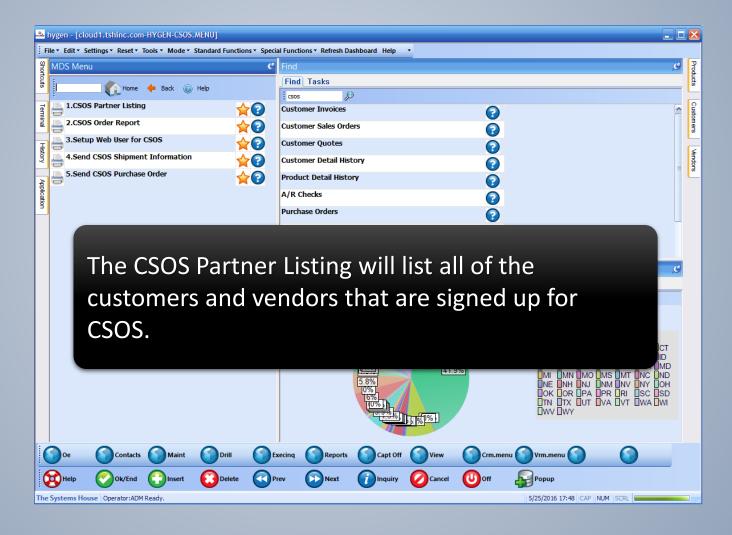




- For those selling controlled drugs:
  - Utilizing CSOS Integrated system with Legisym and their product Express222
  - Various Setup Options:
    - > Integrated with RemoteNet
    - > EDI
    - Order Entry
  - MDS optional module









SORT CSOS.PARTNER DEA.NO PARTNERID USERNAME ID-SUPP LPTR 05:47:56pm 25 May 2016 PAGE 1
DEA#.... Partner ID Username.....

FM2503692 102878 102871

1 records listed.



SORT CSOS.XREF CSOS.TRACKNO FILEKEY FILENAME E222ORDERID SIGNED.DATE SENT.DATE ID-SUPP LPTR 05:54:07pm 25 May 2016 PAGE 1 Tracking Number File Key.. File ..... CSOS Order Id Date.... Date Shipped

16XN00001 142091 WEB.ORDER 765174

16XN00002 142168 WEB.ORDER 766237 03/04/16

2 records listed.



SORT CSOS.XREF CSOS.TRACKNO FILEKEY FILENAME E222ORDERID SIGNED.DATE SENT.DATE ID-SUPP LPTR 05:54:07pm 25 May 2016 PAGE 1 Tracking Number File Key. File ..... CSOS Order Id Date.... Date Shipped

16XN00001 142091 WEB.ORDER 765174

16XN00002 142168 WEB.ORDER 766237 03/04/16

2 records listed.

The CSOS Order Report will show all incoming orders with their tracking numbers, date placed and shipped.



### The Pedigree (T3)

- > The three sections of the Pedigree:
  - Transaction Information (TI)
  - Transaction History (TH)
  - Transaction Statement (TS)



### The Pedigree (T3)

**Base Medical Supply** 

#### Drug Supply Chain Security Act Document Doc#0000001250

#### (TI) Transaction Information

Drug Name, Strength, Dosage Form, Container Size: Phentoin Sodium ER 100mg 1000ct,

NDC: 54221-4511-02

Lot Number	Quantity	Unique Serial #
H6546-6134	1	1708220000023

Reference Number:

er: 01A02351 Invoice

Document Type: Reference Date:

08/28/17

#### (TH) Transaction History

Manufacturer's Name: Mckesson United

Manufacturer's information: 1100 Corporate Way NEW YORK, NY 12344 mck@mckesson.com 212-555-1212

SOLD TO:

SOL Nam

Addr

SOL

Addr

Date

Name: Mckesson United Address: 1100 Corporate Way

NEW YORK NY 12344

Date Purchased & Ref : 08/11/17 5645441

SHIPPED TO:

Name: Mckesson United Address: 1100 Corporate Way NEW YORK NY 12344

Date Received & Ref :

- TI Transaction Information The description of the drug
- TH Transaction History Tracks each step of the supply chain, back to the manufacturer
- TS Transaction Statement Provides the legal statement of compliance

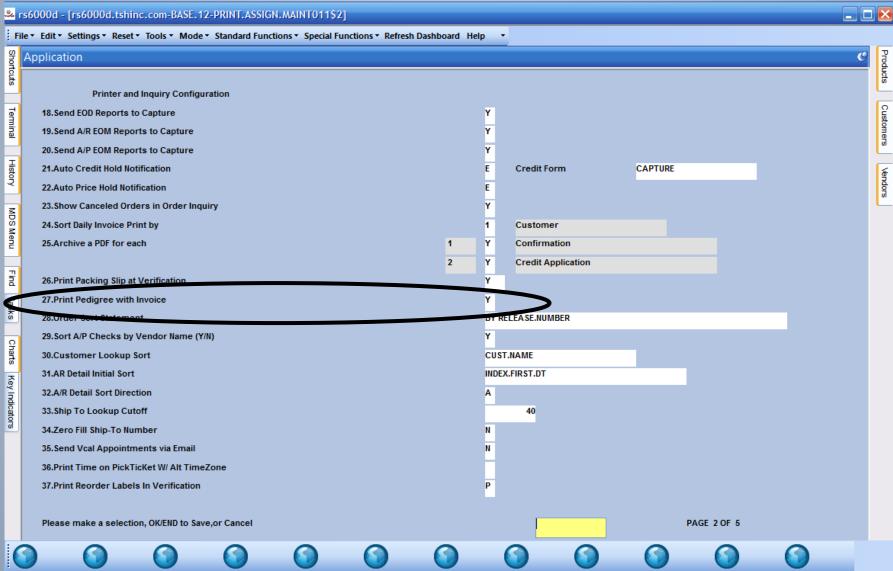
(TS) Transaction Statement: This Company complied with each applicable subsection of FDCA Sec. 581 (27) (A) - (G)

- (A) is authorized as required under the Drug Supply Chain Security Act;
- (B) received the product from a person that is authorized as required under the Drug Supply Chain Security Act;
- (C) received transaction information and a transaction statement from the prior owner of the product, as required under section 582;
- (D) did not knowingly ship a suspect or illegitimate product;
- (E) had systems and processes in place to comply with verification requirements under section 582;
- (F) did not knowingly provide false transaction information; and
- (G) did not knowingly alter the transaction history.

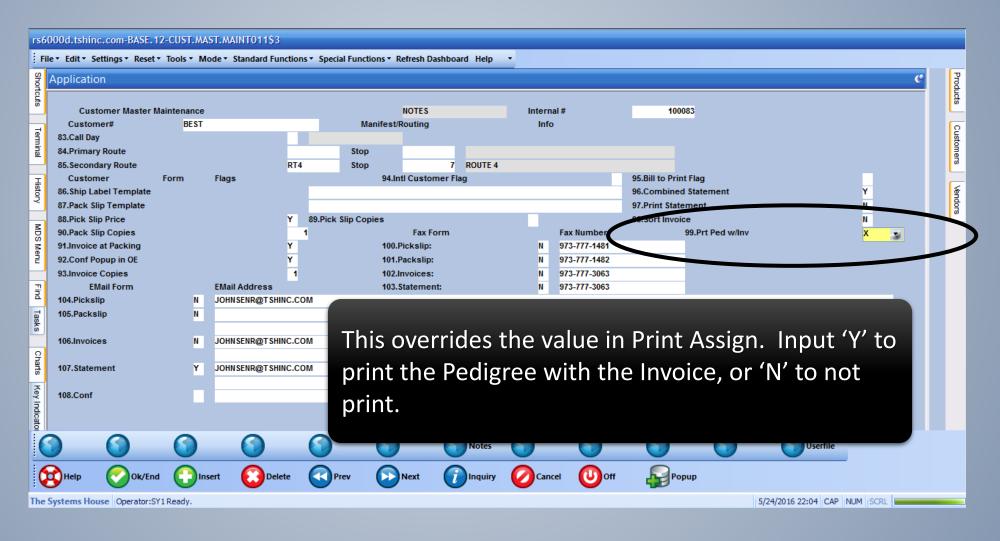


- > Options on when to print the Pedigree
- > Option to show credits/returns on the printed Pedigree
- > Optional Repackaging module









#### Drug Supply Chain Security Act Document Doc# 00000001250

#### (TI) Transaction Information

Drug Name, Strength, Dosage Form, Container Size: Phentoin Sodium ER 100mg 1000ct,

NDC: 54221-4511-02

Lot Number	Quantity	Unique Serial #
H6546-6134	1	1708220000023

Reference Number: Document Type: 01A02351

Invoice

08/28/17

Reference Date:

#### (TH) Transaction History

Manufacturer's Name: Mckesson United

Manufacturer's information: 1100 Corporate Way NEW YORK, NY 12344 mck@mckesson.com 212-555-1212

Wallulacturer's illionilation. Troo corporate way NEW TORK,	141 12544 IIICK@ IIICK@55011.COIII 212-555-1212
SOLD TO: Name: Mckesson United Address: 1100 Corporate Way NEW YORK NY 12344 Date Purchased & Ref : 08/11/17 5645441	SHIPPED TO: Name: Mckesson United Address: 1100 Corporate Way NEW YORK NY 12344 Date Received & Ref :
SOLD TO: Name: Base Medical Supply Address: 1033 US HIGHWAY 46 East CLIFTON NJ 07013 Date Purchased & Ref: 08/22/17 PO#01136151	SHIPPED TO: Name: Base Medical Supply Address: 1033 US HIGHWAY 46 East CLIFTON NJ 07013 Date Received & Ref: 08/22/17 RC#008803
SOLD TO: Name: BEST MEDICAL SUPPLY Address: 1033 RT 46 HOWELL HI 07731 Date Purchased & Ref: 08/28/17	SHIPPED TO: Name: BEST MEDICAL SUPPLY Address: 1033 RT 46 HOWELL HI 07731 Date Received & Ref: 08/28/17
SOLD TO: Name: Address: Date Purchased & Ref :	SHIPPED TO: Name: Address: Date Received & Ref :
SOLD TO: Name: Address:	SHIPPED TO: Name: Address:
Date Purchased & Ref :	Date Received & Ref :

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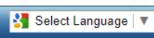
# Trace and Trace Options The Pedigree (T3)

For those using Remotenet, your customers can view and print their Pedigree's directly from the website.



Best Selling

Vaccines



Search

Search Tools + | -

Looking for y NDC# To see order detail click GO.

Closeouts
Hot Items
Latest Items
Most Frequently Ordered
OverStock Items
Top Selling
Trending Items

Closeouts
Line
No.

Order-Re

1 Item

HyGen"

HyGen Pharmaceuticals, Inc.

Doc# 10000050031

#### Pharmaceuticals, Inc. Drug Supply Chain Security Act Document

#### (TI) Transaction Information

Drug Name, Strength, Dosage Form, Container Size:
Afluria® QIV 2017-18 5ml MDV 10 ,
Dose SEQI (Influenza Vaccine)
NDC: 33332-0417-10

Lot Number Quantity Unique Serial # Reference Date: 09/07/17

O1044611A 8

#### (TH) Transaction History

Manufacturer's Name: Seqirus, Inc Manufacturer's information: Cambridge, MA

SOLD TO: Name: Seqirus, Inc Address:	SHIPPED TO: Name: Seqirus, Inc Address:	
Cambridge MA	Cambridge MA	
Date Purchased & Ref :	Date Received & Ref :	
SOLD TO:	SHIPPED TO:	

SOLD TO	D:		SHIPPED TO:					
Name:	HyGen Pharmaceuticals, Inc.		Name: HyGen Pharmaceuticals, Inc.					
Address:	8635 154th AVE NE		Address: 8635 154th AVE NE					
\$500 A500 000	Redmond WA 98052		Redmond WA 98052					
Date Pur	chased & Ref : 08/16/17	PO#01025223	Date Received & Ref: 09/05/17 RC#02448					

SOLD TO	D:			SHIPPED TO:					
Name:	ne: Genoa-QoL Phcy CO -20133				Name: GENOA-QOL PHCY CO -20133				
Address:	18300 Cascad	e AVE S		Address: 8745 COUNTY ROAD 9 SOUTH					
	Tukwila WA 98	3188		ALAMOSA CO 81101					
Date Pur	chased & Ref :	09/07/17	01140904001	Date Red	ceived & Ref: 09/07/17	01140904001			

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Address:	Address:
Secretary Company Control of the Con	CONTROL CONTRO
Date Purchased & Ref :	Date Received & Ref :

SOLD TO:	SHIPPED TO:	
Name:	Name:	
Address:	Address:	
Date Purchased & Ref :	Date Received & Ref :	

#### (TS) Transaction Statement: This Company complied with each applicable subsection of FDCA Sec. 581 (27) (A) - (G)

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- (G) did not knowingly alter the transaction history.

This wholesale distributor purchased the specific unit of the prescription drug directly from the manufacturer.

Page: 1

of 1

pages.

Search

Search

Our Specials + | 
Current Order + | 
Live Help

Do you have questions?

Call us: 877-630-9198
E-mail us:

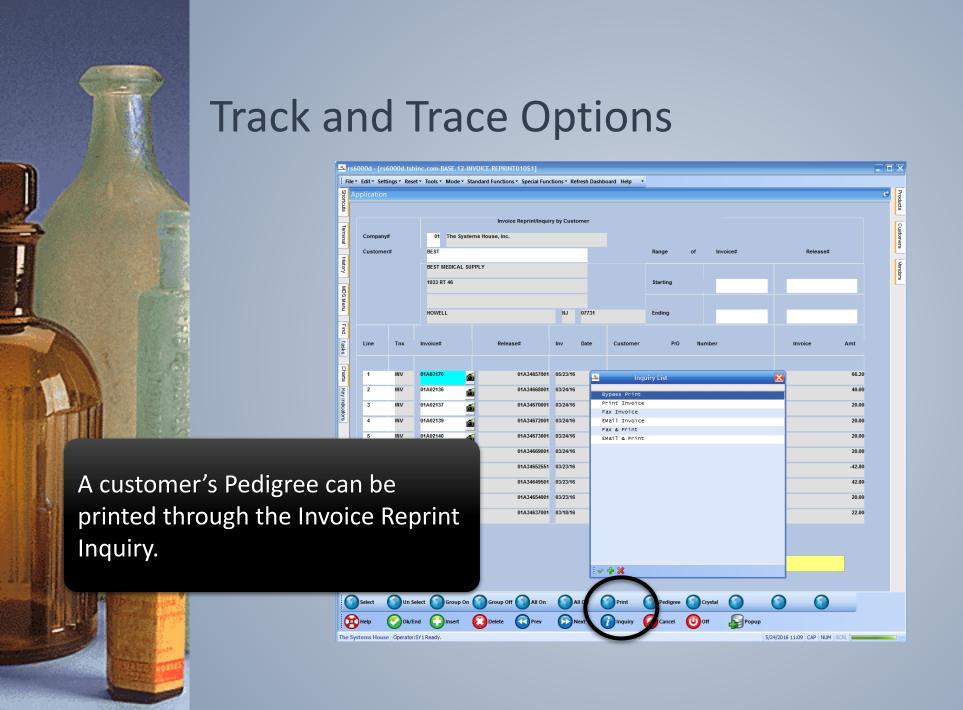
Your Account Representative

Sales Contact : Qol

Call:

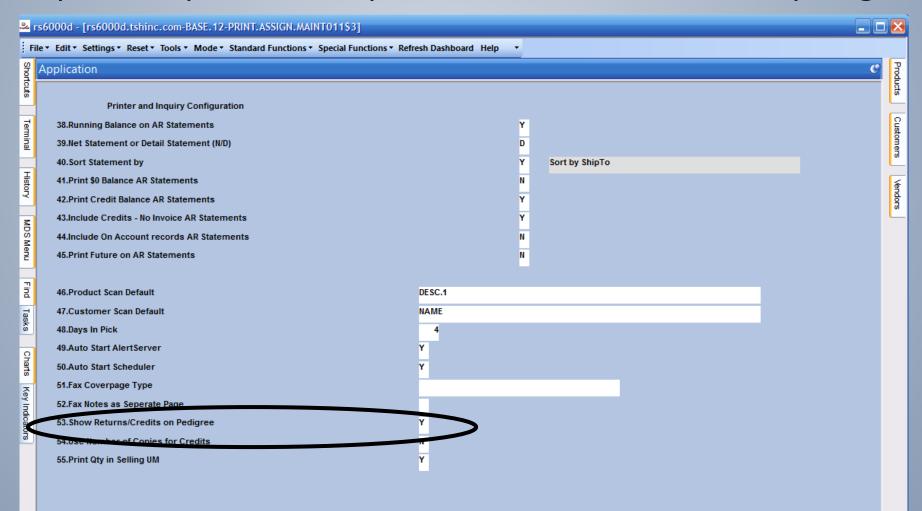
E-mail: AHo@genoa-qol.com

weborder@hygenpharma.com





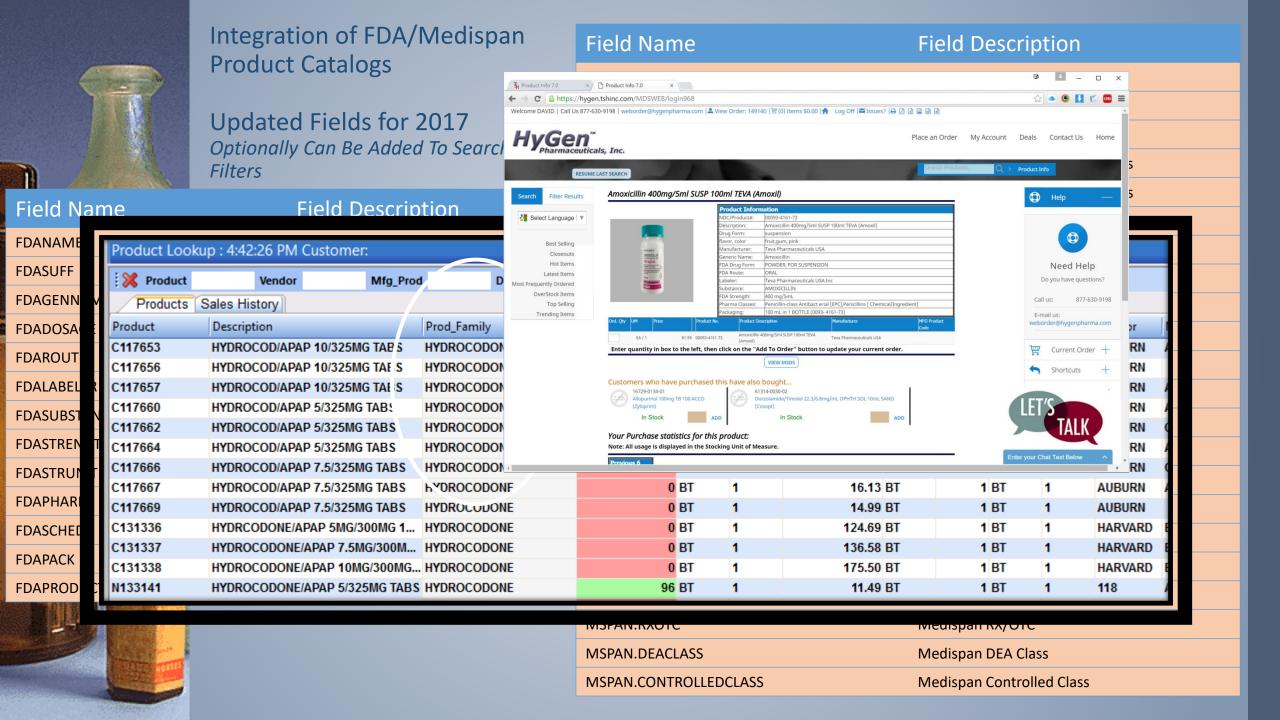
> Option to print or not print credits/returns on the pedigree





directly through MDS.

<b>US</b> MEDSOURCE	US MedSource, LLC  Drug Supply Chain Secur	ity Act	(Repackager's Name)  Document Doc# 00000001366	
(TI) Transaction Information: Des Drug Name, Strength, Dosage Form, Conte Manufacturer / Repackager Name on Conte NDC on Container: Lot Number Quantity 000026 1	niner Size: LIDOCAINE HCL 2% MDV INJECTION,	PH:866-543 6024 e	-4414	
(TI) Transaction Information: Description of Drug Received	IE MOUNTAIN, GA 30083 877-946-7747			
Product Information: USE HOS-0427702 Lotz: 41-407-DK-01 Supplier: GENERAL INJECTIBLES & VAC 80 SUMMIT VIEW LANE BASTIAN, VA 24314	SOLD TO: Name: US MEDSOURCE SARASOTA Address: 2280 TRAILMATE DRIVE SARASOTA FL 34243 Date Purchased & Ref: 0608/15 LOT 0	00026	SHIPPED TO: Name: US MEDSOURCE SARASOTA Address: 2280 TRAILMATE DRIVE SARASOTA FL 34243 Date Received & Ref: 06/08/15 DOC 010010	14001
Date Purchassed/Ref#: DOC 12335329 DOC 12: Date Received/Ref#: DOC 12335329 DOC 12: NDC#: 00409427702 Unique Serial #: Product Information: USE HOS-0427702 Lot#: 41-407-DK-01 Oby: 25	SOLD TO: Name: THOMAS G SERIO, MD Address: 1802 MICCOSUKEE COMMONS DR TALLAHASSEE FL 32308 Date Purchased & Ref: 01/14/16 01110	644001	SHIPPED TO: Name: THOMAS G SERIO, MD Address: 1802 MICCOSUKEE COMMONS DR TALLAHASSEE FL 32308 Date Received & Ref: 01/14/16 01110644001	
Supplier: INSOURCE INCOLORS	SOLD TO: Name: Address:		SHIPPED TO: Name: Address:	
System, you	Date Purchased & Ref :  SOLD TO: Name: Address:		Date Received & Ref :  SHIPPED TO: Name: Address:	
ckaging	Date Purchased & Ref : (TS) Transaction Statement: This Company com	plied with e	Date Received & Ref :  ach applicable subsection of FDCA Sec. 581 (27) (A) -	· (G)
	(A) is authorized as required under the Drug Supply Chain Se (B) received the product from a person that is authorized as re (C) received transaction information and a transaction statem (D) did not knowingly ship a suspect or illegitimate product; (E) had systems and processes in place to comply with verific (F) did not knowingly provide raise transaction information; an (G) did not knowingly after the transaction history.	equired under the ent from the price ation requirement	or owner of the product, as required under section 582;	pages.



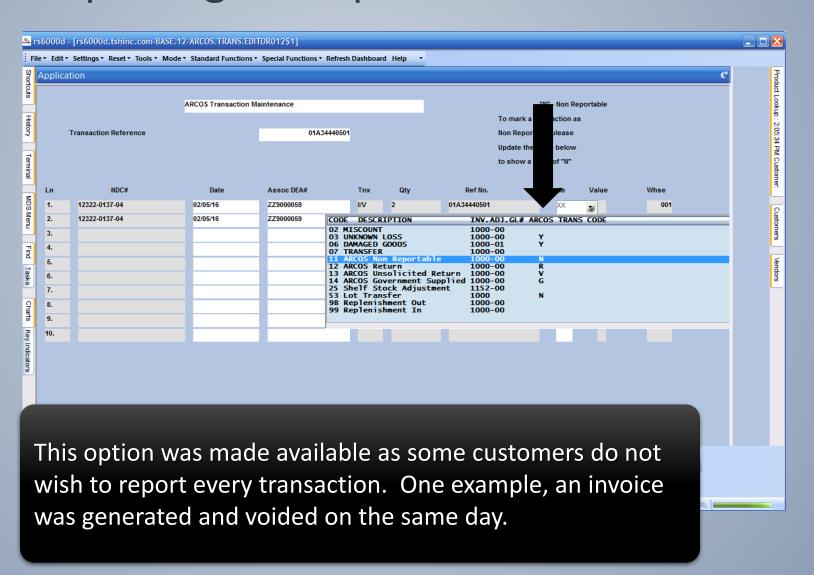


#### **Arcos Reporting and Updates**

- Added options for selection of Acquisition, Purchase, and Sales transactions to the ARCOS Transaction Report
- > Updated the ARCOS EOY format with the new requirements
- New report option based off the ARCOS, State Pharma Report. This would be used for OARRS.
- Added warehouse prompts to the DEA Inventory Report, DEA Receipts Posting Register and Lot Tracking Report
- ARCOS Transaction Maintenance gives the user the option to exclude transactions from being reported



#### **Arcos Reporting and Updates**





#### Pharma Enhancements Recap

- > HDMA EDI 856/E-Pedigree Track and Trace
- > Serialization and Traceability
- > Suspicious Order Monitoring System (Excessive Product Usage)
- > CSOS Options
- > Pedigree
- > Track and Trace Options
- > ARCOS and Reporting Updates

