We all know that serialization deadlines are looming. Some of you have serialization projects well under way while others are waiting to get their projects started. Either way, you have questions that you need answers to and, according to people we are talking to, these answers are proving pretty hard to find.

So we decided to help you out. We sat down with two of our lead serialization consultants – Liam O'Riordan and Linda Murphy to ask them the questions you have asked us in the past few months. We hope that this interview will give you some valuable insights into serialization requirements around the world and to help you decipher your DQSA from your NHRN.

Before we begin, it's important to point out that the views expressed in this interview are based on ESPs understanding of current legislation and our experience in this market. We would strongly advise that you carry out your own research into legislation in your relevant markets before undertaking any serialization project.

Let's start with the US…

Q: "How are manufacturers preparing for the US 1st Jan 2015 lot tracing TI/TH/TS deadline?"

LM: Typically we see our clients assessing how they currently communicate with downstream trading partners whether that is by email, fax, hard copy or electronically from the impacted sites. Clients are assessing the impact on current warehouse and distribution operations such as the impact to shipping processes, impact to master data and determining how best to manage the different communication mediums to distribution partners. The DSCSA gives some details on the data that needs to be included in the TH/TI and TS but manufacturers are also watching closely for guidance from the FDA on standards for the interoperable exchange of transaction information/history/ statement in paper or electronic form. The FDA have less than one year i.e. to the 27th November 2014 to publish this guidance but the sooner the better as far as manufacturers are concerned!

Q: What guidance is currently in the DSCSA on TH/TI and TS?

LOR: The act states that the transaction history is a statement in paper or electronic form which includes the transaction information for all prior transactions going back to the manufacture of the product. The act lists the information to be included in the transaction information including items that were also required in California ePedigree requirements:

1. The name of the product
2. The strength and dosage form of the product
3. The NDC of the product
4. The container size and number of containers
5. The lot number of the product
6. Date of the transaction
7. Date of shipment if more than 24 hours after the Date of Transaction
8. Business name and address of person transferring ownership
9. Business name and address of person receiving ownership

The transaction statement is a statement in paper or electronic form that the entity transferring ownership in a transaction:

1. Is authorized under the DSCSA
2. Received the product from person that is authorized under DSCSA
3. Received TI and a TS from prior owner of the product
4. Did not knowingly provide false information or ship a suspect or illegitimate product
5. Did not knowingly alter the transaction history

Essentially, it is a statement asserting the legitimacy of the transaction.

Q: "What are the implications of the recent change in US legislation concerning Track & Trace for lot level packaging after 2017?"

LM: After November 27th 2017, lot level transaction information must be electronic. Lot level transaction information is still required but the manufacturer will no longer have the option of using a paper based method. The required information i.e. transaction information, transaction history and transaction statement does not change. Potentially, this means that EDI (Electronic Document Interchange) can be used for the electronic transaction of lot level information but this is be clarified when the FDA publish their draft guidance establishing standards for the interoperable exchange of transaction history/information and statement later this year (2014).

Q: "What exactly is the National Healthcare Reimbursement Number (NHRN)?"

LOR: GS1 developed the NHRN to meet the needs of global supply chain participants who need to cater for national numbers. The NHRN allows association of the national number to the global GTIN of the product in databases and data carriers in a GS1 compliant fashion. Thus, when necessary the national number and the GTIN can be

captured in the same barcode in a single scan.

At this stage GS1 has allocated AI's for 4 NHRN: NHRN AI for Germany PZN AI 710, France CIP AI 711, Spain CN AI 712, Brazil DRN AI 713 and have stated that if additional NHRN AIs are required a request for a new NHRN AI needs to be made to GS1. There are other known NHRNs in use today and this gives the flexibility to add additional NHRN at a later date. Brazil, in their serialization requirements, have stipulated that AI713 must be encoded in the Unique Medication Identifier on each pack and current EFPIA pack coding guidelines (who are the European Federation of Pharmaceutical Industries and Associations based out of Brussels whose membership is made up of national organizations and pharmaceutical manufacturers) recommend that the NHRN is included in the 2D DataMatrix.

It's probably wise to note that the NHRN should only be used for compliance with regulatory requirements where the GTIN on its own in the barcode does not meet requirements.

Q: "One piece of legislation mentioned in Brazil legislation is the "code identifier" of the transport packaging. Have you come across this and can you explain what this is?

LM: My understanding is that the code identifier of the transport packaging is the identification code of the parent shipper of the product that is being moved or transported. So for example if the product being moved or transported is just one 10 pack carton of a human pharmaceutical drug product that is not bundled but is placed directly into a shipper, the identification code of the shipper must be recorded in the database.

Q: "In the EU is serialization going to affect a whole range of products or only reimbursed products"

LOR: The requirements around the falsified medicines directive (FMD) do no draw specific distinction between reimbursed products and that which is not reimbursed. The concept is that in principal, prescription drugs will be on a "white list" and non-prescription drugs will be on a "black list". All "white list" drugs will be required to be serialized and all "black list" drugs will not require serialization. However drugs, be they prescription or not, may be moved by the EU between those lists on a risk based approach. From a concept document I read, these risks will include;

1. Price
2. Sales volume
3. Number and frequency of previous reported falsified incidents
4. Specific characteristics of the product (delivered direct from manufacturer to hospital pharmacies)
5. Seriousness of conditions to be treated
6. Other potential risks to health

Q: "Have the EU issued guidance on randomization at this stage?"

LOR: The delegated act to the falsified medicines directive, with more specific technical details on how to proceed, is expected at the end of 2014 / start of 2015. For now, the EFPIA has issued guidance that the probability of guessing a serial number should be less than 1 in 10,000. They have also recommended that the serial number substrings should not contain fixed blocks of fixed digits and that any randomization substring should be independent of other substrings. Also it must not be easy to decipher the algorithm when knowing a set of serial numbers.

Q: "Are you aware of the current state of the European Medicines Verification System?"

LOR: I know that the contract to develop and operate the system has been awarded to SolidSoft - a UK based company specializing in application development and application integration. Microsoft Windows Azure has been selected as the cloud based platform.

The EMVS will be connected to national data repositories where product authentication can be verified by registered parties like pharmacies and hospitals. The intent of the system is that it is interoperable between countries and it will also allow those countries who do not want to set up their own national database the chance to use a pre-configured verification solution (called the National Blueprint System).

Q: "What is your understanding of the progress of implementation of the Falsified Medicines Directive (FMD) by EU member states?"

LOR: My current understanding is that the vast majority of member states have passed/transposed the FMD into law with only a few countries yet to ratify the directive. Last I heard these countries were Italy, Poland, Slovenia and Ireland. Completion late 2014 or early 2015

Q: "Do you know what the next steps are on Saudi Arabian serialization laws?"

LM: We currently understand that the addition of the DataMatrix will be implemented in two phases. Manufacturers will need to add a DataMatrix containing GTIN, expiry date and lot number by March 2015. The serial number must then be added to the DataMatrix by March 2016.. The Saudi FDA are urging all drug manufacturers in Saudi Arabia and international manufacturers

exporting to Saudi Arabia to adopt GS1 supply chain standards. They expect industry:

1. To get in contact with GS1 to discuss getting GTIN, GLN and DataMatrix if they are not in place already
2. Prepare the production lines for printing and verifying new barcodes
3. Plan to be logistically ready for serializing all products in the future

We are watching closely for the next official communication from the SFDA.

Q: "The current legislation pertaining to South Korea mentions that the 2015 deadline applies to human drugs manufactured in South Korea or imported into the country on or after Jan 1st 2015. Does this mean if human drugs are imported into South Korea on or before 31st December 2014 these drugs are exempt?"

LM: South Korea is very much in focus at the moment as the January 1st 2015 deadline approaches. Yes serialization of the secondary pack from January 1st 2015 will only apply to human drugs manufactured in South Korea or imported into the country on or after Jan 1st 2015. It does not apply to product that has been imported into South Korea before this date. This is an important point as it allows manufacturers to build inventory in country prior to the deadline and should be considered by manufacturers when planning their compliance strategy for Korea 2015.

Q: "Staying with South Korea, three data carriers are allowed GS1-128, 2D DataMatrix or RFID as per South Korean regulations. In your experience, what are manufacturers printing to comply with Korean requirements?"

LM: In my experience, while clients we worked with were considering RFID to meet requirements, most, if not all, have now decided to use the 2D DataMatrix.

Q: "The mandatory barcode for China is a linear 1D 128C code. How does this differ from your typical 2D DataMatrix?"

LM: 1D barcodes contain data in the lines and spacing of parallel lines while 2D barcodes can have patterns of squares and other shapes which allow them to hold much more data than linear barcodes in a much smaller space. Most of the countries with serialization regulatory requirements are recommending the use of the 2D DataMatrix for these exact reasons – the small real estate needed on artwork and the large amount of data that can be encoded (2,335 alphanumeric characters 3,116 numeric).

The CFDA in China have been very clear that they require a linear 1D 128C code. Type 128C can only encodes digits (00-99) and FNC1 but this is ok for China as there are no alpha characters contained in the 20 digit EDMC. As the EDMC code is not encoded with your lot specific lot number and expiry date you have the advantage of being able to pre-print barcodes offline.

Q: "It seems many countries require randomization. Can you please summarize which countries stipulate the use of randomized numbers?"

LOR: We currently understand that Brazil who require a 13 digit serial number require randomization, the EU require randomization, Ukraine potentially will require randomization and China who issue manufacturers 20 digit EDMC codes and randomize the last four digits have a partially randomized serial code.

Q: "How can I convince senior management that serialization needs to be implemented as a corporate strategy and not just an artwork and labelling issue?"

LM: Serialization impacts your entire business and entire supply chain, across global markets. A unified corporate strategy is needed to oversee and guide pilot and overall program execution to ensure that a coherent approach is taken to meeting the deadlines. If the serialization program is executed at a corporate level your organization should be able to identify solutions and workarounds such as utilizing an existing CMO or transferring packaging of a product (s) to another site to meet a serialization regulatory requirement. A fragmented approach will not allow identification of these potential synergies.

Q: "How can we streamline our serialization approach and avoid unnecessary complexity?"

LOR: Your organization should first aim to fully understand the serialization requirements in each of your impacted markets and then determine exactly what changes you need to make to your existing systems from the packaging line up. Serialization projects are complex and consume valuable resources so unless there are indirect business benefits there is no justification to implement additional functionality i.e. aggregation line equipment and business processes when only the unit of sale needs to be serialized.

Also with artwork and labelling changes, you can plan to standardize where possible. You should aim to have as low a number as possible of generic label formats that will support all your labelling requirements.

Liam O'Riordan is Director of Serialization for Enterprise System Partners. He has over 25 years professional experience managing

serialization projects, in the electronics, mobile phone, automotive, medical device & pharmaceutical industries.

Linda Murphy is a Senior VP of Operations in the West Coast of US. She has over 7 years' experience in serialization having begun her career in Ireland before relocating to the US with ESP. She has experience of managing serialization rollouts for the US and Irish markets.