3C Excellis Europe's Regulatory Requirements Radar Pharmaceuticals

Actionable Intelligence, At a Glance.

Why a Regulatory Requirements Radar is needed

Serialisation and Traceability requirements have become a hot topic for discussion in the pharmaceutical industry, starting with pharma manufacturers but more recently also affecting wholesalers, distributors, dispensers, pharmacists in many different branches of the industry down to patients who are becoming aware of a momentous trend in the industry.

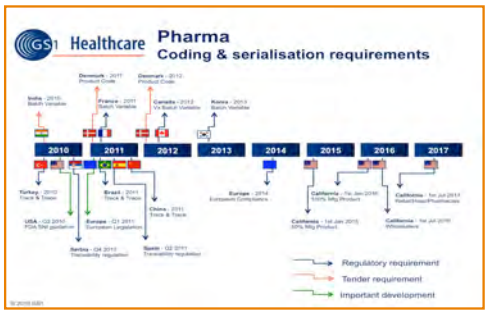
Governments and regulators have become increasingly active in this area. As a result, there has been a striking expansion of markets where serialisation and traceability requirements have been drawn up as part of the effort to protect patients from the illegal trade in medicines.

Serialisation Requirements, then and now:

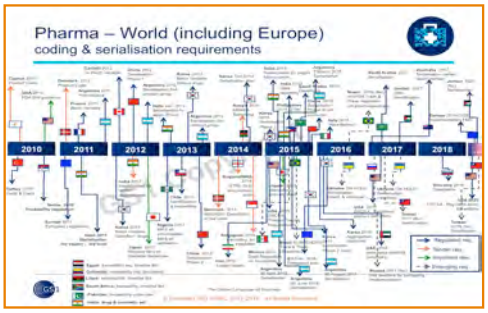
These two maps of global coding and serialisation requirements published by GS1 provide a dramatic illustration of the growing popularity of the serialisation / traceability approach with regulators and legislators across the globe.

Each flag is a requirement in a specific market for a specific deadline: The complexity of the current position is clear as more and more markets and customers demand serialisation, and it is a trend that shows no signs of slowing down.

2010



2016



Illustrations © GS1

Many companies, however, are still only just waking up to the challenge that is facing them and are now asking many questions: What are the specifications? What are the technical requirements? What are the formats and quality requirements for the serial numbers that need to be applied? What items need to be coded, and how? Who creates the serial numbers? Who needs to receive them, and how? What are the data management requirements affecting our company?

The sense emerges that this is an overwhelming challenge consisting of conflicting, ill-defined and changeable requirements that are issued – and changed – with short notice and put an impossible burden on pharmaceutical manufacturers and their trading partners.

How can 3C Excellis Europe help?

Our practical experience and long-time engagement in Serialisation / Traceability programmes as well our close involvement with organisations such as GS1 Healthcare, EFPIA and EMVO, who are working closely to European legislators and regulators, places us in a unique position.

> ***3C Excellis Europe*** *provides a unique level of expertise to strategically support your serialization journey with a strong experience in the domains of Regulatory, Manufacturing, ERP- EPCIS, MES, warehouse, supply chain and validation for MAH, CMO, distributors and re-packagers.*
>
> ***3C Excellis Europe*** *specialise in working with pharma companies – brand owners, generic manufacturers and contract packers, from large enterprises that are active world-wide to small specialized companies – in defining, planning and delivering their serialisation programmes.*
>
> *3C Excellis with unrivalled* ***experience*** *brings a* ***proven methodology*** *and offers* ***world-class consulting resources*** *consisting of experienced individuals and subject matter experts from both innovative consulting environments and leading business and technology organizations.*

The 3C Excellis Europe Regulatory Requirements Radar

The information contained in 3C Excellis Europe's Regulatory Requirements Radar will help pharmaceutical manufacturers to understand the requirements, at a glance and in wider context, and to understand how to plan a response that will allow them implement an effective readiness program for currently known and future anticipated requirements.

Unlike other lists of requirements that are available, the 3C Excellis Europe Requirements Radar focuses on the "So what?", offering an expert interpretation of the requirements and what they mean for pharma manufacturers, leading into practical guidance on understanding the requirements in the wider context and preparing an effective manufacturer readiness programme both to address the immediate requirements but also tackling this work strategically in the more long-term context.

The 3C Excellis Europe Regulatory Radar focuses on serialisation and traceability requirements. The radar aims to provide a comprehensive, systematic overview of existing and anticipated regulatory requirements for coding of pharmaceutical products.

The radar also details the enablers/capabilities necessary to fulfil the requirements along with a view of the role of supply chain participants in the requirement and their obligations

As well as recording technical details of specific coding requirements, the 3C Excellis Radar provides early warning of new and emerging coding requirements in order to feed the regulatory monitoring and assessment processes of pharma supply chain participants.

The information contained in the 3C Ex Radar should be adequate to allow requirements to be understood and an impact assessment made in order to determine actions necessary to achieve compliance.

The document sets out to detail the background to the requirement, the scope of the requirement, effective dates and details of the coding requirement at different pack levels are then also recorded.

3C Excellis Europe's Regulatory Requirements Radar *provides a comprehensive, systematic overview of existing and anticipated regulatory requirements for coding of pharmaceutical products.*

The 3C Excellis Europe Regulatory Radar:

- *Provides early warning of new and emerging coding requirements;*
- *Notes the background to the requirement, the scope of the requirement and the effective dates;*
- *Records the details of specific coding requirements at different pack level;*
- *Captures the role and obligations of the different trading partners;*
- *Offers a guide to the capabilities and enablers required to fulfill the requirements;*
- *Can be used to inform the regulatory monitoring and assessment processes of pharma supply chain participants.*

Scope of the 3C Excellis Europe Regulatory Radar:

The 3C Excellis Europe Regulatory Radar aims to provide information and guidance specifically for the serialisation / traceability requirement area that is less well understood and presents particular and new challenges.

The trigger point for inclusion in the 3C Excellis Europe Regulatory Radar is the need to introduce new capability beyond that required to print conventional variable data e.g. batch number and expiry date. This means that the 3C Excellis Europe Regulatory Radar does not duplicate the information pre-dating serialisation and traceability requirements that the regulatory function of pharmaceutical companies routinely manage today.

The 3C Excellis Europe Regulatory Radar:

- *Focuses on serialisation / traceability requirements;*
- *Does not replace the in-house pack coding guidelines, code books, packaging manuals etc. that are well understood and established;*
- *Can support but not replace the expertise and processes of a pharma manufacturers regulatory, packaging and artwork specialists.*

In Scope

The current scope of the 3C Excellis Europe Regulatory Radar includes:

- All requirements impacting medicinal products for human use;
- All global markets;
- Legal, regulatory as well as known market access/tender requirements;
- Currently defined and future requirements where there is reasonably firm / published evidence.

Out of Scope

Out of scope of this version are:

- Medical Devices
- Veterinary Products
- Non-pharmaceutical products

Purchasing the 3C Excellis Regulatory Requirements Radar:

The 3C Excellis Europe Regulatory Radar is offered on a subscription basis in two versions:

	Full Version featuring Customer-specific alerts	**Basic Version**
Onboarding	Initial 3hr Introduction Session by conference call. As an outcome from this session, a customer-specific alert list will be built (see "Alerts" below). The introduction session can also be offered face-to-face (customer pays for travel and expenses)	Initial 1hr Introduction Session by conference call, to introduce the Radar concepts and background
Radar Document	Radar document (electronic version) plus 2 print copies	Radar document (electronic version)
Updates	Quarterly; next update: October 2016	
Ongoing offer	Monthly 1-hr personalised call available	Quarterly document updates
Alerts	Real-time alerts as relevant based on customer-specific alert list	None
Restrictions / Limitations	"Multi User Licence": Open to nominated company contacts, from define short-list (i.e. in-market regulatory teams)	"Single User Licence": One nominated company contact for communications in both directions

Disclaimer:

The information contained in document has been prepared with care by 3C Integrity / 3C Excellis Europe based on requirements published officially or shared for consultation and discussion. It has been reviewed and commented on by serialisation / track & trace subject matter experts and practitioners to give clear and accurate information and guidance but due to the nature of these requirements, uncertainties inherent in the information published, changes over time and differences in interpretation applied, the information provided cannot be taken as a definitive guidance to drive corporate decisions which need to be based on accessing the original information provided by regulators, legislators and customers and needs to be interpreted by the company's designated experts accountable for analysing external compliance requirements.

The data contained in this document should form a substantial part of the intelligence gathering activity necessary to feed the internal requirements monitoring and assessment process.

Whilst every effort is made to ensure that the information contained in this document is complete and up to date – companies should always engage local market regulatory and other resource to validate the requirements as stated and ensure that there are no local interpretations emerging.