Excellis Regulatory Requirements Radar™

Excellis Health Solution's ***Regulatory Requirements Radar™*** provides a **comprehensive guide to all existing and anticipated global requirements** for **coding and serialization of pharmaceutical products.**

- **One-glance overview:** The Radar offers a one-glance overview of all requirements using EHS's unique and trade-marked Radar-style display as well as a systematic **detailed assessment of each requirement**.
- **Expert interpretation** The Radar also includes expert interpretation of the **requirements impact** and clear guidance on **recommended approaches** that customers should consider.

In contrast to other requirement overviews provided by vendors and solution providers, the Excellis Requirements Radar offers a **vendor-neutral view** on the requirements and an **expert interpretation of the required capabilities** that need to be established that is completely independent of any commercial solution-specific interest.

Excellis team's of experts are recognized for their best in class experience and expertise in the Pharmaceutical Industry and the Healthcare Supply Chain as the world's leading advice on Pharma Serialisation and Traceability in Healthcare.

Purpose of the *Regulatory Requirements Radar™*

- Comprehensive overview of Serialization and Coding Requirements and Capabilities required to address these
- The Radar records technical details of specific Serialization and coding requirements
- Provides early warning of new and emerging Serialization and coding requirements
- Can be used to inform the regulatory monitoring and assessment processes of pharma supply chain participants.

The information contained in the document should be adequate to allow requirements to be understood and an impact assessment carried out in order to determine actions necessary to achieve compliance.

Content of the Excellis *Requirements Radar™*

- Recommended Requirements Monitoring Process
- One-glance overview of all requirements
- Emerging requirement watch
- Detail, background, scope and effective dates of requirements and reference to the published requirement documentation
- Details of the coding requirement at different pack levels.
- Enablers/capabilities necessary to fulfill the requirements
- Interpretation of the role of supply chain participants and their obligations
- Expert guidance on how to approach the readiness for every affected stakeholder

Scope:

The trigger point for inclusion in this analysis is the need to introduce new capability beyond that required to print conventional variable data e.g. batch number and expiry date.

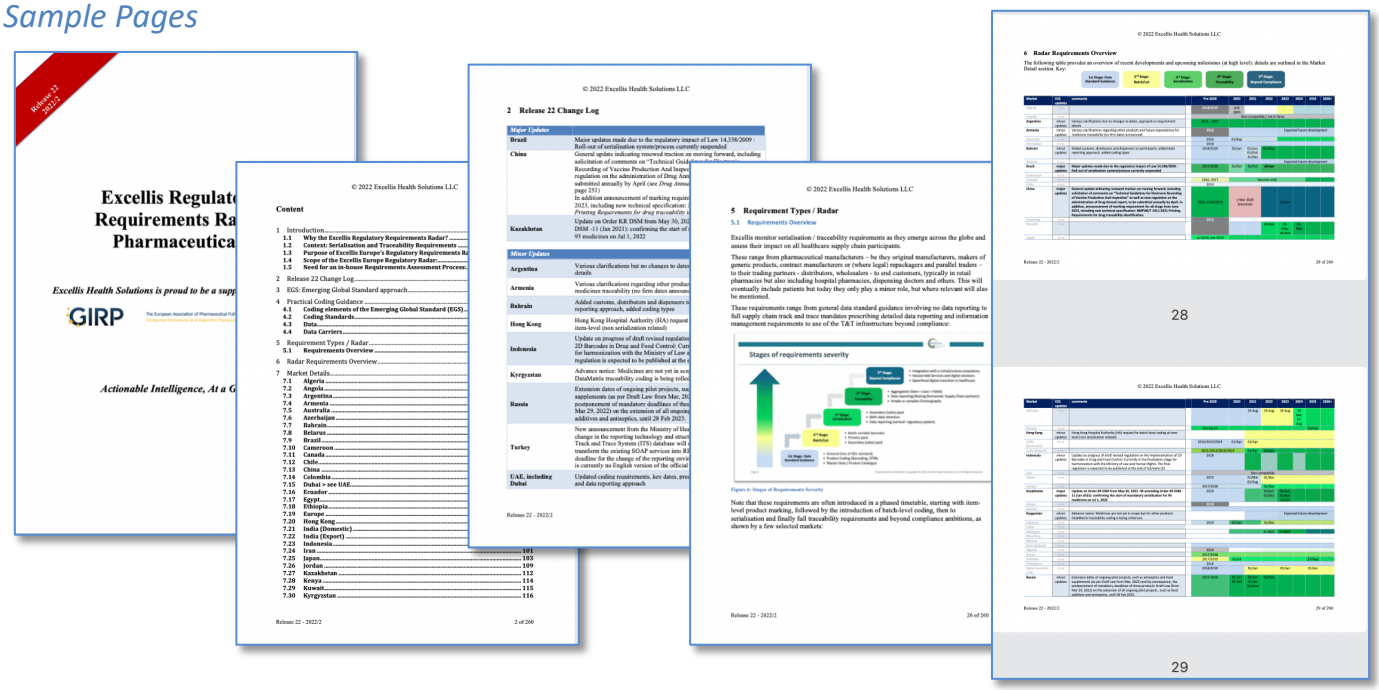
In scope of this document are

- All coding requirements impacting medicinal products for use in humans;
- 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 of the current version are:

- File layout, technical interface descriptions; these will be provided by the repository system provider
- Medical Devices (on demand)
- Veterinary Products (on demand)
- Non-pharmaceutical products. (on demand)

Sample Pages



Subscription

The ***Regulatory Requirements Radar™*** is available as a one-off product or on a subscription basis. Different subscription levels are offered including the quarterly updated Radar with live ad-hoc alerts, monthly updates and regular conference calls that provide enhanced background, in-depth impact assessment and discussion of topics of particular interest to clients.

Disclaimer

Due to the varying nature of this information and the particular and unique circumstances of every pharma company, customers must be aware that the information in 3C Excellis Europe's *Regulatory Requirements Radar™* can form a substantial part of the intelligence gathering activity necessary to feed the internal requirements monitoring and assessment process but cannot be relied on as the sole guide to requirements interpretation and impact assessment. Whilst every effort is made to ensure that the information in the Excellis *Regulatory Requirements Radar™* is complete and up to date, customers must always engage local market regulatory and other resource to validate the requirements.