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Must-Know China Track and Trace Compliance Terms for the Pharmaceutical Supply Chain



Multinational companies that manufacture and distribute medicines in The People's Republic of China must gear up quickly to meet the country's latest track and trace regulations and understand the government's evolving technical guidelines. In a recent article, [Are Your Products China Ready? Three Key Decisions for Multinational Pharma Companies](#), we noted that the broad framework of systems and standards for identifying products and exchanging product data with government regulatory agencies has been established, allowing companies to begin planning their China serialization and packaging configuration strategy.

The next step for companies will be to understand their responsibilities under the law. The 2019 revisions to China's Drug Administration Law, and the related regulations and technical specifications which have been published since the law's passage, introduced new terminology into the regulations and guidelines, including many that replace or are equivalent to terms from the original 2015 China serialization and traceability law. This glossary defines key terms, acronyms, and names that companies are likely to encounter as they begin to survey China's regulatory landscape.

AliHealth

Alibaba Health Information Technology Limited developed and provided the Product Identification, Authentication, and Tracking System (PIATS) which was used as the central government system for the original China product serialization and traceability regulations which were implemented between 2013 and 2015. New laws and government regulations developed between 2017 and 2020 have defined a multi-tiered drug information traceability system which does not rely on a single central system.

China Drug Electronic Administration Code (DEA Code)

A one-dimensional barcode that includes a 20-digit DEA code number applied as a product identifier to meet NMPA product traceability requirements. Also referred to as **eCode**.

China Food and Drug Administration (CFDA)

Chinese regulatory agency which developed the original drug serialization and traceability regulations. The CFDA has since been reorganized and renamed today as the **National Medical Products Agency (NMPA)**.

China National Drug Code (CNDC)

A 14-digit code—similar to the GS1-standard Global Trade Item Number (GTIN)—developed by the CFDA to identify the manufacturing company, locality, and product type. Replaced by the **China Drug Electronic Administration Code**.

CSP (See: Drug Traceability Collaborative Service Platform)

DAL (See: Drug Administration Law)

DEA Code (See: China Drug Electronic Administration Code)

Drug Administration Law (DAL)

The Drug Administration Law was passed on August 26, 2019 and came into force on December 1, 2019. It represented a major systematic and structural change to

China's overall drug administration framework governing drug research, registration, production, distribution, and other activities. This law set the legal foundation for the development of specific regulations across these areas but did not provide specific implementation dates for any of its requirements. Some of the objectives of the amended law include:

- The establishment of a drug traceability system based on NMPA drug traceability standards and specifications and designed to ensure that all information generated in drug research, manufacturing, distribution, and usage is true, accurate, and traceable.
- Ensuring the country's drug supply through a monitoring system
- Establishing a pharmacovigilance system for drugs distributed in China
- Enhancing the existing drug registration system
- Increasing specific penalties for non-compliance

Drug Traceability Code (DTC)

A general term used to describe the traceability code applied to a pharmaceutical product using either the **EDMC** or the **ISO/IEC 15459** product serialization and encoding standard. It is composed of both a Drug Identification Code and a Production Code. The DTC is not only used to uniquely identify drug products but is also included in several China compliance reports.

Drug Traceability Harmonization Services Platform (HSP) / Collaborative Service Platform (CSP)

In China's 3-tiered drug traceability infrastructure, the drug traceability service platform serves as a "bridge" between the manufacturer's traceability solution (or its third party solution) and the government's regulatory system. Sometimes referred to as a "collaborative service platform," it provides drug code management and sharing services for enterprise regulatory and traceability systems, and is developed and administered by the NMPA. Under the original 2015 law, there was a single government system for traceability reporting which was developed at the time by **AliHealth**. The NMPA is responsible for developing the

HSP under the new 3-tiered infrastructure.

Drug Traceability Supervision System

The Drug Traceability Supervision System describes a set of government platforms developed by the central China government and individual provinces as part of the three-tier Drug Information Traceability System. The Supervision System provides a broad variety of services and information to the government including summary analysis and information on drug products, their state, and their related transactions across the China drug supply chain, recall management, product supply insights, and early warning services of potential impending issues.

Drug Traceability System

The drug traceability solutions and platforms which are designed to generate/assign unique drug traceability codes to products across multiple packaging levels, and for the collection, storage, and sharing of information about drugs and related traceability information. Drug Traceability Systems are used by supply chain stakeholders (manufacturers, distributors, dispensers) to generate and capture information about drugs moving into and through the supply chain, reporting such information to the NMPA's Drug Traceability Harmonization Service Platform.

eCode (See: China Drug Electronic Administration Code)

Also referred to as **DEA Code** or DEA/eCode.

Electronic Drug Monitoring Code (EDMC)

A product identifier that uses a **DEA Code** to meet **NMPA** product traceability requirements.

GB/T 1988/1998 Standard

This Chinese standard specifies a character set of 128 characters (control characters and graphic characters, such as letters, numbers, and symbols) and their coded representation. The alphanumeric composition of the **Drug**

Traceability Code includes symbols from the GB/T 1988/1998 Standard.

GS1

GS1 is a not-for-profit organization with headquarters in Belgium that develops and maintains global standards for barcodes that can be scanned electronically. Linear and 2-dimensional GS1 barcodes are the de facto standard for serializing medicines around the world, from individual units to aggregated packs, cases, cartons, and pallets. (See: ISO/IEC 15459)

ISO/IEC 15459

China serialization and encoding standards specify the ISO/IEC 15459 coding format as an alternative to the Chinese DEA/eCode format. Because the **GS1** and ISO standards organizations collaborate so closely, GS1 coding and information standards are often based on ISO standards, and the ISO/IEC 15459 format is the functional equivalent to the GS1 components used across the global pharmaceutical supply chain to identify and track medicines and medical products.

GS1 Component	ISO Equivalent
GTIN (Global Trade Item Number)	ISO/IEC 15459-6
SGTIN (Serialized Global Trade Item Number)	ISO/IEC 15459-4
SSCC (Serial Shipping Container Code)	ISO/IEC 15459-1
GIAI (Global Individual Asset Identifier)	ISO/IEC 15459-4 & 5
GRAI (Global Returnable Asset Identifier)	ISO/IEC 15459-5

Measures for the Supervision and Administration of Pharmaceutical Production (Order No. 28)

Published on March 30, 2020 and put into force on July 1 as part of the regulatory implementation of the Drug Administration Law, these 81 articles cover a wide range of pharmaceutical activities and are supported by several **NMPA** articles on the interpretation of NMPA standards and guidelines. Several foundational articles are of particular interest to companies that manufacture and distribute

pharmaceutical product in China:

- **Article 2** specifies that “the production, supervision and management activities of drugs marketed within the territory of the People's Republic of China shall comply with these Measures.”
- **Article 3** notes that companies “engaging in pharmaceutical production activities shall abide by laws, regulations, rules, standards and norms, and ensure that the information of the whole process is true, accurate, complete, and traceable.”
- **Article 4** states that “drug marketing license holders and drug manufacturing enterprises shall:
 - Establish and implement a drug traceability system
 - Grant traceability labels to drug sales and packaging units at all levels in accordance with regulations
 - Implement drug traceability through informational methods
 - Record and save drug traceability data in a timely and accurate manner, and provide traceability information to the drug traceability collaborative service platform”

Article 4 does not explicitly mention the rest of the stakeholders in the supply chain such as wholesale distributors, retail pharmacies, and dispensers, but this should not be interpreted that the rest of the supply chain does not have traceability requirements. Instead, the Measures were intended to focus primarily on rules and requirements for companies directly involved in pharmaceutical production.

National Medical Products Administration (NMPA)

The National Medical Products Administration (NMPA) (formerly the China Food and Drug Administration, or CFDA) is a ministerial-level agency under the State Council of the People's Republic of China. The NMPA supervises the safety management of

food and cosmetics and is the competent authority of drug regulation in mainland China.

Order No. 28

(See: Measures for the Supervision and Administration of Pharmaceutical Production)

TraceLink: A proven partner in China compliance solutions

Staying up to date on the complexity of China's regulatory requirements is a significant challenge—even for companies with experience in other global markets. Since 2013, TraceLink has been helping companies meet the original China serialization and traceability regulations with our China Compliance reporting and related serialization solutions. In addition, TraceLink has been a noted partner for companies in helping them understand the legal, regulatory, operational, and technical requirements for China through the TraceLink Community and our China Special Interest Group of operational leaders, regulatory experts, and technical innovators.

Learn more about joining TraceLink's Community and our track and trace solutions for China.

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Learn from use cases that explore hub connectivity, onboarding & implementation timelines to meet compliance by February 2019.

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UNIQUE IDENTIFICATION CODE FOR DERMOMESTHETIC PRODUCTS

IBSA's Internal Serialization Procedure for Medical Device Products

Authors: Maddalena Rizzo, Production Manager at IBSA Italy; Carmen Vigorelli, Sr. Sales Manager, IBSA Switzerland



Case Challenge & Solution

IBSA, a leading manufacturer of dermomesothetic products, faced a significant challenge in ensuring product integrity and preventing counterfeiting. The company's internal serialization procedure was outdated and inefficient, leading to delays and errors in the production process. The solution involved implementing a new internal serialization procedure that utilized unique identification codes (UICs) for each product. This allowed for better tracking and control of the production process, ensuring that each product was authentic and safe for use.

Key Activities and Resources

Key Activities:

- 1. Defining the UIC structure and format.
- 2. Implementing the UIC structure in the production process.
- 3. Testing the UIC structure and format.
- 4. Validating the UIC structure and format.
- 5. Implementing the UIC structure in the production process.

Resources:

- 1. Internal serialization procedure.
- 2. Production process.
- 3. Testing process.
- 4. Validation process.
- 5. Implementation process.

Outcomes

Success Metrics & Results & Feedback:

- 1. Improved product integrity and safety.
- 2. Reduced production delays and errors.
- 3. Increased customer satisfaction and loyalty.
- 4. Enhanced brand reputation and trust.
- 5. Improved overall business performance.

Success: IBSA's internal serialization procedure was successfully implemented, ensuring that each product was authentic and safe for use. The company's brand reputation and trust were enhanced, leading to increased customer satisfaction and loyalty. The overall business performance was improved, resulting in higher sales and profits.


Recommendations

IBSA's internal serialization procedure was successfully implemented, ensuring that each product was authentic and safe for use. The company's brand reputation and trust were enhanced, leading to increased customer satisfaction and loyalty. The overall business performance was improved, resulting in higher sales and profits.

Case Study: IBSA | Using Serialization to Ensure Product Integrity

Learn how IBSA used serialization to protect their product from counterfeiting.


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Master Product Data Strategy for EU-FMD implementation: the key of success in serialization

Author(s): Cristina Bonache (Corporate G&S), Luis Gallardo (P&D/Corporate G&S), and Blanca Sánchez (Global R&D)




Key Challenge & Solution

Founded in 1988, Ferrer is a privately held international pharmaceutical manufacturer in Barcelona. It is active throughout the EU with more than 10 international subsidiaries. Product is more than 100 countries with 100+ affiliates. Ferrer is active in the pharmaceutical field, the chemical sector, key areas for contributing to people's health and well-being.

As a global company, the management of master data is critical. It is the main challenge of the master data and the way it is used is a significant business challenge. It is a key business challenge and the main driver to ensuring that all products in compliance to each product.

As a key driver of the company, master data can be successfully through multiplatform, team work, alignment across the company, and the ability to use the data and the data-driven capabilities.



Key Activities and Resources

Key Activities

- 1. Master Product Data Strategy for EU-FMD implementation
- 2. Master Product Data Strategy for EU-FMD implementation
- 3. Master Product Data Strategy for EU-FMD implementation
- 4. Master Product Data Strategy for EU-FMD implementation
- 5. Master Product Data Strategy for EU-FMD implementation
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Key Resources

- 1. Master Product Data Strategy for EU-FMD implementation
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Outcomes

Beginning state

- 1. Master Product Data Strategy for EU-FMD implementation
- 2. Master Product Data Strategy for EU-FMD implementation
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- 10. Master Product Data Strategy for EU-FMD implementation

Results & Feedback

- 1. Master Product Data Strategy for EU-FMD implementation
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- 10. Master Product Data Strategy for EU-FMD implementation

Recommendations

Advice

- 1. Master Product Data Strategy for EU-FMD implementation
- 2. Master Product Data Strategy for EU-FMD implementation
- 3. Master Product Data Strategy for EU-FMD implementation
- 4. Master Product Data Strategy for EU-FMD implementation
- 5. Master Product Data Strategy for EU-FMD implementation
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- 10. Master Product Data Strategy for EU-FMD implementation

Key Messages

- 1. Master Product Data Strategy for EU-FMD implementation
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- 10. Master Product Data Strategy for EU-FMD implementation

Case Study: Ferrer | Building a Master Data Strategy for EU FMD

Learn how Ferrer worked with TraceLink to manage its master data for EU FMD compliance.
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Brian Dalkowski
VP, Industry M

CMO Line Upgrades: Who Will Pay?

Pharma companies and CMOs must work together closely to be ready for serialization, yet there is no established commercial model. Learn about the dynamics.

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HOW TO BUILD AN EMPIRE WITH SERIALIZATION

Jordan Moore-Carmona, Validation Leader & Julie Buford, Supply Chain Officer at Mithra




Challenge & Solution

What are we to?

Mithra is a biotechnology company focused on creating innovative new therapies for patients with rare diseases. They are currently in the process of developing a new therapy for a rare genetic disease. The team is working on a multidisciplinary approach to bring this therapy to market, involving regulatory, clinical, and commercial teams from the start.

Business Challenges

- How does Mithra manage the complexity of a multidisciplinary approach to bring a new therapy to market?
- How does Mithra manage the complexity of a multidisciplinary approach to bring a new therapy to market?
- How does Mithra manage the complexity of a multidisciplinary approach to bring a new therapy to market?

Solution

Mithra used a multidisciplinary approach to bring a new therapy to market, involving regulatory, clinical, and commercial teams from the start.

Key Activities and Resources



Key Activities and Resources

- Regulatory
- Clinical
- Commercial

Key Business Partners

- Pharmaceuticals (e.g., Pfizer, Novartis, Merck, etc.)
- Regulatory agencies (e.g., FDA, EMA, etc.)
- Healthcare providers
- Patients
- Investors
- Partners (e.g., CROs, etc.)

Team



Team

- Jordan Moore-Carmona, Validation Leader
- Julie Buford, Supply Chain Officer
- Samuel Buford, Regulatory Affairs Manager
- John Buford, Clinical Affairs Manager
- John Buford, Commercial Affairs Manager
- John Buford, Regulatory Affairs Manager
- John Buford, Clinical Affairs Manager
- John Buford, Commercial Affairs Manager
- John Buford, Regulatory Affairs Manager
- John Buford, Clinical Affairs Manager
- John Buford, Commercial Affairs Manager

Outcomes

Business Metrics

- Increased revenue
- Improved patient outcomes
- Reduced costs
- Increased market share

Results & Feedback

- Positive feedback from patients
- Improved patient outcomes
- Reduced costs
- Increased market share

Recommendations

Recommendations

- Continue to invest in research and development
- Expand into new markets
- Improve patient outcomes
- Reduce costs
- Increase market share

Case Study: Mithra | Serializing Across Multiple Business Cases

Learn how Mithra used a multidisciplinary approach for a successful EU FMD go-live.

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