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IDENTIFICATION OF MEDICINAL PRODUCTS

IDMP: The Drive Towards Common Global Standards

IDMP is the Identification of Medicinal Products, an International Standards Organization (ISO) standards initiative to provide identification to drug products and enhance patient safety. This standard—a set of common global standards for data elements, formats, and terminologies for the unique identification of and the exchange of information on medicines—is being adopted globally by health authority agencies and organizations such as the World Health Organization.

From Understanding to Compliance

IDMP allocates unique IDs to each data point defined in the dictionaries and submitted to the health authorities. These unique IDs are then used to track products against safety for quicker action. IDMP compliance requires that information about products be presented in terms of a set of standard identifiers. There are 5 standards in IDMP: Substances (ISO 11238); Pharmaceutical Dose Forms, Units of Presentation, Routes of Administration, and Packaging (ISO 11239); Units of Measurement (ISO 11240); Regulated Medicinal Product information (ISO 11615); and Regulated Pharmaceutical Product Information (ISO 11616). As of July 1, 2016, the European Commission and EMA require compliance with IDMP in a phased approach.

Compliance with IDMP is as strategic as it is data-driven; therefore, our approach to helping organizations ensure IDMP compliance begins with defining a strategy, identifying gaps and existing IDMP content, data evaluation, cleansing and migration, and ultimately, implementation.

DELIVERING MATURITY ACROSS THE REGULATORY SPECTRUM

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Paragon's Regulatory Optimization Practice

Paragon has expertise crossing all areas of product development and post marketing activities: Regulatory, Clinical, Supply Chain and Manufacturing, Labeling, and Information Management. As a non-software client services organization, Paragon operates with complete non-bias in process development, system implementations, and vendor selection processes. During IDMP evaluations, we provide services as necessary for the organizations in which we are working. IDMP services include:

- **Gap Analysis** – Identification of IDMP content across the organization, systems which house the content, and evaluation of steps necessary for compliance
- **Standardization** – Co-development and application of standards to existing data, data cleansing, and interoperability evaluation / testing
- **Strategy** – IDMP implementation strategy and approach, including Regulatory Information Management (RIM) and Master Data Management (MDM)
- **Process Development** – Cross-functional operations
- **Vendor Evaluations** – RFI and RFP development and review for IDMP/RIM vendors
- **Software Implementations, Validation, and Migration**
- **Training** – Regulatory Standards training for individuals or teams

Our Solutions

What Paragon's solutions deliver is maturity across all aspects of regulatory design. From data mining and cleansing, evaluation and strategy of content during expansion, vendor landscape evaluations, e-submission best practices, and training, to intelligence gathering and tracking. Paragon is focused on strategy, processes, and best practices across all functional areas:

- **Regulatory Information Management Services and Solutions**
- **Regulatory Compliance Strategies & Solutions**
- **Regulatory Operations Optimization**
- **Regulatory Intelligence Services and Solutions**

About Paragon

Paragon is a consulting firm that helps health and life sciences companies become high-performing, compliant, and digitally connected. Paragon powers business transformation and delivers better business outcomes by providing valuable consulting services as a trusted partner to our clients. We do this by building long-term client relationships based on our domain expertise, creative ideas, pragmatic consulting services, and quality delivery of solutions.

For more information, visit us online at www.consultparagon.com, or call 1.800.462.5582.

Paragon Client Roster

Our client roster includes life science industry leaders such as:

- **AbbVie**
- **AstraZeneca**
- **Bausch & Lomb**
- **Bayer**
- **Bristol-Myers Squibb**
- **Celgene**
- **CSL Behring**
- **Daiichi-Sankyo**
- **GSK**
- **Lilly**
- **MedImmune**
- **Merck**
- **Novo Nordisk**
- **Otsuka**
- **Roche**
- **Shire**
- **Chiltern**
- **inVentiv Health**
- **Worldwide Clinical Trials**
- **Regeneron**