

Achieving Information Consistency and Transparency with the CCDS

BROCHURE

CHALLENGE

Pharmaceutical companies are under pressure from all sides to demonstrate the efficacy and safety of their products. For instance, they must provide extensive amounts of information for regulators and inspectors to prevent any detrimental actions such as referrals or, potentially, withdrawal of indications for a product.

Such vital information must reside in the one document that is central to all of the regulatory and pharmacovigilance activities related to a product: the company core data sheet (CCDS). An efficient and comprehensive CCDS that combines all corresponding information and related processes across the life of the product forms the backbone at both the information management level and the organisational level.

During inspections and audits throughout Europe, authorities all too frequently uncover inadequacies in the CCDS. The finding creates serious problems for companies because the CCDS has become the benchmark against which all promotional and marketing claims have to be verified.

The information contained in the CCDS is the source for (1) several critical documents—including the summary of product characteristics, the periodic safety update report (PSUR), and other safety-related documents—and (2) the preparation of variations, supplements, and renewals. Furthermore, the CCDS is the authoritative source for data elements required by the eXtended EudraVigilance Medicinal Product Dictionary and the forthcoming Identification of Medicinal Products.

Without comprehensive management of the CCDS, core pieces of data are likely to be inconsistent across the enterprise, raising alarm bells with regulatory authorities.

OFFERINGS

ProductLife Group helps companies bridge information gaps in the CCDS through a blended approach that includes information and process management and regulatory and pharmacovigilance expertise to achieve regulatory vigilance.

STRATEGIC CONSULTING

A CCDS overhaul starts with an overview of the current state of the document, assessment of the information, and steps to build all of the data links to make the CCDS compliant. ProductLife Group experts carry out both the review and associated corrections. Project activities are:

- Gap analysis to identify major areas of concern
- Help to harmonise data sheets and develop a common taxonomy for defining the information in the CCDS
- Assessment of the levels of accuracy and consistency of the data in the document
- Development and deployment of the company's information management system connected to the CCDS
- Help to search for supporting data and links needed to substantiate marketing campaigns

PROJECT MANAGEMENT

Beyond initial consulting to help address current issues with the CCDS and related documents and systems, ProductLife Group also provides process-related consulting expertise to help companies establish efficient practices from the outset.

Because the CCDS is the key source of information about a product, management of the information contained in it as well as across related data sets and documents presents a challenge. There must be both a focus on consistency of data across other information management systems and harmonisation of practices by different stakeholders in creating, updating, consulting, and assessing the whole set of data and documents supporting the CCDS.

The approach ProductLife Group takes to managing the CCDS and to deciding whether to integrate data sets gets tailored to a company's specific needs, circumstances, and existing processes. For example, when it comes to addressing safety, ProductLife Group's experts help companies assess new data and determine any potentially critical issues for the product and portfolio, consider escalation procedures, and gauge the impact on risk management.

Both information management and decision processes have to be analysed, adapted, and assessed against all commercial developments such as the portfolio itself, acquisitions, partnerships, and expansion into new markets. When required, ProductLife Group will propose a change management approach to address any potential issues. Drawing on its familiarity and extensive experience with document and data management processes and commercial decision making, ProductLife Group provides:

- Current process review and gap analysis to uncover potential scenarios and the resulting impact based on the company's business model
- Creation of associated processes around the CCDS and training in those processes to ensure ongoing best practices and consistency
- Support for change management to address any issues with existing processes or issues related to the impact of the company's evolution as well as regulatory and safety issues. Such change management recommendations include taking an incremental approach that would minimise disruption
- The establishment of governance for continuous evaluation and monitoring of the changes

In addition, our experts help clients implement data stewardship to support the information needs of all stakeholders: pharmacovigilance, regulatory, clinical, marketing, and beyond.

BENEFITS

ProductLife Group supports clients throughout the CCDS's overhaul and throughout associated processes to help clients achieve consistency, transparency, and process standardisation. In so doing, ProductLife Group helps companies (1) become better able to support claims, (2) respond to demands for information required in the renewal process and during inspections and audits, and (3) reduce duplication and inconsistencies across other documents, such as the PSUR and risk management plans so as to enhance products' life cycle management.

A proactive approach to the CCDS enables a company to establish the basis for a multidisciplinary approach to pharmacovigilance and to instil a safety-driven culture.

The CCDS is the primary reference document for all products with regard to both regulatory authorities and licencing partners during negotiations for the sale or purchase of a product. How the data and supporting documentation within that CCDS are managed and maintained is therefore critical to a company's regulatory and market success.

For more information, visit our Web site: www.productlifegroup.com.

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ProductLife Group specialises in helping international life sciences organisations more effectively get their products and therapies to market by providing those clients with functional support across all of the regulated stages of the product life cycle—from development to launch, to postmarketing.

Performing successfully for more than 20 years, ProductLife Group has an established global presence in Europe, North America, and Asia Pacific. We deliver services via an innovative, platform-and-hub operating model, enabling our clients to achieve continuous improvement, increased quality, enhanced performance, reduced risk, better compliance, and overall cost benefit. That approach, combined with our collaborative, partnership-oriented culture, empowers life sciences organisations to realise the commercial potential of their own international operations.