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Clinical documentation supporting core labels for generics/OTC products

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The CCDS/CCSI (Company Core Data Sheet/Safety Information) was introduced in 1996 with ICH guideline E2C in the context of PSUR creation and then most significantly further evaluated with CIOMS' working group on the preparation of CCSI. CCDS/CCSI still remains the cornerstone of the benefit/risk evaluation of the medicinal products. With the advent and practice of Evidence Based Medicine (EBM), it is important that the CCDS/CCSI is supported by current best evidence that support the use of drugs/biologics in various approved therapeutic indications. The novel therapeutics are developed based on the unmet medical need and follow the current practices and standards of development. The documentation also follows the current thinking of the health authorities and agencies across the world to receive the approvals. Most companies face major challenge in documentation of CCDS/CCSI for generic/OTC products, which have been in market for many years. It is difficult to track the developmental history and document the scientific rationale for these products as they have been developed in age old times when there was limited regulatory oversight. The scientific information may be limited to understanding the mechanism of action, few *in vitro* and animal studies. The randomized controlled studies and clinical overviews which form the pivot for any regulatory approval and label creation today are missing from the list of available resources for supporting the CCDS/CCSI documentation for these products. The presentation describes the strategy used by companies to create and update the clinical overviews to support the CCDS/CCSI of generic/OTC products.

Biography

Aswin Kumar Allupati is a Medical Graduate from Government Medical College in Orissa and has worked for over a decade in various roles of increasing seniority in drug development. He has worked in reputed organizations like RCRS, Accenture and Hospira. He is currently working as Medical Expert at Freyr Solutions. In his current role, he provides expert advice on the clinical documentation for core labels of OTC/generic products, including the medical review of CCDS and clinical overviews.

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