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ABSTRACT: REGULATORY PUBLISHING TOOLS MUST ALSO SUPPORT DEVELOPMENTAL REGULATORY DOSSIER FORMATS AND SUBMISSIONS

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Many publishing tools are sold to the pharmaceutical sector, based on the need to ensure compliance with the incoming regulatory requirements for e-CTD format for new Marketing Authorization Applications (MAA). Within the context of drug development, and for many Small Medium Enterprises (SME) in particular, the MAA is likely however to make up a small minority of the regulatory applications and documents filed.

During the development of a new drug, a company is likely to produce a range of regulatory dossiers and documents, filed to a variety of countries, each with their own respective formats and life-cycles. Examples include EU Clinical Trial Applications (CTAs), Investigational Medicinal Product Dossiers (IMPD), US Investigational New Drug Applications (IND), Clinical Study Reports (CSRs) Scientific Advice Supporting Dossiers, Paediatric Investigation Plans (PIP's), Developmental Safety Update Reports (DSUR), Risk Management Plans (RMPs), Site Master Files (SMF), Pharmacovigilance Master Files, Drug Master Files (DMF) etc.

As the drug development life-cycle progresses, new information becomes available to populate these documents; previously written documents become superseded and information amendments / updates will need to be filed with regulatory authorities. Significant commercial value (and regulatory compliance) can therefore be achieved during the development phases by ensuring that key regulatory data and documents are kept up to date and available.

Moreover, provided consideration is given to the granularity of information at the time of writing, there is significant opportunity for small companies to achieve financial and resource economies by re-using already prepared documents within several different regulatory submissions, and which ultimately could contribute to the information in the MAA itself.

Key to optimising the delivery of these developmental regulatory submissions is the preparation (and agreement) of appropriate publishing templates, which aid in the granularity of data and support companies and regulatory authorities in the preparation and review of "standardised" developmental regulatory submissions.

In an ever increasing electronic world, in which regulators have already agreed (and indeed expect) an electronic standard for exchanging regulatory submissions for the evaluation of marketing applications, namely e-CTD, it is now time to ensure that developmental regulatory submissions can also be prepared using this standard.