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M.A.R.S.: A process for establishing consistent standards

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Multinational companies face an increasing number of challenges when deploying a common standard across different affiliated country offices or sites (referred to as affiliates in this article). This is particularly relevant in the pharmaceutical industry where standards of quality and expectations are high. There is often a path of destruction that results when a regulatory agency such as the U.S. Food and Drug Administration, Medicines and Healthcare products Regulatory Agency, or European Medicines Agency routinely conducts inspections across international borders, companies fail to effectively deploy a common global standard.

From a country affiliate office perspective, it is also difficult. They are usually restrained by resources and have local country requirements to accommodate, apart from an international and global standard required by the company. The benefits of a flexible, local quality management system (QMS) are recognised as positive reinforcement for a mature QMS and have already been discussed in a previous publication.[1] This reference discusses the impedance of implementing consistent messaging to reinforce compliance to policy intent. The process described in this article is at an even deeper level of operationalization where consistent compliance is required to various operational standards.

To add to the complexity, there are often different levels of required standards, depending on whether there is manufacturing and/or testing at the country level. This leads to a requirement for cross-functional governance. There may also be different cultural implications that can affect the levels of understanding or effectiveness of deployment, and the different levels of available resource between large and small country affiliates also cannot be underestimated. Somewhere between everyone having good intent and the effective delivery of policy and actual procedures and processes, there is a disconnect. The end result is that global functions think they have deployed the intended standard adequately, and the affiliate assumes they have implemented it satisfactorily. Sadly, the reality can be that neither has occurred.

Many regulatory agencies have over the last decade made inroads to take a more holistic approach for compliance to standards, quality, and risk assessment for good manufacturing practice (GMP). Good practice (GxP) guidelines (synonymous with best practice) were established in the U.S. by the Food and Drug Administration. The "x" stands for a particular field, whether that's GMP, or good distribution practice (GDP), for example. In 2006, the U.S. released its *Guidance for Industry: Quality Systems Approach to Pharmaceutical CGMP Regulations*,[2] and the European Medicines Agency also released the "ICH guideline Q10 on pharmaceutical quality system" in 2008.[3]

Similarly, compliance standards of best practice issued by the Foreign Corrupt Practices Act[4] and the

Department of Justice[5] also call for consistent deployment of policies and practices.The Department of Justice, for example, emphasizes the importance of a compliance program "implemented, reviewed, and revised, as appropriate, in an effective manner" versus simply having a "paper program" in place.[6]