

## A convergence of regulatory policies at FDA and EMA

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In December 2010 the EU parliament passed the XEVMPD [Article 57 (2)] regulation mandating electronic submissions to the EMA's medicinal products dictionary. With the passing of this regulation, the European Medicines Agency also made public its plan to adopt ISO IDMP standards in support of ICH M5 initiative by 2015-16. The USFDA followed suit in August 2011 with the 'Advancing Regulatory Science Strategic Plan'. The FDA indicated that it will also mandate similar standards by 2015. Most important global pharmaceutical regulatory authorities including PMDA, Japan are expected to follow in ICH's footsteps. This is setting in motion a global convergence on ISO IDMP standards. The first authority to get there will be the EMA. The impact of this convergence will be comprehensive and long term, demanding a change in the conventional outlook to regulatory affairs. Pharmaceutical companies will now have to become more proactive by driving compliance and supporting strategic decision making. From a strategic perspective, it will be important for all pharmaceutical, biotechnology and/or medical devices companies to know the plans and ways of functioning of their regulatory agencies in order to remain ahead of the curve in preparing for upcoming regulatory mandates. Functionally, this increases workloads on all major compliance functions need dynamic resource-activity-roadmap planning. In this session, we will discuss some of the strategies for pharmaceutical companies to prepare themselves for this regulatory convergence well in advance.

### Biography

Mallika Rajasekaran is the senior product manager of the Regulatory Affairs business unit at Aris Global, a world leader in regulatory information management applications. She has over 12 years of work experience during which she has helped design, develop and launch high quality regulatory information management and quality management systems for compliance and risk management focused on pharmaceutical and life sciences companies. Prior to joining Aris Global, she held key customer-facing product management and business analysis position at Fortune 100 companies such as Siemens and IBM. Mallika holds an MCA (Computer Applications) from NIT Rourkela.

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