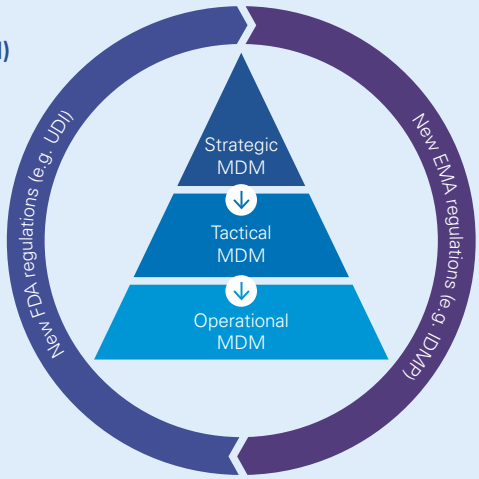
Preparing for the next wave

Master Data Management

"As new regulations in the United States (Unique Device Identifier – UDI) and Europe (Identification of medicinal products – IDMP) are enacted, many organizations struggle with collecting product attribution data. KPMG has a well-established methodology to assist clients dealing with the new regulations and in managing their data."

Insufficient consideration of regulatory standards in today's global life sciences sector can result in government fines, product recalls, adverse media coverage and bad brand recognition. As regulatory institutions continue to come up with new rules for product information, life sciences companies will need to demonstrate active and comprehensive compliance programs across their business and clinical operations, including commercial, R&D, and supply chain.



Potential client issues

- Uncertainty in the MDM strategy due to upcoming new regulations
- Lack of resources and short implementation timeframe to implement the new regulations
- Conflicting and overlapping activities with ongoing and/or completed MDM initiatives
- Compliance risks and issues due to heterogeneous system landscape and decentralized master data management

How can KPMG support?

Analysis
Are all new regulations and initiatives clear?
Which systems are in consideration and ensure proper data quality?
Which roles and responsibilities need to be addressed?

Design
Which tools enable to implement regulations?
Which concurring MDM initiatives are in place?
Are data sources controlled and documentation addressed towards product/process owners?

Execution
What support level is foreseen for implementing the design?
Are resources allocated to ensure and monitor the execution?
Who is managing the test phase?

Roll-out
What is the approach of the roll-out?
What kind of support level is required to provide a successful outcome?
How can the change be managed addressing FDA/EMA* equirements?

Independent Compliance Check

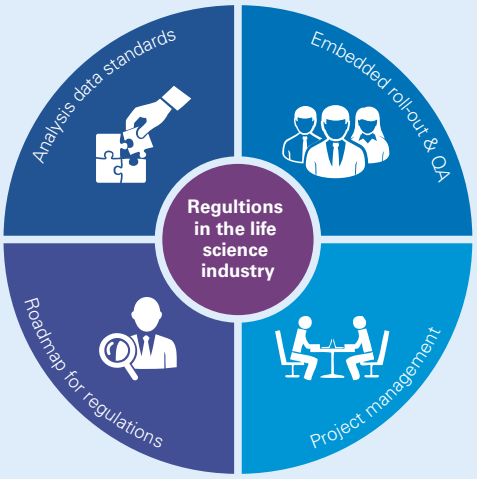
*FDA: Food and Drug Administration/EMA: European Medicines Agency

Why KPMG?

- Our service offerings are based on state-of-the-art methodologies that KPMG has successfully implemented, which takes into account the new regulations released worldwide
- KPMG provides deep expertise in implementing regulations in the life sciences industry
- We understand the impact of the new regulations on MDM services, including: Global MDM services, including roadmap for regulations, analysis of data standards, project management and embedded quality assurance
- KPMG has performed numerous MDM transformation projects in the framework of regulatory requirements

KPMG has a recognized methodology for the implementation of new regulations in Life Sciences

- Analysis of data standards: We assess system landscape, data quality and benchmark quality standards. We provide a fit & gap matrix and manage follow-up actions.
- Embedded roll-out and quality assurance: We accompany during the roll-out providing training and documentation as well as a risk and quality based approach that enables a successful organizational transformation.
- Project management: We enable project management planning and guidance from the beginning throughout the implementation. We support during testing with specialized focus on regulatory requirements.
- Roadmap for regulations: We help identifying regulatory requirements that may affect businesses providing a market overview of regulatory driven solutions.



Key preparation

The implementation of new regulations requires sufficient preparation in order to ensure meeting the requirements timely and successfully by July 2016. Key preparation steps are:

- Readiness assessment, analysis of the requirements and data quality evaluation
- Impact assessment on the system landscape with focus on master data and its structure
- Create stakeholder awareness of new regulations

Client benefit

The client benefit is to be compliant in a timely manner. In addition, KPMG brings the following benefits:

- Improvement of data compliance and reduced risk of adverse audit findings
- Avoid potential sanctions from the regulators through accurate and timely implementation
- Optimization of master data through the lifecycle of a product, avoiding redundancies
- Reducing costs, by optimizing master data and simplifying the supply chain
- Efficient and effective assessment of master data quality, including an extensive set of analysis rules

Service Overview

Analysis
- Review regulatory requirements (FDA/EMA)
- Impact analysis on system landscape and data quality
- Impact reporting with key findings for MDM
- PMO Services (e.g. Project Planning)

Design
- Software evaluation and selection based on KPMG's best practices
- Impact analysis on other MDM activities
- Change Management within a regulatory driven environment

Execution
- Decision paper for implementation partner (in-house or vendor)
- Test Strategy, Test Management, Reporting
- Execution Monitoring by ensuring correct implementation through entire product lifecycle

Roll-out
- Assessment of Roll-out approach considering foreign regulations
- User training and country-specific documentation
- Continuous improvement in order to keep the MDM strategy up-to-date

Independent Compliance Check

Contact

KPMG AG
Badenerstrasse 172
PO Box
8036 Zurich

kpmg.ch

René Koets
Partner
Consulting

+41 58 249 42 69
rkoets2@kpmg.com