

Key performance indicator implementation by regulatory affairs

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The process by which organizations align their global and local resources processes, tools, internal and external resources to strategic objectives and priorities is "Performance Management", which is supported by Key Performance Indicators (KPIs). Various dashboards, like Balance Scorecard (BSC) and Individual Objectives include the KPIs. The setting of meaningful Regulatory Affairs (RA) KPIs is one of most challenging of the pharmaceutical industry due to the difficulty to measure the quality of a submission in term of long-term value and to ensure that the chosen regulatory strategy would meet the long-term trend by the agencies. The pitfall of measuring short term success as the number of approvals or renewals which are not always linked to marketing goals demonstrate the necessity of multi-year KPIs with top-down and bottom-up approaches and alignment with R&D, marketing and global and local units. Tactical points, like manufacturing variations are part of them. The art of Performance Management by RA is to implement KPIs covering the six basic perspectives: Finance, R&D pipeline, marketing, internal business process, external compliance and learning. RA KPIs contribute heavily to the company success. Many RA KPIs are endorsed totally or partially by most of the company departments. One of the challenges of the KPI implementation is the related payout as bonus based one year period as the RA KPI results are measured over many years. Practical examples, included KPI sharing with external providers, illustrate the risks and benefits of classes of Regulatory Affairs KPIs which promote good behaviors and avoid possible misuses.

Biography

Philippe Berclaz was Director, Global Regulatory Operational & Performance Management and Site Head of RA at the Headquarter by Merck Serono during 5 years. He has implemented KPIs and BSCs by RA (up to 440 employees), by R&D and by the complete pharmaceutical division. He was also project leader of the outsourcing of an important part of the RA. He is an independent consultant in Biopharma and IT Outsourcing supporting pharmaceutical companies and vendors from concept to operations, including the implementation of shared KPIs and related governance.

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