Global Submission Planning at Bristol-Myers Squibb

BMS is transforming their operations with an authoritative source for regulatory information, including new processes for scheduling submissions and developing submission content plans.

HEADQUARTERS

UNIFIED RIM PLATFORM

AFFILIATES

The new processes balance headquarters' knowledge and need for control with that of affiliates to improve global visibility and operating efficiency.

BMS decides to submit a new application or expand a registered indication or formulation.

Global Submission Plan

Headquarters creates a global submission planning record describing the business objective.

Affiliates enter best-case and base-case approval dates, plus other core information.

Country Planning Records

Country-specific planning records capture affiliates' input into the corporate planning process.

The Global Regulatory Team maintains a calendar of all BMS submissions globally.

Proposed dates reviewed by international strategy leads in headquarters.

Global Regulatory Team evaluates feasibility of affiliates' dates and establishes **cross-functional alignment with clinical, CMC, manufacturing, regulatory operations and others** on planned submission dates.

❶ Cross functional governance committee **evaluates whether teams can deliver** dossier by proposed date(s) before approving plan.

❷ Governance-approved dates are entered into Global Submissions Plan and notifications sent to all involved.

Country Tracking Records

Country-specific tracking records aggregate all submissions and correspondence related to the original business objective.

Approved dates don't change without governance sign-off.

HIGH LEVEL SCHEDULING AND PLANNING

GRANULAR CONTENT PLANNING BEGINS 12 MONTHS AHEAD OF THE APPROVED COMPLETION DATE

Submission Content Plan

The RIM system auto-generates a submission content plan based on pre-defined parameters.

Functional area representatives **commit to completion dates** for each component.

Submission Documents

A dashboard shows completion status of each module as documents are authored, reviewed, and approved.

Tracking baseline, target, and approval dates for each component provides metrics for **continuous process improvement.**

Personalized dashboards show planned dates for relevant submissions by month, country, or indication.

Final content plan with **approved documents,** provides basis **for local dossiers** in each reference country.

Archived Dossier

The final published output is archived within the global RIM platform and linked to the original submission planning record. (Coming 2019)